Winter 12-2-2021

Butte-Silver Bow Medical Monitoring Program Plan

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December 2, 2021

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RE: Butte-Silver Bow Medical Monitoring Program Plan

Agency Representatives:

The Butte-Silver Bow Medical Monitoring Management Program Plan is being submitted on behalf of Atlantic Richfield and Butte-Silver Bow. This Plan has been revised through collaborative efforts and communication with the Agencies between Atlantic Richfield and Butte-Silver Bow to address comments.

The report may be downloaded at the following link:

https://pioneertechnicalservices.sharepoint.com/:f:/s/submitted/EsjUXEnIkKtLo4b4ymezzlgB7TmvorWasNGZIseGw3oByw.

If you have any questions or comments, please call me at (907) 355-3914.

Sincerely,

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Butte-Silver Bow

Medical Monitoring Program Plan

Butte-Silver Bow
Department of Reclamation & Environmental Services

December 2021

Contents

List of Attachments:

Site Background and Program Establishment

Decades of historical mining activities in Butte-Silver Bow, Montana, have led to elevated levels of lead, arsenic, and, to a lesser extent, mercury in the community, especially within the boundaries of the Butte Priority Soils Operable Unit (BPSOU). Elevated metals content, particularly related to lead, has been found in residential yards and attics within the BPSOU. The Residential Metals Abatement Program (RMAP) was established to address the elevated metals levels and mitigate the impact to human health, particularly among children. The RMAP is a public health program, with the Butte-Silver Bow County Health Department (Health Department) and RMAP collaborating to determine blood-lead levels in the community and mitigate lead exposure to children and adults whenever possible.

Management

Staff

The medical monitoring program for young children and pregnant women is operated by the Women, Infants, and Children (WIC) Program in the Community Health Division of the Health Department. The Community Health Division is directed by the Health Officer who works for the Chief Executive and the Board of Health. The department organization chart is included as **Attachment A.**

The Community Health Division Manager and WIC Program Manager provide patient intake, capillary blood testing, and coordinate venous confirmation sampling. This same staff is responsible for documenting results of capillary screening in the Medical Monitoring Database and the input of venous confirmation sampling. The staff is also responsible for coordinating environmental sampling with the RMAP in cases where confirmed blood leads are identified and for providing analyses of urine arsenic and mercury.

Problem Definition

Exposure to lead, arsenic, or mercury is possible in residential locations in Butte. Butte-Silver Bow provides a medical monitoring program free of charge to Butte residents to determine if exposure has occurred and offers an environmental sampling program to eliminate the possibility of exposure in the home. The first element is a well-developed program to screen children for blood lead. The second is an environmental sampling program to determine if contamination is present at the residence.

To ensure public and environmental health of the residents of Butte, the RMAP provides medical monitoring (biomonitoring) services to identify resident exposure to lead, arsenic, or mercury. The WIC Program seeks to obtain blood lead samples from all young children who participate in the WIC program regardless of whether their residence has been tested. Biomonitoring services are also available to other Butte residents, particularly if an environmental investigation reveals lead, arsenic, or mercury contamination above action levels. Affected populations, as determined through biomonitoring, have elevated levels of lead in blood samples or elevated arsenic or mercury in urine samples.

If an elevated blood lead is found, an environmental investigation of the residence where the participant resides will be scheduled to potentially determine the source of contamination. The prioritization for environmental assessment is described in Section 4 of the *Revised Final Multi-Pathway Residential Metals Abatement Program Plan* (RMAP Program Plan) (BSB/Atlantic Richfield Company, 2021). Affected populations shall be prioritized for an environmental assessment and remediation if contamination is identified during the environmental investigation.

The RMAP performs routine environmental sampling efforts in residences throughout the BPSOU and the RMAP Expanded Area. This program is detailed in the RMAP Program Plan and focuses on eliminating the potential for exposure to contamination by identifying whether contamination is present and performing remediation if it is.

Biomonitoring Thresholds

Biomonitoring data for the U.S. provides a source of population reference values that can be used to identify elevated levels of blood lead, and urine arsenic and mercury. Values considered elevated are listed in Table 1 and an explanation is provided in the following text. Biomonitoring of sensitive populations within Butte-Silver Bow is also described in Section 3 of the RMAP Program Plan.

Table 1. Indicators of Potential Exposure to Environmental Lead, Mercury, and Arsenic

Analysis	Value Considered Elevated
Blood lead	≥ 5 µg/dL, confirmed
Urine mercury	≥ 1 µg/g creatinine
Inorganic arsenic-related species in urine	≥ 24 µg/g creatinine for children < 6 years old ≥ 16 µg/g creatinine for older children and adults

≥: greater than or equal to. µg/dL: microgram per deciliter. µg/g: microgram per gram

Lead

Consistent with Montana Department of Public Health and Human Services (MDPHHS) guidance (https://dphhs.mt.gov/publichealth/cdepi/diseases/lead), confirmed blood lead levels greater than or equal to 5 micrograms per deciliter (µg/dL) will be considered elevated for children less than 6 years of age. This value was based on the 97.5th percentile of blood lead levels in young children in the U.S. during the mid-2000s. Blood lead is analyzed by performing a capillary draw and venous confirmation sampling for participants, which is evaluated against the Medical Monitoring Program biomonitoring thresholds. Detailed methods are described below.

Mercury

Mercury in urine is used as a biomarker for inorganic mercury exposure. Blood mercury is used as a biomarker of methylmercury exposure, which is primarily from fish and other foods. Since elemental or inorganic mercury is the concern in Butte, urine mercury will be used as the biomarker for mercury exposure. Urine mercury can be reported either as a urine concentration in micrograms mercury per liter (µg/L) or as micrograms mercury per gram of creatinine (µg/g creatinine), which uses the amount of the metabolite, creatinine, excreted in the urine to adjust for variations in hydration state (i.e., how concentrated or dilute the urine is)[1]. MDPHHS identifies urine levels that indicate mercury poisoning (greater than or equal to 200 µg/L total mercury or greater than or equal to 20 µg elemental mercury/g creatinine); however, these levels are far higher than population reference levels. Population reference values for total mercury in urine were selected based on U.S. biomonitoring data from 2011 through 2016 reported in the 2019 updated tables in the National Report on Human Exposure to Environmental Chemicals, https://www.cdc.gov/exposurereport/index.html, see Attachment B – Extracts from the tables. Urinary mercury levels greater than or equal to 1 µg/g creatinine will be considered as elevated mercury levels for all participants. The selected value is the 95th percentile of the U.S. population values for children and for adults. The analytical method may vary based on the analytical laboratory conducting the

[1] Creatinine is a waste product excreted by the kidneys that is produced by muscles from the breakdown of a compound called creatine.

analyses. Note that potential for exposure from dental amalgams will be assessed by the physician prior to assuming environmental exposure.

Arsenic

Analysis of total arsenic in urine is used to assess exposure to arsenic in food, as well as other sources. Much of the arsenic in food is organic forms that are relatively non-toxic. Consequently, total arsenic in urine may reflect recent meals that included fish, shellfish, rice, or other foods high in arsenic, and is not considered a reliable indicator of inorganic arsenic exposure. Instead, analytical methods that test for inorganic arsenic and its metabolites (termed speciated arsenic or inorganic arsenic-related species) are considered more reliable. Some foods such as rice and shellfish may still cause false positives in results for inorganic arsenic so retesting may be required after a period of at least 72 hours without consuming these foods to provide reliable information on potential environmental exposure to inorganic arsenic. Similar to mercury, urine arsenic can be reported either as a urine concentration in µg/L or as µg/g creatinine, which adjusts for variations in hydration state (i.e., how concentrated or diluted the urine is).

Population reference values for inorganic arsenic-related species in urine (as µg/g creatinine) were selected based on U.S. biomonitoring data from 2011-2016 reported in the 2019 updated tables in the National Report on Human Exposure to Environmental Chemicals, https://www.cdc.gov/exposurereport/index.html, see Attachment B – Extracts from the tables. For the inorganic arsenic-related species, a value greater than or equal to 24 µg/g creatinine was selected for children less than 6 years old, and a value of greater than or equal to 16 µg/g creatinine was selected for older children and adults. The selected values are the 95th percentile of the U.S. population values for young children and for adults. The analytical method may vary based on the analytical laboratory conducting the analyses. One laboratory that may be selected performs arsenic speciation by ion chromatography inductively coupled plasma collision reaction cell mass spectrometry (IC-ICP-CRC-MS). Arsenic species are first chromatographically separated on an ion exchange column and then quantified using ICP-CRC-MS. Results are provided for arsenite, arsenate, monomethylarsonic acid (MMA), and dimethylarsinic acid (DMA).

Program Protocols

The biomonitoring services of the RMAP program are provided by the Health Department through the WIC program. Since the WIC program serves a particularly at-risk population it was selected to be the site at which medical monitoring is carried out, focusing on low-income children.

Biomonitoring participants or their guardian will be required to complete a consent form for participation and an individual questionnaire for urinary collection (Attachment C1). Blood lead screening will be conducted by the WIC program and subsequent venous sample analysis will be conducted by an accredited laboratory.[2] Urinary arsenic and mercury samples will be collected by participants using sample collection cups provided by the Health Department (see instruction flyer in Attachment C2). The Health Department will then ship the samples to the contracted laboratory.

Participation in the blood lead program will be encouraged through a variety of means, such as the existing WIC program and referrals from local physicians. Residents will also be encouraged to participate when they are contacted for residential sampling access. Participation is voluntary and

[2] During much of 2020 and into 2021, the WIC program has not been able to conduct any blood lead screening due to pandemic restrictions on in-person visits.

available to all residents. Primary emphasis is placed on children and pregnant or nursing mothers, but all other residents are eligible with a recommendation from program staff.

WIC staff manages the programmatic responsibilities of the medical monitoring process. Their responsibilities include participant communication and outreach, sample collection, documentation, shipping, and result documentation, quality control elements including chain of custody, shipping, and result receipt. Finally, they provide result information to the participant.

When individuals are found to have a confirmed elevated blood lead, urinary mercury, or urinary arsenic, the home where the affected person or persons live will be scheduled for immediate sampling and evaluation. Elevated blood lead values will be confirmed by multiple tests. Influencing factors such as food consumption for arsenic, (i.e., seafood) and dental amalgams for mercury will be taken into consideration.

The details of the program process are further defined and described in subsequent sections of this document.

Collection

Participant Intake

WIC uses a proprietary database system to capture pertinent information for the client. This includes medical monitoring data, consent for services, and releases of information. The local WIC office will, to the extent legally permissible, begin to collect information pertaining to individual characteristics such as race, maternal education, and household income level to improve result interpretation and evaluate community trends.

Blood Lead Sampling Procedures

Screening

The WIC program uses the LeadCare® II system to perform lead screening services. The protocols are attached to this document as Attachment D1, which describe the kit contents and required materials. The procedure is as follows:

1. Perform capillary draw.
    a. Thoroughly wash hands and don powder-free gloves, face shield, and mask.
    b. Clean patient skin surface.
    c. Prick patient finger and draw blood.
2. Perform calibration procedure, if necessary.
3. Perform quality control to monitor accuracy and precision, if necessary.
4. Prepare the sample.
    a. Label the tube with Patient ID.
    b. Holding the capillary tube almost horizontally with the green band on top, fill the capillary to the 50 microliter (µL) black line.
    c. Inspect the capillary tube for proper filling.
    d. Place the capillary tube into the treatment reagent tube. Insert a plunger into the top of the capillary tube and push down, ensuring the entire volume of sample is dispensed into the treatment reagent.
    e. Replace the tube cap. Invert 8 to 10 times to mix the sample completely.
    f. The sample is ready when the mixture turns brown. Samples may be stored up to one week if refrigerated.
5. Analyze the sample.

a. Remove a sensor from the sensor container.
b. Insert the sensor under the sensor guides on the sensor deck. Insert completely into the analyzer until it beeps.
c. Make sure the sensor lot number matches the display.
d. Make sure the sample is thoroughly mixed. Allow samples that were stored refrigerated to reach room temperature before use.
e. Remove the cap from the treatment reagent tube. Squeeze the walls of the dropper and insert into the sample. Release the pressure to draw some sample into the dropper.
f. Touch the dropper tip to the x on the sensor and squeeze the walls to dispense the sample. The analyzer will "beep" and begin the 3-minute countdown.
g. Wait 3 minutes until the test is done.
h. Record the test results on the LeadCare® II worksheet.
i. Remove the sensor immediately after recording the test result.
j. Discard materials in appropriate containers.

6. Interpret patient test results.
    a. The result is in micrograms of lead per deciliter of whole blood. No calculation is needed. Results are displayed to one decimal place. The reportable range of the test is 3.3 to 65 µg/dL.
    b. "Low" in the display window indicates a blood lead test result less than 3.3 µg/dL. When this occurs, report the blood lead results as less than 3.3 µg/dL.
    c. "High" in the display window indicates a blood lead test result greater than 65 µg/dL. When this occurs, report the blood lead result as greater than 65 µg/dL. "High" results on LeadCare® II should be followed up immediately as an emergency laboratory test.

Venous Confirmation

When results from the blood lead analyzer LeadCare® II capillary test are greater than or equal to 5 µg/dL, confirmatory testing will occur. The contents of the Venipuncture Collection Kit are attached as Attachment D2.

1. Venipuncture collection:
    a. Thoroughly wash hands and don powder-free gloves.
        i. Expose the selected antecubital fossa and apply tourniquet to mid-biceps. Scrub the puncture site briskly with the alcohol pad to remove any environmental contamination and to increase blood flow.
        ii. Allow the site to air dry or use the sterile gauze to dry the area.
    b. Collection of the sample:
        i. Prepare needle assembly, either needle and vacutainer holder or needle and syringe.
        ii. Perform venipuncture per standard operating procedures. Make sure the vacutainer tube is completely filled before stopping collection. If using a needle and syringe, obtain a minimum of 2 milliliters (mL) of whole blood.
        iii. Remove tourniquet first, then remove the needle from the arm.
        iv. Apply pressure to the puncture site with a gauze pad to stop the patient's bleeding. Parent/guardian or child may continue holding direct pressure on the puncture site.
        v. If drawn directly into vacutainer tube, immediately mix the specimen manually by inverting a minimum of 10 times.

vi. If drawn with a needle into the syringe, immediately inject the blood from the syringe into the vacutainer tube, gently mixing while filling. Continue to mix the specimen by inverting 10 times.
vii. Dispose of used needle and syringe equipment into puncture proof sharps container.
viii. Identify each skin puncture specimen with the patient's name, at a minimum, and collection date.

Shipping

1. Standing Orders: Venipuncture Specimens for Transport
    a. Specimens should be clearly labeled with two patient identifiers (name and date of birth) and collection date.
    b. Complete a Montana Public Health Laboratory Request Form to include the patient's name, date of birth, gender, collection date, and submitter information (see Attachment E for the Montana Public Health Laboratory Request form).
    c. Place the well-mixed, unclotted blood specimen in an individual biohazard zip lock bag containing absorbent material and seal bag tightly. Fold the requisition form and place it in the sleeve of the bag
    d. Store specimen(s) in the refrigerator until transported to the St. James Healthcare Laboratory the same day, to coincide with the courier schedule to the Montana Public Health Laboratory in Helena, Mont. Specimens are stable for 7 days at refrigeration temperatures.

Analysis

Refer to Attachment F, Montana Public Health Laboratory Services Manual. Please find Montana Public Health Laboratory CLIA certificate attached as Attachment G.

Quality Control

Refer to Attachment F, Montana Public Health Laboratory Services Manual.

Sample Documentation

- If screening via LeadCare® II identifies a blood lead greater than 5 µg/dL, a confirmatory venous draw is coordinated. Currently, venous draws are completed by local doctors' offices, but given the difficulties with participant follow-up and data collection, the program will utilize the following process:
    - A patient entry is created in the Medical Monitoring Database incorporating name, address, telephone number, physician, and demographic information such as family status and income.
    - The results of the screening sample collected through capillary draw and analyzed via the LeadCare® II system will be entered in the system.
    - If a result is greater than 5 µg/dL, then the on-site Medical Monitoring Nurse/environmental health full time employee (FTE) will be contacted and same day venous confirmation sampling will take place.
    - The venous draw sample will be shipped according to the previously described procedure to the local St. James Laboratory.
    - The results will be provided to the Medical Monitoring Nurse/environmental health FTE and the lab results will be entered in the Medical Monitoring Database.

- If an elevated blood lead is identified, the Medical Monitoring Nurse/environmental health FTE will then coordinate participant follow-up, which includes environmental assessment through the RMAP Program.

Result Documentation

The Montana Public Health Laboratory emails the ordering provider when lab results are entered into state systems – these orders are issued under standing orders from the Health Department's medical director (see the Montana Public Health Laboratory Services Manual in Attachment F).

Database

These data are currently entered into an Excel spreadsheet by the WIC program manager. The current Excel spreadsheet, containing anonymous information, is available to medical monitoring team members, including the Health Department, RMAP, and associated research personnel.

Data review

Sample information and laboratory results will be reviewed and entered in the Medical Monitoring Database by the Medical Monitoring Nurse/environmental health FTE, per concurrence from Atlantic Richfield Company (Atlantic Richfield). Data validation procedures will be provided by the Environmental Protection Agency (EPA).

Participant Communication and Outreach

Participant Intake

WIC standards prevent medical monitoring data entry into the WIC system. Because of this, medical monitoring data, such as consent forms (which contain areas for information about blood-lead data) and releases of information are scanned into the WIC client's file. Separately, anonymous blood-lead data are entered onto an Excel spreadsheet which serves as the Medical Monitoring Database. These data are eventually provided to medical monitoring officials for the five-year health studies.

Communication of Results

Per Health Department standing orders, after test results are received by the department from the state lab, the patient (or parent/legal guardian) is contacted to discuss the results and any next steps if applicable. EPA will provide example result letters and any fact sheets that will be provided to the public to aid in result interpretation.

Environmental Assessment Coordination

If WIC program staff identifies a participant with elevated blood lead, confirmed by venous sample, then WIC staff coordinates with the Reclamation Department Human Health Program Manager to schedule an environmental assessment.

RMAP staff will reach out via telephone to schedule a time for an environmental assessment. Samples will be collected in accordance with the protocols described in Section 6 and Section 7 of the RMAP Program Plan.

Periodic Evaluation of Medical Monitoring Data and Approaches (Health Studies)

Collecting and analyzing medical monitoring data is part of a continuous biomonitoring process within the RMAP. In addition to blood lead screening, confirmation sampling, and communication of laboratory results to participants, data is summarized and interpreted in a comprehensive report every five years.

Butte-Silver Bow evaluates biomonitoring approaches and data compiled under the RMAP every 5 years and will continue this evaluation schedule for a period of 30 years. The first and second of these studies

(Phase 1 and Phase 2 studies) were completed and approved by EPA in 2014 and 2020, respectively. Four additional periodic evaluations will be conducted over the next 20 years (2025, 2030, 2035, and 2040).

These evaluations will be overseen by a Medical Monitoring Working Group that includes representatives of the relevant regulatory agencies, responsible parties, and community, (i.e., the stakeholders). The Medical Monitoring Group is composed of representatives who bring knowledge of the daily operations of the RMAP program, its biomonitoring aspect, the stipulated responsibilities of the biomonitoring program, and advocacy for sensitive populations. The Medical Monitoring Working Group's responsibilities are singularly focused on the preparation of the 5-year evaluations and interpretation of data associated with that period not the day-to-day operations of the program itself unless specifically charged with that responsibility as part of a job duty or board term of service.

The Medical Monitoring Working Group may expand to other reviews and potential studies that may be conducted beyond medical monitoring data associated with the medical monitoring program. This will occur through collaborative discussions with the stakeholder group over the next 20 years, and as funding is available, with the Health Department as the lead agency in coordinating these reviews and studies. The Agency for Toxic Substances and Disease Control and the MDPHHS will be substantially involved in this effort, along with EPA and the Montana Department of Environmental Quality (DEQ). As the expanded RMAP is developed, EPA and DEQ will work with community members and Butte Silver Bow County to continually address public health concerns associated with historical mining waste and current public health issues to the extent practical and as funding is available.

Reports documenting these periodic evaluations will be available to the public, the EPA, Montana DEQ, and potentially responsible parties for the BPSOU. All stakeholder parties will continue to facilitate, participate, and contribute to the Medical Monitoring Working Group and other public health reviews and studies. However, the data associated with this analysis and interpretation will respect the privacy of the participants. Specifically, the biomonitoring data associated with specific names or addresses will be scrubbed to ensure no identifying characteristics associated with personal health information is shared with the working group or the public.

While the RMAP has focused on arsenic, lead, and mercury, lead has proven to be the primary metal triggering abatements and is the only metal routinely included in biomonitoring. Thus, periodic evaluations will focus on lead. While not a focus, any applicable data for arsenic and mercury will also be reviewed. Similarly, periodic evaluations will focus on affected and sensitive populations as defined by the RMAP. Data gathered through the RMAP's routine activities, as well as the results of prior periodic evaluations, will be considered in each periodic evaluation.

The purpose of conducting periodic evaluation of biomonitoring data compiled in conjunction with the RMAP is two-fold. First, because the state of the science related to collection and interpretation of biomonitoring data continues to evolve, it is necessary to periodically evaluate the medical monitoring approaches used to ensure that the biomonitoring data can continue to be used to support the RMAP's mitigation of potentially harmful exposures of BPSOU residents to sources of lead, arsenic, and mercury contamination. Second, examination of the complete biomonitoring database every five years can provide valuable information regarding exposure trends over time. Information and analysis supporting both purposes can inform potential improvements to routine activities as needed to ensure the RMAP's continued effectiveness.

In addition to evaluation of the biomonitoring data, the Phase 2 study included evaluations of topics identified by Butte citizens at public meetings and from community stakeholders. The primary Phase 2 study elements included:

- Butte Superfund History and Community Characteristics – A summary of the history of Superfund remediation in Butte with a focus on BPSOU and residential areas. Other community characteristics and information about health status that are important determinants of public health were described, followed by a description of a survey of perceptions of environmental health issues in Butte.
- Review of Risk Assessments and Cleanup Levels – Prior human health risk assessments (HHRAs) conducted within and near the BPSOU were summarized as well as the derivation of cleanup levels and the periodic review of cleanup levels during the reviews conducted every 5 years of the *Record of Decision* (ROD), *Butte Priority Soils Operable Unit* (EPA, 2006)
- Review of Past Exposure/Biomonitoring Studies – Current biomonitoring sampling procedures, analytical methods, and concentration benchmarks, and assessment of the need for any potential updates/improvements. Prior BPSOU exposure studies (including the Phase 1 study) were summarized.
- Review of Disease Prevalence and Rate Studies – Prior studies of disease prevalence in Butte were summarized, including results of an updated MDPHHS analysis of morbidity and mortality statistics for the Butte population compared with state and national data. Additional relevant published literature was also described.
- Phase 2 Blood Lead Data Analysis – Blood lead data from 2012 through 2017 and summary statistics were compiled. Exposure trends over time, by Butte neighborhood, and (to the extent supported by available data) in comparison to a defined reference population were evaluated.
- Key Findings and Recommendations – A final section presented key findings related to epidemiological and exposure studies, as well as recommendations of any areas where changes to activities conducted via the RMAP might be useful. Recommendations for public outreach were also provided.

It is anticipated that much of the information provided in the Phase 2 study report will provide a baseline of information that can be updated in subsequent studies. For each remaining evaluation period, the following activities are anticipated:

- The Medical Monitoring Working Group will meet periodically during and between studies to ensure that data needed for each subsequent study is being collected.
- Community outreach will solicit input at the beginning of each subsequent phase, starting with a reminder of the prior study findings.
- Summary statistics for available arsenic, lead, and mercury biomonitoring data will be updated with biomonitoring data for BPSOU populations of interest that have been compiled since the prior evaluation period. Quality assurance review of the database will seek to identify and address incomplete or missing records from the compilation.
- The most recent biomonitoring database will be used to describe exposure trends over time. To the extent supported by the available data the approaches and methodologies of the 2014 or 2020 evaluations will be used to compare blood lead data across Butte neighborhoods. If feasible, the data will also be compared to a defined reference population.
- As available, recent peer-reviewed epidemiology studies examining the relationship between environmental exposures to arsenic, lead, and/or mercury and diseases with increased incidence in Butte will be reviewed and summarized.
- As available, the results of recent morbidity and mortality statistics for the Butte population reported by the Montana state public health entities will be reviewed and summarized.

- Recommendations of any improvements or additions to activities conducted via the RMAP will be developed. Specifically, the current state of the science regarding collection and interpretation of biomonitoring data will be reviewed to determine whether any updates are needed to the sampling, analysis, and interpretation of biomonitoring data collected in conjunction with the RMAP. This will include review of the benchmarks currently being used to assess elevated biomonitoring results for the RMAP.
- Recommendations for other reviews and potential health studies will be considered.
- After EPA approval, a report will be issued with the results of each study and study results will be shared with the community.

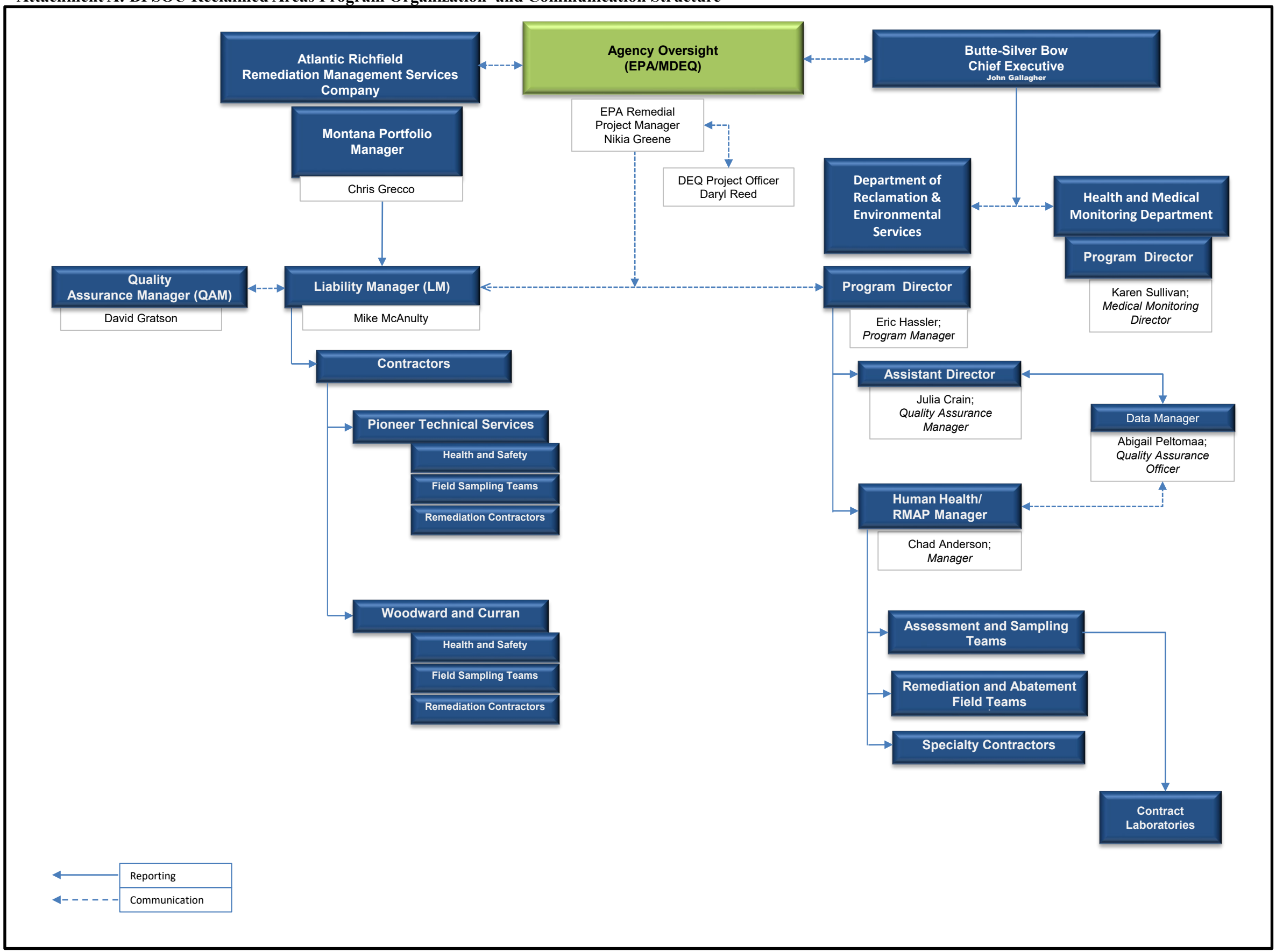
References

BSB/Atlantic Richfield Company, 2021. Revised Final Multi-Pathway Residential Metals Abatement Program Plan. City and County of Butte Silver Bow and Atlantic Richfield Company, November 2021.

EPA, 2006. Record of Decision, Butte Priority Soils Operable Unit, Silver Bow Creek/Butte Area NPL Site. U.S. Environmental Protection Agency, September 2006.

Attachment A: RMAP Organizational Chart

Attachment A: BPSOU Reclaimed Areas Program Organization and Communication Structure



Attachment B: National Report on Human Exposure to Environmental Chemicals Table Extracts

Urinary Total Arsenic (2011 – 2016)

CAS Number 7440-38-2

Geometric mean and selected percentiles of urine concentrations (in µg/L) for the U.S. population from the National Health and Nutrition Examination Survey.

Categories (Survey Years)	**Geometric Mean** (95% conf. interval)	**50th Percentile** (95% conf. interval)	**75th Percentile** (95% conf. interval)	**90th Percentile** (95% conf. interval)	**95th Percentile** (95% conf. interval)	**Sample Size**
Total population (2011 - 2012)	6.85 (5.85-8.02)	6.09 (5.22-7.12)	13.0 (10.9-16.6)	32.0 (25.9-39.0)	52.5 (41.9-66.2)	2504
Total population (2013 - 2014)	6.29 (5.58-7.08)	5.82 (5.10-6.69)	11.7 (10.5-13.2)	26.6 (23.7-30.1)	46.0 (37.5-56.1)	2662
Total population (2015 - 2016)	5.96 (5.53-6.43)	5.41 (4.92-5.84)	11.1 (9.91-12.2)	25.0 (20.8-30.0)	44.6 (35.7-53.8)	3061
Age 3-5 years (2015 - 2016)	4.05 (3.58-4.58)	3.72 (3.27-4.23)	6.67 (5.66-8.35)	12.8 (9.93-19.9)	22.4 (13.4-54.8)	486
Age 6-11 years (2011 - 2012)	6.02 (5.03-7.19)	5.50 (4.58-6.56)	10.5 (7.93-14.1)	30.1 (16.7-46.5)	53.0 (37.5-70.3)	399
Age 6-11 years (2013 - 2014)	5.21 (4.57-5.95)	4.78 (4.27-5.57)	8.79 (7.52-10.3)	17.1 (12.4-25.3)	29.0 (17.9-47.7)	402
Age 6-11 years (2015 - 2016)	4.89 (4.29-5.56)	4.51 (4.21-4.96)	7.59 (6.66-8.71)	15.7 (11.1-22.7)	28.9 (17.1-56.9)	379
Age 12-19 years (2011 - 2012)	6.01 (4.45-8.11)	5.26 (3.95-7.47)	10.9 (7.74-16.9)	25.9 (16.6-44.0)	44.0 (25.9-153)	390
Age 12-19 years (2013 - 2014)	5.79 (4.96-6.75)	5.33 (4.83-5.91)	9.40 (8.44-11.8)	22.0 (17.4-28.1)	44.1 (27.0-90.8)	451
Age 12-19 years (2015 - 2016)	5.00 (4.52-5.54)	4.75 (4.07-5.23)	8.78 (7.64-10.6)	17.1 (14.6-20.1)	29.8 (19.2-35.6)	402

Limit of detection (LOD, see Data Analysis section) for Survey years 11-12, 13-14, and 15-16 are 0.05, 0.13, and 0.13, respectively.

Biomonitoring Summary: https://www.cdc.gov/biomonitoring/Mercury_BiomonitoringSummary.html
Factsheet: https://www.cdc.gov/biomonitoring/Mercury_FactSheet.html

Urinary Total Arsenic (creatinine corrected) (2011 – 2016)

CAS Number 7440-38-2

Geometric mean and selected percentiles of urine concentrations (in µg/g of creatinine) for the U.S. population from the National Health and Nutrition Examination Survey.

Categories (Survey Years)	**Geometric Mean** (95% conf. interval)	**50th Percentile** (95% conf. interval)	**75th Percentile** (95% conf. interval)	**90th Percentile** (95% conf. interval)	**95th Percentile** (95% conf. interval)	**Sample Size**
Total population (2011 - 2012)	7.77 (6.85-8.81)	6.39 (5.57-7.24)	13.7 (11.5-16.5)	30.8 (24.6-38.6)	50.4 (38.2-70.1)	2502
Total population (2013 - 2014)	7.27 (6.62-7.99)	6.10 (5.39-6.88)	11.9 (10.5-13.5)	27.6 (23.8-32.8)	52.0 (43.5-60.9)	2661
Total population (2015 - 2016)	6.69 (6.32-7.08)	5.56 (5.32-5.85)	10.7 (9.74-11.5)	24.9 (20.1-30.0)	45.8 (32.0-65.3)	3058
Age 3-5 years (2015 - 2016)	9.31 (8.18-10.6)	8.27 (7.40-9.15)	12.5 (10.6-14.9)	21.1 (17.3-28.8)	40.9 (22.8-83.5)	485
Age 6-11 years (2011 - 2012)	8.63 (7.26-10.3)	6.87 (5.84-8.00)	12.3 (9.58-15.5)	27.7 (17.7-57.7)	91.2 (26.2-129)	398
Age 6-11 years (2013 - 2014)	7.78 (7.08-8.54)	6.91 (5.91-7.65)	12.5 (10.3-13.6)	17.7 (16.1-21.1)	29.9 (20.4-52.1)	402
Age 6-11 years (2015 - 2016)	6.93 (6.48-7.41)	6.09 (5.66-6.56)	9.53 (8.15-11.0)	18.2 (13.6-25.0)	28.1 (21.9-40.6)	379
Age 12-19 years (2011 - 2012)	5.75 (4.49-7.36)	4.69 (3.70-5.73)	8.73 (6.26-13.3)	22.1 (11.5-52.6)	34.9 (21.1-159)	390
Age 12-19 years (2013 - 2014)	5.24 (4.53-6.06)	4.21 (3.61-4.61)	7.92 (5.75-10.3)	17.6 (12.6-23.0)	30.5 (20.3-54.1)	451
Age 12-19 years (2015 - 2016)	4.67 (4.34-5.03)	3.94 (3.55-4.54)	7.09 (5.91-7.91)	14.7 (11.6-16.8)	22.3 (15.4-31.5)	402

Biomonitoring Summary: https://www.cdc.gov/biomonitoring/Mercury_BiomonitoringSummary.html
Factsheet: https://www.cdc.gov/biomonitoring/Mercury_FactSheet.html

Urinary Inorganic-related Arsenic Species (2011 – 2016)

CAS Number 7440-38-2

Geometric mean and selected percentiles of urine concentrations (in µg As/L) for the U.S. population from the National Health and Nutrition Examination Survey.

Categories (Survey Years)	**Geometric Mean** (95% conf. interval)	**50th Percentile** (95% conf. interval)	**75th Percentile** (95% conf. interval)	**90th Percentile** (95% conf. interval)	**95th Percentile** (95% conf. interval)	**Sample Size**
Total population (2011 - 2012)	5.59 (5.24-5.96)	5.15 (4.73-5.56)	7.73 (7.09-8.57)	12.2 (11.1-13.9)	17.2 (14.6-19.9)	2517
Total population (2013 - 2014)	4.80 (4.53-5.09)	4.53 (4.18-4.94)	7.22 (6.74-7.70)	11.2 (10.3-12.0)	14.7 (13.5-16.8)	2654
Total population (2015 - 2016)	4.41 (4.17-4.67)	4.08 (3.79-4.49)	6.55 (6.16-7.06)	10.5 (9.43-11.7)	14.5 (12.8-17.3)	3094
Age 3-5 years (2015 - 2016)	4.03 (3.71-4.36)	3.75 (3.50-3.96)	5.57 (5.12-6.43)	9.54 (7.82-11.8)	13.2 (10.3-20.6)	507
Age 6-11 years (2011 - 2012)	5.48 (5.05-5.95)	5.36 (4.50-5.98)	7.58 (7.08-8.34)	11.2 (9.93-12.1)	13.4 (11.6-16.2)	401
Age 6-11 years (2013 - 2014)	4.91 (4.44-5.43)	4.59 (4.02-5.00)	7.21 (6.20-8.38)	11.3 (9.91-13.9)	14.2 (11.4-19.6)	397
Age 6-11 years (2015 - 2016)	4.32 (4.00-4.68)	4.12 (3.66-4.56)	6.15 (5.45-6.66)	9.05 (7.98-11.1)	13.1 (10.2-21.0)	380
Age 12-19 years (2011 - 2012)	5.37 (4.67-6.17)	5.09 (4.24-6.00)	7.28 (6.27-8.32)	11.1 (8.34-14.9)	15.6 (10.8-23.9)	392
Age 12-19 years (2013 - 2014)	5.09 (4.64-5.57)	5.02 (4.51-5.46)	7.29 (6.53-8.08)	11.9 (9.80-13.7)	14.5 (12.5-15.9)	450
Age 12-19 years (2015 - 2016)	4.32 (3.97-4.70)	4.01 (3.58-4.52)	6.03 (5.37-6.77)	10.1 (8.75-11.8)	14.2 (11.2-17.1)	402

**See Calculation of Inorganic-related Arsenic Species for additional information. Limit of detection (LOD, see Data Analysis section) for Survey years 11-12, 13-14, and 15-16 are 4.04, 3.02, and 3.02, respectively.

Biomonitoring Summary: https://www.cdc.gov/biomonitoring/Mercury_BiomonitoringSummary.html
Factsheet: https://www.cdc.gov/biomonitoring/Mercury_FactSheet.html

Urinary Inorganic-related Arsenic Species (creatinine corrected) (2011 – 2016)

CAS Number 7440-38-2

Geometric mean and selected percentiles of urine concentrations (in µg As/g of creatinine) for the U.S. population from the National Health and Nutrition Examination Survey.

Categories (Survey Years)	**Geometric Mean** (95% conf. interval)	**50th Percentile** (95% conf. interval)	**75th Percentile** (95% conf. interval)	**90th Percentile** (95% conf. interval)	**95th Percentile** (95% conf. interval)	**Sample Size**
Total population (2011 - 2012)	6.31 (6.02-6.63)	6.00 (5.64-6.37)	9.46 (8.88-10.1)	15.1 (13.4-16.5)	19.6 (18.3-20.4)	2516
Total population (2013 - 2014)	5.53 (5.24-5.83)	5.28 (4.91-5.61)	8.09 (7.61-8.62)	13.0 (11.9-14.1)	17.4 (15.6-18.8)	2653
Total population (2015 - 2016)	4.94 (4.70-5.20)	4.77 (4.60-5.05)	7.51 (7.29-7.66)	11.6 (10.7-12.5)	16.2 (14.3-17.9)	3091
Age 3-5 years (2015 - 2016)	8.95 (8.20-9.78)	8.52 (7.89-9.27)	12.9 (11.4-14.1)	19.0 (15.4-22.4)	23.7 (21.3-30.4)	506
Age 6-11 years (2011 - 2012)	7.77 (7.36-8.20)	7.33 (6.95-8.26)	10.6 (9.74-11.9)	15.9 (14.3-16.8)	20.2 (16.8-22.3)	401
Age 6-11 years (2013 - 2014)	7.38 (6.78-8.04)	6.73 (5.99-8.30)	10.4 (9.30-12.3)	15.4 (14.1-16.8)	17.8 (15.5-19.4)	397
Age 6-11 years (2015 - 2016)	6.16 (5.78-6.56)	5.92 (5.49-6.27)	8.53 (7.98-9.36)	12.6 (11.2-15.2)	17.7 (14.2-20.7)	380
Age 12-19 years (2011 - 2012)	5.13 (4.48-5.88)	4.76 (4.40-5.11)	7.40 (5.86-8.81)	11.4 (8.17-16.8)	16.8 (11.4-28.7)	392
Age 12-19 years (2013 - 2014)	4.61 (4.14-5.15)	4.38 (3.92-4.81)	6.57 (5.55-7.69)	9.38 (8.11-11.1)	11.7 (9.46-16.7)	450
Age 12-19 years (2015 - 2016)	4.04 (3.78-4.31)	3.96 (3.46-4.43)	5.59 (5.20-6.16)	8.64 (7.50-10.2)	12.9 (9.76-15.3)	402

**See Calculation of Inorganic-related Arsenic Species for additional information.

Biomonitoring Summary: https://www.cdc.gov/biomonitoring/Mercury_BiomonitoringSummary.html
Factsheet: https://www.cdc.gov/biomonitoring/Mercury_FactSheet.html

Urinary Mercury (2011 – 2016)

CAS Number 92786-62-4

Geometric mean and selected percentiles of urine concentrations (in µg/L) for the U.S. population from the National Health and Nutrition Examination Survey.

Categories (Survey Years)	**Geometric Mean** (95% conf. interval)	**50th Percentile** (95% conf. interval)	**75th Percentile** (95% conf. interval)	**90th Percentile** (95% conf. interval)	**95th Percentile** (95% conf. interval)	**Sample Size**
Total population (2011 - 2012)	.324 (.285-.368)	.320 (.280-.370)	.660 (.580-.770)	1.37 (1.15-1.59)	1.83 (1.62-2.14)	2507
Total population (2013 - 2014)	.246 (.221-.273)	.200 (.170-.240)	.470 (.400-.570)	1.07 (.900-1.22)	1.64 (1.35-1.96)	2666
Total population (2015 - 2016)	*	< LOD	.280 (.250-.320)	.680 (.570-.780)	1.18 (.920-1.29)	3080
Age 3-5 years (2015 - 2016)	*	< LOD	< LOD	.160 (<LOD-.240)	.280 (.190-.510)	496
Age 6-11 years (2011 - 2012)	.241 (.206-.283)	.220 (.190-.270)	.450 (.390-.530)	.930 (.680-1.36)	1.37 (.990-2.03)	401
Age 6-11 years (2013 - 2014)	*	< LOD	.220 (.150-.310)	.560 (.340-.840)	.890 (.640-1.10)	401
Age 6-11 years (2015 - 2016)	*	< LOD	< LOD	.300 (.200-.380)	.520 (.360-.700)	380
Age 12-19 years (2011 - 2012)	.257 (.212-.312)	.270 (.220-.340)	.490 (.390-.600)	.840 (.650-1.24)	1.31 (.920-1.75)	390
Age 12-19 years (2013 - 2014)	*	< LOD	.240 (.200-.310)	.560 (.400-.860)	1.02 (.610-1.81)	452
Age 12-19 years (2015 - 2016)	*	< LOD	.130 (<LOD-.160)	.350 (.200-.470)	.610 (.380-1.14)	402

Limit of detection (LOD, see Data Analysis section) for Survey years 11-12, 13-14, and 15-16 are 0.05, 0.13, and 0.13, respectively.

< LOD means less than the limit of detection, which may vary for some chemicals by year and by individual sample.

* Not calculated: proportion of results below limit of detection was too high to provide a valid result.

Biomonitoring Summary: https://www.cdc.gov/biomonitoring/Mercury_BiomonitoringSummary.html
Factsheet: https://www.cdc.gov/biomonitoring/Mercury_FactSheet.html

Urinary Mercury (creatinine corrected) (2011 – 2016)

CAS Number 92786-62-4

Geometric mean and selected percentiles of urine concentrations (in µg/g of creatinine) for the U.S. population from the National Health and Nutrition Examination Survey.

Categories (Survey Years)	**Geometric Mean** (95% conf. interval)	**50th Percentile** (95% conf. interval)	**75th Percentile** (95% conf. interval)	**90th Percentile** (95% conf. interval)	**95th Percentile** (95% conf. interval)	**Sample Size**
Total population (2011 - 2012)	.367 (.333-.405)	.353 (.306-.394)	.676 (.623-.754)	1.33 (1.13-1.50)	1.75 (1.49-2.32)	2505
Total population (2013 - 2014)	.283 (.260-.309)	.270 (.250-.290)	.571 (.511-.644)	1.20 (1.05-1.36)	1.61 (1.47-1.81)	2665
Total population (2015 - 2016)	*	< LOD	.356 (.318-.391)	.708 (.628-.817)	1.10 (.912-1.25)	3077
Age 3-5 years (2015 - 2016)	*	< LOD	< LOD	.667 (<LOD-.818)	.994 (.818-1.13)	495
Age 6-11 years (2011 - 2012)	.345 (.298-.398)	.306 (.276-.344)	.537 (.441-.613)	1.08 (.884-1.43)	1.62 (1.07-2.34)	400
Age 6-11 years (2013 - 2014)	*	< LOD	.429 (.310-.529)	.750 (.563-.897)	1.11 (.713-1.72)	401
Age 6-11 years (2015 - 2016)	*	< LOD	< LOD	.474 (.409-.529)	.643 (.500-1.00)	380
Age 12-19 years (2011 - 2012)	.246 (.219-.277)	.221 (.190-.269)	.405 (.368-.453)	.735 (.571-1.11)	1.21 (.742-1.49)	390
Age 12-19 years (2013 - 2014)	*	< LOD	.257 (.200-.281)	.580 (.391-.735)	.846 (.580-1.07)	452
Age 12-19 years (2015 - 2016)	*	< LOD	.194 (<LOD-.220)	.320 (.246-.568)	.650 (.385-.967)	402

< LOD means less than the limit of detection, which may vary for some chemicals by year and by individual sample.

* Not calculated: proportion of results below limit of detection was too high to provide a valid result.

Biomonitoring Summary: https://www.cdc.gov/biomonitoring/Mercury_BiomonitoringSummary.html
Factsheet: https://www.cdc.gov/biomonitoring/Mercury_FactSheet.html

Attachment C1: Lead, and Arsenic and Mercury Exposure Questionnaires

Lead Investigation Questionnaire

Address:
Property Owner:

Current Resident:

Children/Children's Habits:

1. (a) Do any children live in the home? Yes No
   (b) If yes, how many? ____ Ages? ____ ____ ____ ____
   (c) Record blood lead levels, if known. ____ ____ ____ ____
   (d) Are women of child-bearing age present? Yes No

2. Location of the rooms/areas where each child sleeps, eats, and plays.

Child	Location of BR	Rooms where child eats	Primary location where child plays indoors	Primary location where child plays outdoors.

3. Where are toys stored/kept? _____
4. Is there any evidence of chewed or peeling paint on woodwork, furniture, or toys? Yes No

Family Use Patterns:

5. Which entrances are used most frequently?
6. Which windows are opened most frequently?
   (a) Which windows are inoperable?
7. Do you use a window air conditioner? Yes No
   If yes, where?
8. (a) Do any household members garden? Yes No
   (b) Location of garden
   (c) Are there plans to do any landscaping activities that will remove grass or ground covering? Yes No
9. (a) How often is household cleaned?
   (b) What cleaning methods are used? ___wet mopping ___sweeping___vacuuming___dusting
10. (a) Were building renovations recently conducted? Yes No
    (b) If yes, where?
    (d) Was building debris stored in the yard? If yes, where?
11. Are renovations planned? Y N If yes, where?
12. Occupation/workplace of household members:

Observations:

Housekeeping: Good____ Fair____ Poor____
Pets: Inside____ Outside____
Personal hygiene: Good____ Fair____ Poor____
Flooring: Carpet_____ Cleanable surfaces_____

Lead Investigation Questionnaire

Housing Condition (List Locations):

Generally deteriorated paint:

Paint being abraded:

Paint chipping due to impact:

Roof or plumbing leaks:

Paint in exterior soil? Yes No

Other painted structures (garage, shed, fence)?

Arsenic and Mercury Exposure Investigation Questionnaire

Introduction - Hello my name is {SAY NAME}.

We are part of the RMAP team from the Health Department conducting environmental sampling in Butte. We are following up with you because we have found arsenic or mercury above action levels at your home, or because you have requested analyses of arsenic or mercury in urine. We will be asking you some common questions like your name and address. We will also ask questions on your potential contact with arsenic or mercury. We are asking these questions to better understand all the data we collect.

The questions should take about 20 minutes. Once we receive the results for your samples, you will be given a copy and details of the testing results for you and your children (if you have them). Generally, we are able to get results to you within 12 weeks.

1. Person Administering Questionnaire _____
2. Date Questionnaire Administered _____
3. Participant last name _____
4. Participants first name _____
5. Address: _____

   _____

   _____

6. Mailing address if different from home address: _____

   _____

   _____

7. **Laboratory ID _____**

Now I want to ask you questions about how I can contact you. I will also be asking how long you have lived at or visited certain places. This is needed to find out how long you may have had contact with arsenic or mercury and how long it may have lasted. We will also ask your age, address, and about how you spend your time (e.g, child at daycare, how often they play outside, your jobs and hobbies). This is useful to help us better understand your test results.

8. Is the person being interviewed a minor?

   Yes

   No (skip to question 15)

Arsenic and Mercury Exposure Investigation Questionnaire

9. Name of person answering questions for minor child:

10. Relationship to child:

    Mother

    Father

    Grandparent

    Guardian

11. Does the child put their hands or toys in their mouth?

    Yes

    No (skip to question 13)

12. If yes, what and how often?

13. Have you noticed the child eating dirt while playing outside?

    Yes

    No (skip to question 15)

14. If yes, how often?

Demographic Questions. Script: The next questions are about qualities of the person who is being tested (you or your child/ward). This information and will help us better understand your test results.

15. What is your or your child/ward's sex?

    Male

    Female

16. What is your or your child/ward's age and date of birth?

    Age

    Date of Birth

17. If female between 15-44 yrs, are you pregnant? If yes in what month of pregnancy?

    Don't know

No

Yes, 0 to 3 months

Yes, 4 to 6 months

Yes, 7 to 9 months

18. Do you or your child/ward regularly spend time at another location outside the home (e.g., work or daycare/school)?

Yes

No (skip to question 22)

19. If yes, how long are your or your child/ward out of the house during the day?

1 to 4 hours

5 to 8 hours

Over 8 hours

Don't know

20. If you or your child/ward are out of the house during the day, how many times per week?

1-3 days per week

4 or more days per week

Don't know

21. How many hours per day do you or your child/ward typically spend outdoors?

Do not spend time outdoors

Less than 2 hours per day

2 to 4 hours per day

4 to 6 hours per day

Over 6 hours per day

Don't know

22. Does you or your child/ward wash hands before eating?

    Always

    Sometimes

    Never

23. How long have you lived at this address?

    Less than 6 months

    6 months to less than 2 years

    2 to 5 years

    6 to 10 years

    More than 10 years

24. How long have you lived in Butte, MT?

    Less than 6 months

    6 months to less than 2 years

    2 to 5 years

    6 to 10 years

    More than 10 years

Attributes of the Structure or Home. The following questions are about the qualities and characteristics of your home.

25. Do you live in a(n):

    Apartment

    Single Family Home

    Townhouse or Condominium

    Mobile Home

Other

No

Don't know

26. How often do you clean your home using a wet mop?

Daily

Several times a week

Weekly

Monthly

Other

27. How often do you clean your home using a vacuum cleaner?

Daily

Several times a week

Weekly

Monthly

Other

28. Do you have an attic in your home?

Yes

No (skip to question 32)

29. If you have an attic in your home, how often do you enter the attic?

Daily

Weekly

Monthly

Yearly

Never

30. Has your attic been cleaned by a professional?

Yes

No

31. If yes, when was it cleaned?

Soil Information (Tracking inside home)

32. Does your home have a yard with bare dirt?

    Yes

    No

33. Has soil in your yard been removed and replaced with clean soil?

    Yes

    No (skip to question 35)

34. If yes, when was it done?

35. How often do you or your child/ward remove shoes before entering your home?

    Never do this

    Seldom do this

    Sometimes do this

    Always do this

36. Does anyone in the home work primarily outdoors in a job with frequent soil or slag contact? (slag reprocessor, construction worker, landscaping, etc.) (if NO, skip to question 38)

    Yes

    No

    Don’t know

37. How often do they change clothing when entering the home after work outdoors?

    Never do this

    Seldom do this

Sometimes do this

Always do this

Arsenic Exposure Questions

38. Do you have a job that may bring you into contact with arsenic?

    Wood preservation

    Arsenate pesticide production

    Sand blaster

    Other

39. How many portions of fish and other seafood (including shrimp, canned tuna and clam chowder) did you or your child/ward eat in the past week?

    None

    1-2

    3-4

    5 or more

    Don't know

40. How many portions of rice (white or brown) did you or your child/ward eat in the past week?

    None

    1-2

    3-4

    5 or more

    Don't know

Mercury Exposure Question

41. Do you or your child/ward have mercury amalgam fillings?

    Yes (if yes, approximately how many?)

No

42. Is there anything you want us to know about you or your child that we did not ask about?

Attachment C2: Urine Collection Instructions

URINE COLLECTION INSTRUCTIONS
BUTTE-SILVER BOW EXPOSURE INVESTIGATION

Please READ CAREFULLY:

- Enclosed is a **plastic cup** and a **plastic bag** with an **absorbent pad inside**.
- DO NOT take the cap off the cup until you are about to collect your urine.
- We would like you to collect your first morning urine, if possible
- Make sure you fill out all the items on the plastic cup label before you put your urine in the freezer.

Instructions for collecting your urine:

- Wash your hands with soap and water.
- Rinse and dry your hands with a clean towel.
- Keep the **cup closed** until you are ready to collect your urine.
- **DO NOT TOUCH** the inside of the cup or cap.
- Open the cup and leave the cap turned up.
- **Collect your urine inside the cup**.
- Put the cap back on the filled container and tighten it.
- Wash your hands with soap and water again.
- Fill out the label on the plastic cup as follows:
    - Name
    - Date
    - Time of urine collection
    - First Morning Urine? Yes or No
    - Time urine put into freezer
- **Put the closed cup filled with urine on the absorbent pad in the plastic bag we gave you,**
- **SEAL the BAG**,
- Put the sealed plastic bag with the filled urine cup in the **FREEZER.**
- **Bring the CUP of FROZEN URINE in the sealed plastic bag to your scheduled blood draw appointment.**

Thanks!

Attachment D1: LeadCare® II User's Guide

leadcare® II

LeadCare® II Blood Lead Analyzer

User's Guide

NOTE:	**Instructions for use with Analyzer Firmware Version 1.09 or higher.** Please check the label on the bottom of your analyzer to determine firmware version.

CE IVD Rx Only

Magellan DIAGNOSTICS

Magellan
DIAGNOSTICS

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For use with the LeadCare II Blood Lead Analyzer Model 70-6529

Document Number: 70-6551 Rev 11

EC REP

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Preface

NOTE:

The LeadCare® II Blood Lead Analyzer is a CLIA-waived device. Facilities that perform tests with the LeadCare II system must have a CLIA Certificate of Waiver (COW) or higher, as issued under the authority of the Public Health Service Act (PHSA) (42 U.S.C. 263(a)). In addition to a Certificate of Waiver, all laboratories performing this test must comply with all applicable state and local laws.

All laboratories eligible for a CLIA Certificate of Waiver must follow the manufacturer's instructions as specified in the LeadCare II User's Guide (this guide), LeadCare II Quick Reference Guide and in the LeadCare II Package Insert.

Other LeadCare II Documents

- LeadCare II Quick Reference Guide (English)
- LeadCare II Test Kit Package Insert
- LeadCare II Flash Drive

Troubleshooting

Troubleshooting procedures are described in detail in Chapter 5 of this guide. Read this section carefully. If you continue to experience problems with device operation, contact Magellan Diagnostics Product Support at 1-800-275-0102 or LeadCareSupport@magellandx.com.

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Chapter 1 Before Testing

Read all instructions carefully before you perform a blood lead test.

This chapter contains important information that you need to know before you use the LeadCare® II Blood Lead Analyzer. Please read the following sections before using the analyzer.

- Unpacking the LeadCare II Blood Lead Analyzer
- Setting up the Analyzer
- About the LeadCare II Blood Lead Analyzer
- Intended Use
- Operating Requirements
- Reading the Analyzer Display
- Important Precautions
- How to Get Help

CAUTION: Magellan Diagnostics recommends that you practice using the system before performing a patient test.

Definitions and Precaution Symbols

WARNING: This symbol identifies conditions or practices that could result in injury or loss of life.

CAUTION: This symbol indicates conditions or practices that could cause erroneous results or damage to the analyzer**.**

This symbol indicates that you should read the instructions carefully.

This symbol indicates the potential for electrostatic discharge. Static electricity can damage or destroy the internal components of devices. It can be generated by scuffing shoes on a carpet or brushing some other materials such as fabrics. When running the analyzer, discharge static electricity by touching a metal object (such as the outside of a computer) in your work area.

This symbol indicates a biohazard.

NOTE: A note provides additional information to help you perform procedures correctly, or help you understand how the system works.

Compliance Statements

CE Mark

CE IVD - 98/79/EC (27/10/1998) – Annex I and III

EMC

EMC Standard EN 61326-1 (2005) also FCC Part 15 Subpart B Class B

Safety

Complies with:
Low Voltage Directive 2006/95/EC, EN61010-1:2001 (EU) UL61010-1:2004 (USA) CSA C22.2 No. 61010-1:2004 (Canada) and Requirements for *In Vitro* Diagnostic (IVD) IEC 61010-2-101:2002.

NOTE: Protection of this equipment may be impaired if operated in a way not described in this User's Guide. Use only the accessories and cables supplied or specified.

The ETL label on the bottom of the instrument indicates that Intertek Electrical Testing Labs (ETL) has certified the LeadCare II to the applicable safety standards.

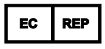
This device complies with Part 15 of the FCC rules. Operation is subject to the following two rules:

1. This device may not cause harmful interference.
2. This device must accept any interference received, including interference that may cause undesired operation.

This device complies with the Waste Electrical and Electronic Equipment (WEEE) directive of the European Union (EU). For information regarding the proper decontamination procedure for this product please contact Magellan Diagnostics. Instruments labeled with the associated symbol (see left) **must not** be disposed of as regular waste material.

Symbols

The following symbols are used in the labeling of the LeadCare II Analyzer and Blood Lead Test Kit.

Symbol	Description
CE	This product fulfills the requirements of Directive 98/79/EC on In Vitro Diagnostic Medical Devices.
	Temperature Limitation
	Use By
	Manufacturer
	Batch Code
	Biological Risk
	Caution: See Instructions for Use
	Caution: Risk of Electric Shock
	Consult Instructions for Use
	Catalog Number
	Serial Number
	In Vitro Diagnostic Medical Device
	Authorized Representative in the European Union
O	Off (supply)
I	On (supply)
	Prescription Use Only

Unpacking the LeadCare II Blood Lead Analyzer

LeadCare II materials are contained in two (2) packages:

1. LeadCare II Analyzer Kit

    - Analyzer
    - AC Adapter & International Power Plug Set
    - 4 AA Alkaline Batteries
    - Quick Reference Guide (not pictured)
    - LeadCare II Flash Drive (contains User's Guide and Instructional Videos)

Figure 1-1 Analyzer Kit Contents

2. LeadCare II Test Kit

- 48 Blood Lead Sensors
- 48 LeadCare Treatment Reagent Tubes
- 50 LeadCare II Heparinized Capillary Tubes and Plungers
- 50 LeadCare II Droppers
- Level 1 Control
- Level 2 Control
- Calibration Button
- LeadCare II Package Insert
- LeadCare Labels, Worksheets and Assayed Control Sheet

Figure 1-2 Test Kit Contents

WARNING: Be careful when handling the LeadCare II Treatment Reagent. This reagent contains dilute Hydrochloric acid. Refer to the LeadCare Treatment Reagent Safety Data Sheet that appears in Appendix D of this manual for safe handling instructions.

Register Your System

Please take a moment to complete the registration form online at: https://www.magellandx.com/leadcare-products/leadcare-ii/support/getting-started/

Registering your analyzer with Magellan Diagnostics will allow you to receive important updates about your LeadCare II Test System.

Setting up the Analyzer

The Work Area

Set up the LeadCare II Blood Lead Analyzer in an area that is free of drafts and temperature extremes. The analyzer needs a stable temperature to operate. You can use the analyzer with an AC power adapter or with batteries.

Using the Analyzer with a Power Adapter

CAUTION: Use only the AC adapter supplied with this unit. Attempting to use a different type of manufacturer's product could damage the analyzer.

To use the analyzer with a power adapter:

1. Plug the DC connector into the back of the analyzer as shown in Figure 1-3.

Figure 1-3 Plug in DC Connector/AC Adapter

2. Plug the adapter into an AC power outlet.

3. Move the power switch to the left to turn the analyzer on.

Installing Batteries

CAUTION: When replacing batteries, use only 1.5 V AA size alkaline or lithium batteries (4 ea). Shut the analyzer off prior to battery removal. Dispose according to local, state and country regulations.

WARNING: Batteries may explode if mishandled or replaced incorrectly. Do NOT dispose of batteries in fire. Do NOT attempt to disassemble or recharge batteries. Keep batteries away from children.

The battery holder is located at the rear of the analyzer. To install the batteries:

1. Turn the analyzer to access the battery area.
2. Remove the DC input connector.
3. Remove the battery cover as shown in Figure 1-4.

Figure 1-4 Remove Battery Holder Cover

4. Press on the locking tab with one or both thumbs and slide it away from the analyzer.
5. Insert four 1.5 V AA size alkaline or lithium batteries as shown in Figure 1-5.

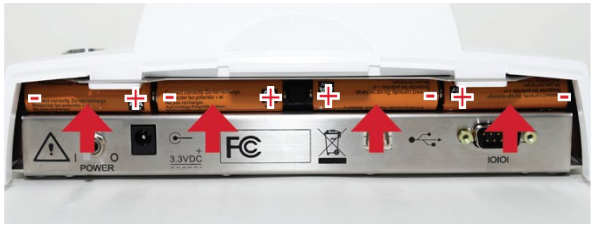


Figure 1-5 Insert Batteries

CAUTION: Observe the polarity of each battery. Inserting one backwards could damage the analyzer.

6. Replace the cover by sliding it back on. Make sure it “clicks” into place.

NOTE: When the analyzer is not in use it will automatically shut off:
Battery: 15 minutes AC Adapter: 60 minutes

Test results are lost when the analyzer becomes idle.

About the LeadCare II Blood Lead Analyzer

The LeadCare II Blood Lead Analyzer is a portable device for testing the amount of lead in capillary whole blood.

Figure 1-6 LeadCare II Blood Lead Analyzer

About Blood Lead Testing

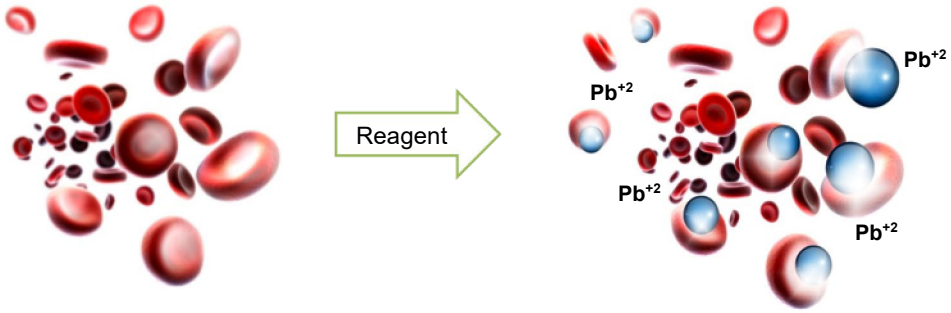
According to the US Centers for Disease Control (CDC), there is no known safe level of lead. Consult your local public health department and/or CDC recommendations for information on the management of blood lead levels.

How the LeadCare II System Works

The LeadCare II System uses an electrochemical technique called Anodic Stripping Voltammetry (ASV) to determine the amount of lead in a blood sample. The diagram below illustrates the methodology.

1

Blood is mixed with LeadCare Treatment Reagent and the red blood cells (RBC) are lysed, which releases the lead that is bound to the RBC wall.

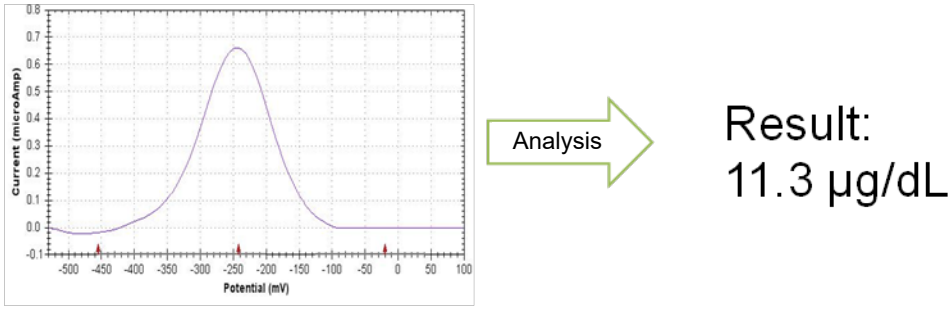


2

A negative potential is applied to the sensor to accumulate lead atoms on the test electrode. The potential is rapidly reversed releasing the lead ions.

3

The current produced is directly proportional to the amount of lead in the sample. The area underneath the curve is used to calculate a quantitative blood lead result.



Intended Use

The LeadCare II Blood Lead Analyzer and Test Kit provide a measurement of the amount of lead in a fresh capillary whole blood sample. The LeadCare II Blood Lead Analyzer is intended for *in vitro* (external) use only. It is for lead testing only. The test kit components are designed for use only with the LeadCare II Blood Lead Analyzer. This test system is for professional use only.

Operating Requirements

CAUTION: Do NOT place the LeadCare II Blood Lead Analyzer in a drafty area. For example, do NOT place the analyzer near air conditioning or heating vents. If the temperature is out of operating range, or if the temperature is unstable, the following messages appear on the display.

TEMP IS TOO HOT
PLEASE WAIT UNTIL
ANALYZER IS IN
TEMP RANGE

TEMP IS TOO COLD
PLEASE WAIT UNTIL
ANALYZER IS IN
TEMP RANGE

If the temperature is unstable, the WARNING message appears on the display and flashes on for 2 seconds. Move the analyzer to a more suitable location and try again later.

WARNING
TEMP IS UNSTABLE
TEST MAY FAIL

Reading the Analyzer Display

The LeadCare II Blood Lead Analyzer displays messages that guide you through the test. Do NOT go to the next step until the message tells you to proceed. The test takes three (3) minutes. When the test is complete, the blood lead level appears on the display. The test result remains on the screen until you insert a new sensor or for a minimum of 15 minutes.

Figure 1-7 Message Display

The analyzer monitors the test conditions and displays error messages on the screen if a problem is detected. Chapter 5, Troubleshooting and Maintenance, includes a list of the messages and what to do if they appear.

Important Precautions

This section lists important things you need to know about using the LeadCare II Blood Lead Analyzer. Understand these precautions.

Precautions When Preparing Samples

WARNING: Use universal precautions while collecting and handling blood samples. Blood can transmit infectious diseases. Follow the procedures set up by your institution for meeting local, state and federal regulations.

CAUTION: When preparing blood samples for testing:

- Wear powder-free gloves to prevent lead contamination. Because there is lead in the environment, it is easy to contaminate blood samples, collection tubes, and test kit items. Contamination of the work environment can cause inaccurate blood lead test results.

- Use only the heparinized capillary tubes provided with the LeadCare II Test Kit. The capillary tube must be filled to the fill line (50 µl) for accurate results. Check to make sure that the tube is free of gaps and bubbles. After collection, wipe off the sides of the capillary tube with a gauze pad (wipe downward). The accuracy of the test depends on a precisely measured sample.

- Use only fresh, unrefrigerated, whole blood with the LeadCare Treatment Reagent. Do NOT refrigerate the blood prior to mixing with the reagent. Blood must be stored at 10º - 32ºC (50º - 90ºF).

- Add blood sample to the treatment reagent within 24 hours of collection. Blood older than 24 hours may produce false negative results. Make sure the blood sample is free of blood clots, which can cause inaccurate results.

- Visual Impairment: Any visual impairment, such as color blindness may affect the operator's ability to detect the sample color change. Operators with vision deficiencies should invert the tube 8 to 10 times to ensure that the sample is properly mixed.

Precautions for Testing a Patient Sample

CAUTION: When testing blood samples:

- Wear powder-free gloves to prevent lead contamination. Because there is lead in the environment, it is easy to contaminate blood samples, collection tubes, and test kit items. Contamination of the work environment can cause inaccurate blood lead test results.

- Do NOT allow the inside of the treatment reagent vial or the vial cap to touch anything. This could cause inaccurate blood lead test results.

- Mix the blood sample with the treatment reagent thoroughly, but do NOT shake the tube. Gently invert the tube ten times until the reagent turns brown. Avoid foam and air bubbles.

CAUTION:

- Do NOT leave the treatment reagent vial uncapped other than to add the sample or remove the sample/reagent solution. The tube and its contents could become contaminated causing inaccurate test results.
- Before placing the sample on the sensor, make sure the display calls for sample addition.
- Keep the sensors in their container until you need them. Do NOT touch “X” on the sensors, except when applying the sample. This could cause contamination and an inaccurate test result.

Precautions When Performing Quality Control Testing

CAUTION: When testing controls, make sure that the value falls within the acceptable range for each control. Do NOT proceed to patient samples if the control results are NOT within acceptable limits. Refer to the Troubleshooting section of the User's Guide, or call Product Support at 1-800-275-0102 to help you resolve any problem.

Using the Control Materials

CAUTION: Treat control material as you would patient samples; add the control to treatment reagent prior to testing. Store the controls at room temperature with all other kit components. Discard unused control material when the kit is finished. Using control material with the wrong kit lot number could yield inaccurate results. Refer to Quality Control chapter for more information about the control test procedures.

More Information

The following references provide additional information about blood sample collection, blood lead testing, and Magellan Diagnostics LeadCare II products.

Blood Sample Collection

Information about sample collection is available from the Clinical Laboratory Standards Institute (CLSI) or the Centers for Disease Control (CDC).

- CLSI (Clinical and Laboratory Standards Institute) GP44-A4: Procedures for the Handling and Processing of Blood Specimens; Approved Guideline – 4th ed. (ISBN 1-56238-724-3). www.clsi.org
- CDC Guidelines for Collecting and Handling Blood Lead Samples - 2004 - Video presentation describes how to collect and handle samples that will be used for blood lead testing. www.cdc.gov/nceh/lead/training/blood_lead_samples.htm

Blood Lead Testing

According to the US Centers for Disease Control (CDC), there is no known safe level of lead. Consult your local public health department and/or CDC recommendations for information on the management of blood lead levels.

LeadCare II Product Information

Visit www.leadcare2.com for additional information about our products and resources.

How to Get Help

A Product Support Specialist is available Monday through Friday, 8:00 a.m. to 6:00 p.m. (EST).

Call LeadCare Product Support at 1-800-275-0102.

Email LeadCareSupport@magellandx.com.

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Chapter 2 Calibrating the Analyzer

This chapter describes how to calibrate the analyzer. The analyzer must be calibrated to the lot of sensors to ensure accurate results. This chapter contains the following topics:

- Turning the Analyzer On and Off
- Analyzer Self-Tests
- About Calibration
- Calibrating the Analyzer

CAUTION:

- Calibration is required for each new lot of test kits. Use the calibration button in the test kit. Use only the button packaged with the kit you are using. Failure to use the correct calibration button with the test kit could cause inaccurate results.

- Do NOT use items from more than one test kit at a time.

- Always make sure that the lot numbers on the sensor container and calibration button match the SENSOR LOT number on the analyzer display.

Turning the Analyzer On and Off

The LeadCare® II Blood Lead Analyzer **power switch** is located at the back of the device as shown in Figure 2-1.

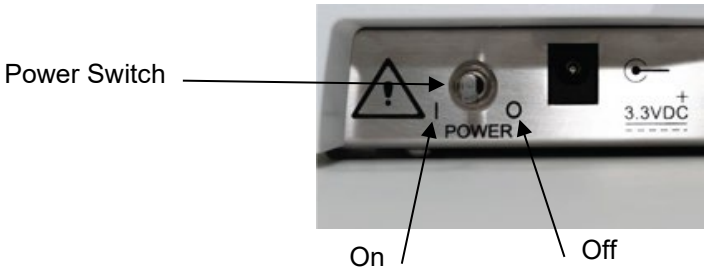


Figure 2-1 Power Switch

If the analyzer is not in use for 15 minutes (battery operation) or 60 minutes (AC operation), it will go into “sleep” mode. Inserting a sensor or moving the power switch to the ON position will restart the analyzer.

Turn On the Analyzer

To turn on the analyzer for the first time:

1. Make sure the analyzer is plugged in using the AC adapter, or that batteries are installed if you are using the analyzer in a remote location.

2. Move the switch on the back of the analyzer to the ON (|) position.

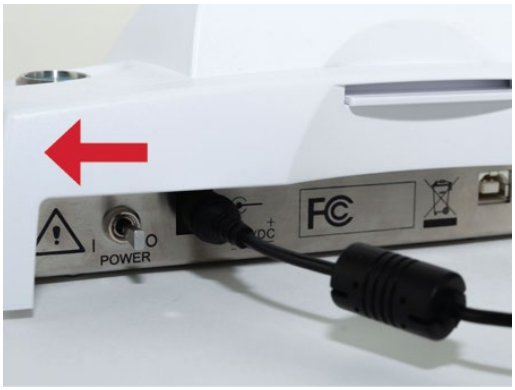


Figure 2-2 Turn Analyzer On

Analyzer Self-Tests

When you first turn on the analyzer, you will hear a beep and see the startup and self-test messages.

The analyzer performs a series of self-tests. The LeadCare II self-test is a set of internal electrical and software checks that ensure the proper operation of the system's electronic components. The purpose of the tests is to ensure that each critical hardware component of the system is operating at the correct level. If any one component of the system fails this initial self-test, the user is warned that the unit requires service and the user is prevented from running any patient samples.

The first time you turn on the analyzer, the screen reads:

PLEASE CALIBRATE
ANALYZER WITH BUTTON

Once the analyzer has been calibrated, the following message appears.

CALIBRATION
SUCCESSFUL

IF NEW LOT
TEST CONTROLS

PREPARE SAMPLE
USE SENSOR LOT XXXX
OR RECALIBRATE
THEN INSERT SENSOR

You can also turn on the analyzer by inserting a sensor.

If you insert a sensor to turn on the analyzer, the following message appears:

ADD SAMPLE
TO X ON SENSOR
SENSOR LOT XXXX

About Calibration

Why Calibration is Important

The analyzer must be calibrated to the lot of sensors to ensure accurate results. You must calibrate the analyzer:

- The first time you use the analyzer.
- Each time you start a new lot of test kits.
- Any time the analyzer displays a recalibration message.

The Calibration Button

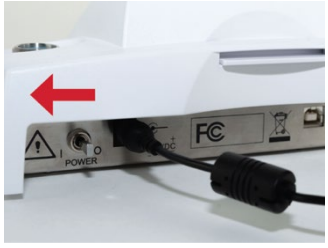
Each LeadCare II Test Kit comes with 48 sensors and a calibration button. The button transfers calibration and expiration information to the analyzer. When you touch the calibration button to the button reader, you will hear an audible beep. The lot number appears on the screen to verify that the button was read properly. The CALIBRATION SUCCESSFUL message flashes for 2 seconds.

Calibrating the Analyzer

CAUTION:

- Calibration is required for each new lot of test kits. Use only the calibration button packaged with the test kit you are using. Failure to use the correct calibration button could cause inaccurate results.
- Do NOT use items from more than one test kit at a time.
- Each test kit comes with a calibration button marked with the sensor lot calibration code. Always make sure that the lot numbers on the sensor container and calibration button match the SENSOR LOT number on the analyzer display.

See calibration instructions below.



1. Turn on the analyzer. The analyzer is ready when the “Prepare Sample” message appears.

NOTE: ***The first time you turn on the analyzer, you will see the “PLEASE CALIBRATE” message.***

PREPARE SAMPLE
USE SENSOR LOT XXXX
OR RECALIBRATE
THEN INSERT SENSOR

2. Locate the calibration button in the test kit. Remove the calibration button from the test kit package.

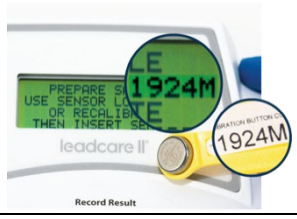
3. Match the lot number on the sensor container with the calibration code on the button.

4. Hold the calibration button to the button reader until you hear the beep. The button must touch both the center contact and metal side of the button reader.

   There is no need to apply pressure.

5. Calibration takes a few seconds. When calibration is complete, the screen briefly reads “CALIBRATION SUCCESSFUL”. Then the screen reads “IF NEW LOT TEST CONTROLS”, followed by the “PREPARE SAMPLE...” message.

CALIBRATION SUCCESSFUL



6. Make sure the number of the button matches the display.

The LeadCare II Blood Lead Analyzer is now ready for testing.

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Chapter 3 Quality Control Procedure

Magellan Diagnostics provides the LeadCare® II Controls in the test kit for quality control. The Level 1 and Level 2 controls are used to verify system performance and accuracy. This chapter covers the following information:

- What is a LeadCare II Lead Control
- Storage and Handling
- How Often Should You Test Controls
- Testing Controls
- Interpreting the Control Test Results

What is a LeadCare II Lead Control

A control is a standard against which test results can be evaluated. The LeadCare II controls are room temperature stable solutions designed to mimic blood, and spiked with lead to specific target values. The product is supplied in a two level format. Each is assigned a target lead value with an associated acceptable range.

The testing of controls will ensure your LeadCare II Blood Lead Analyzer is reporting accurate results.

Storage and Handling

The control material is supplied in liquid form and ready to use. It should be stored at room temperature and should not be used beyond its expiration date.

CAUTION: Controls should only be used with sensors of the same lot number. Discard remaining control solutions when the sensors are gone. Failure to do so may result in inaccurate patient results.

How Often Should You Test Controls

According to CLIA guidelines for Waived Laboratories, controls should be run according to the manufacturer's instructions, which are:[1]

- Each new lot.
- Each new shipment of materials, even if it's the same lot previously received.
- Each new operator (i.e., operator who has not performed the test recently).
- Monthly, as a check on continued storage conditions.
- When problems (storage, operator, instrument, or other) are suspected or identified.
- If otherwise required by your laboratory's standard QC procedures.

NOTE for Non-Waived Laboratories:	Some certification programs may have additional quality control requirements. Follow your federal, state and local guidelines to ensure compliance.

Testing Controls

Test the LeadCare II Lead Control material as you would any whole blood sample. You must run both the Level 1 and Level 2 controls to verify the performance of the system.

CAUTION: When testing controls, make sure that the value falls within the acceptable range for each control. Do NOT proceed to patient samples if the control results are outside acceptable limits. Refer to the Troubleshooting section of the User's Guide, or call Product Support at 1-800-275-0102 to help you resolve any problem.

Testing controls consists of the following steps:

A) Prepare the Sample

1. Label a treatment reagent tube, "Level 1".
2. Gently swirl the control vial. Remove the cap from the Level 1 control and place it *top down* on a clean surface.
3. Fill one capillary tube with the control material. To accomplish this tilt the control vial, insert the capillary tube into the liquid while holding the green end of the capillary tube almost horizontally. Capillary action will fill the tube to the black line.
4. Use a clean wipe to remove excess control material from the outside of the capillary tube.

[1] Benson, Carol 2008, 'Recommendations for Clinical Laboratory Improvement Amendments of 1988 (CLIA) Waiver Applications for manufacturers of in Vitro Diagnostic Devices', Guidance for Industry and FDA Staff:, p.34, viewed 26 January 2009.

B) Mix with Treatment Reagent

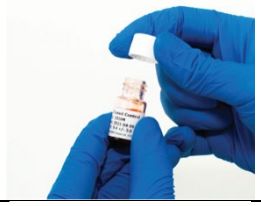
1. Remove the cap from the treatment reagent tube and place it *top down* on a clean surface.
2. Place the full capillary tube into the treatment reagent. Insert a plunger into the top of the capillary tube and push down, ensuring the entire volume of control is dispensed into the treatment reagent.
3. Remove the empty capillary tube and recap the treatment reagent.
4. Invert the treatment reagent tube 8 – 10 times to thoroughly mix the two. The resulting mixture will be red.

C) Test

1. Insert a fresh sensor into the LeadCare II Analyzer.
2. Ensure the lot number on the display matches the sensor lot you are using. It must also match the lot number on the control vial.
3. Invert your sample to ensure the sample is well mixed, then remove the cap.
4. Using a dropper, transfer the sample to the X on the sensor.
5. When the three minute countdown is complete, record your lead result in micrograms per deciliter (µg/dL).
6. Repeat this process for the Level 2 control.

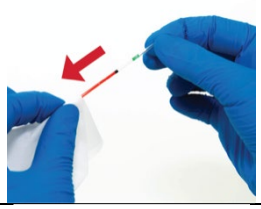
Testing Controls:

1. Label a fresh treatment reagent tube "Level 1 control".

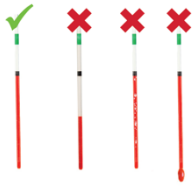


2. Swirl the control vial gently. Remove the cap from the control and place it *top down* on a clean laboratory wipe. Ensure the lot number on the control vial matches the sensor lot number you will be testing.

3. Holding the capillary tube almost horizontally with the green band on top, fill it to the 50 µL ***black*** *line*. Replace the cap on the control vial.

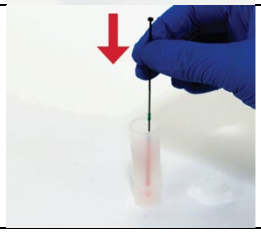


4. Use a downward motion to remove excess control from the outside of the tube with a clean wipe or gauze pad. Use caution not to absorb the control from the end of the capillary tube.

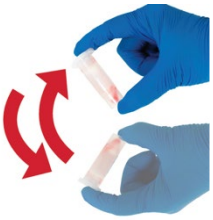


5. Inspect the capillary tube for proper filling. Make sure there are no gaps or bubbles, or any excess control on the outside of the capillary tube.

6. Remove the cap from a vial of treatment reagent and place it *top down* on a clean surface. Do NOT allow the inside of the cap to touch anything. This could cause inaccurate test results.



7. Place the capillary tube into the treatment reagent tube. Insert a plunger into the top of the capillary tube and push down ensuring the entire volume of control is dispensed into the treatment reagent.



8. Replace the tube cap. Invert the tube 8 to 10 times to mix the sample completely. The mixture will remain red.
9. Repeat this process (steps 1 thru 8) for the Level 2 control.
10. Analyze control samples according to the instructions provided in Chapter 4.

Interpreting the Control Test Results

The target values are printed on the control vials. The blood lead level that appears on the LeadCare II Analyzer should be within the acceptable range provided for that control. If the reported value is within the acceptable limits for both the Level 1 and Level 2 controls, your LeadCare II System is operating properly. You may now test patient samples.

If the reported value for the Level 1 and/or Level 2 control is outside the acceptable range, refer to the troubleshooting section of the LeadCare II User's Guide. If, after following the instructions, the control value is still out of range please contact LeadCare Product Support at 1-800-275-0102.

CAUTION: Do NOT proceed to patient samples unless both the Level 1 and Level 2 control results are within the acceptable ranges.

How Magellan Diagnostics Assigns Lead Level Ranges

Acceptable ranges for each lot and lead level are established by Magellan Diagnostics using LeadCare II Blood Lead Testing Systems. Magellan Diagnostics establishes these ranges using extensive replicate analyses and rigid quality control.

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Chapter 4 Blood Lead Testing

Read all instructions carefully before you perform a blood lead test.

This chapter describes how to test a patient's blood for lead. It contains the following topics:

- Overview of the Testing Procedure
- The LeadCare® II Message Display
- Required Materials
- Precautions
- Testing Procedure
- Interpreting Patient Test Results
- Follow-up Testing
- Printing Test Results
- References

Overview of the Testing Procedure

Testing for lead in blood with the LeadCare II Blood Lead Analyzer is fast and easy. Practice lead testing with the control samples or other samples before you perform a blood lead test.

The testing procedure consists of the following steps:

1. Verify you have the required materials.
2. Perform quality control testing on both levels of quality control and verify the results are within the acceptable ranges.
3. Collect capillary blood sample. Check the capillary tube for correct filling.
4. Add blood to the treatment reagent tube.
5. Insert a sensor and match the sensor lot number with the display.
6. Using a dropper, obtain sample from the treatment reagent tube, touch the dropper tip to the X on the sensor and squeeze the walls to dispense the sample.
7. Read and record the test result.
8. Remove used sensor.

The LeadCare II Message Display

The message display screen is designed to guide you through the testing process. Remember to read the display messages.

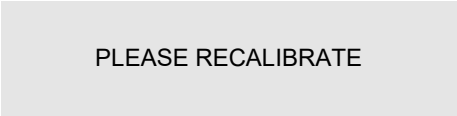


Figure 4-1 Message Display

Required Materials

CAUTION: Make sure the analyzer, test kit, and samples are at room temperature before testing.

- Protective Powder-free Gloves
- Alcohol Wipes, Gauze Pads, Lead Free Wipes (optional)
- Lancets
- Absorbent Liner and Biohazard Waste Container
- LeadCare II Analyzer and Power Cord or Batteries
- LeadCare II Quick Reference Guide
- LeadCare II User's Guide
- LeadCare Test Kit Items:
  - Heparinized Capillary Tubes/Plungers
  - Treatment Reagent Tubes
  - Blood Lead Sensors
  - Calibration Button
  - LeadCare II Lead Controls, Level 1 & 2
  - Droppers

Precautions

Observe the precautions listed throughout this section. Failure to follow these precautions could result in inaccurate test results.

Important precautions for testing are also listed in Chapter 1, Important Precautions.

WARNING:

- Blood can transmit infectious diseases. Use universal precautions while collecting and handling blood samples. Follow the procedures set up by your institution for meeting federal, state, and local regulations.

- Dispose of sensors, capillary tubes, plungers, and droppers in biohazard container.

- Use caution when handling the LeadCare II Treatment Reagent. This reagent contains dilute hydrochloric acid. Refer to the LeadCare Treatment Reagent Safety Data Sheet that appears in Appendix E of this manual for safe handling instructions.

CAUTION:

- Do NOT use sensors that have been dropped, previously handled, broken, scratched or damaged in any way. This could cause inaccurate test results.

- Make sure the sensor is inserted under the sensor guides and sits flush on the sensor deck. Inserting the sensor above the guides could cause inaccurate test results.

- Do NOT use any test kit or its components past the expiration date. This could cause inaccurate test results.

- Do NOT leave the treatment reagent vial uncapped other than to add the sample or remove the sample/reagent solution. The tube and its contents could be contaminated causing inaccurate test results.

Testing Procedure

CAUTION: Do Not proceed to patient testing if the control results are outside acceptable limits. Refer to the Troubleshooting section of the User's Guide, or call Product Support at 1-800-275-0102 to help you resolve any problem.

Gather Testing Materials

NOTE: **Be sure the following items are part of the same test kit. Do NOT mix components from different test kits.**

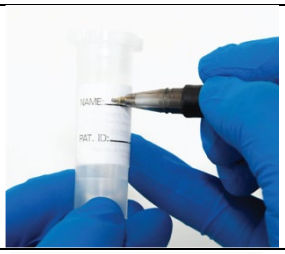
Place the following items in front of you in a clean work space:

- Container with heparinized capillary tubes/plungers
- Treatment reagent tube
- Sensor container
- Dropper for depositing sample on the sensor
- LeadCare II Blood Lead Analyzer

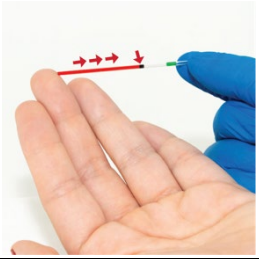
WARNING: Use universal precautions while collecting and handling blood samples. Blood can transmit infectious diseases. Follow the procedures set up by your institution to meet local, state and federal regulations.

Step 1: Collect Blood

CAUTION: Only use the heparinized capillary tubes provided with the LeadCare II Test Kit. The capillary tube must be filled to the fill line (50 µl) for accurate results. Check to make sure that the tube is free of gaps and bubbles. After collection, wipe the capillary tube with a gauze pad (wipe downward). The accuracy of the test depends on a precisely measured sample.

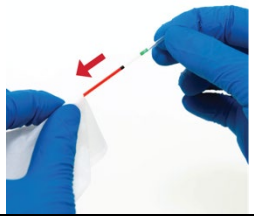


1. Label a treatment reagent tube with the patient ID using the label provided.



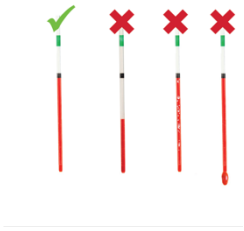
2. Holding the heparinized capillary tube almost horizontally with the green band on top, fill to the 50 µL black line. Filling stops when the sample reaches the black line.

   Do NOT use plasma or serum. Do NOT use venous blood samples.



3. Remove excess blood from the outside of the tube with a clean wipe or gauze pad. Use a downward motion to wipe excess blood from the capillary tube.

   Use caution not to absorb the blood from the end of the capillary tube.



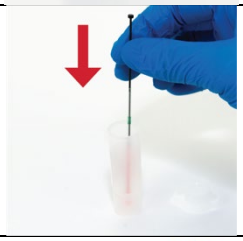
4. Inspect the capillary tube for proper filling. Make sure there are no gaps, air bubbles, or any excess blood on the outside of the capillary tube.

Step 2: Prepare Sample

CAUTION:

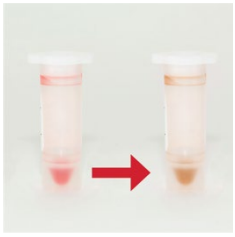
- The system is intended to test fresh capillary whole blood (collected in either EDTA or Heparin). Add the blood to the treatment reagent within 24 hours of collection. Blood older than 24 hours may produce false negative results.
- Use only fresh, unrefrigerated, whole blood with the LeadCare Treatment Reagent. Blood must be stored at 10° - 32°C (50° - 90°F) prior to mixing with treatment reagent.
- Make sure the whole blood sample is free of clots, which can cause inaccurate results.

1. Remove the treatment reagent cap from the tube and place it top down on a clean surface. Do NOT allow the inside of the cap to touch anything. This could contaminate the sample.



2. Place the full capillary tube in the treatment reagent. Insert a plunger into the top of the capillary tube and push down, ensuring to dispense the entire volume into the treatment reagent.

3. Replace the tube cap. Invert the tube 8 to 10 times to mix the sample completely.



4. The test sample is ready when the mixture turns brown. Repeat sample collection and preparation for each sample to be tested.

CAUTION: ***Any visual impairment, such as color blindness may affect the operator's ability to detect the sample color change. Operators with vision deficiencies should invert the tube 8 to 10 times to ensure that the sample is properly mixed.***

Storing Samples

You do not need to test the prepared sample immediately. The mixture of blood and treatment reagent is stable for up to 48 hours at room temperature and up to 7 days refrigerated. If refrigerated, bring to room temperature prior to analysis.

Step 3: Analyze the Sample

1. Remove one sensor from the sensor container. Close the container immediately. Grasp the sensor at the end without the black bars.

⚠ **CAUTION:** ***Keep the sensors in their container until you are ready to use them. Minimize handling to prevent contamination which could cause an inaccurate test result.***

2. Insert a sensor (with the black bars facing up) completely into the analyzer. Make sure the sensor is inserted under the sensor guides and sits flush on the analyzer deck. When the sensor is inserted properly the analyzer beeps and displays the message to the right.

ADD SAMPLE
TO X ON SENSOR

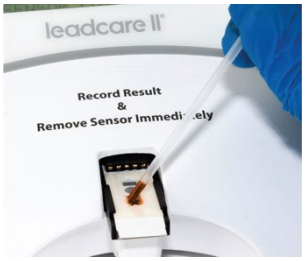
SENSOR LOT 0018A

3. Make sure the sensor lot number matches the lot number on the display. If the number does not match, recalibrate the analyzer and test controls (refer to Chapter 3).

⚠ **CAUTION:** ***The control lot number must match the sensor lot number and the calibration button code.***

4. Make sure that the sample mixture is at room temperature and uniformly mixed before testing.

5. Remove the cap from the treatment reagent. Remove a transfer dropper from its container. Squeeze the walls of the dropper and insert the tip into the sample. Release the pressure to draw the sample into the dropper. There should be approximately ½" of sample in the dropper.

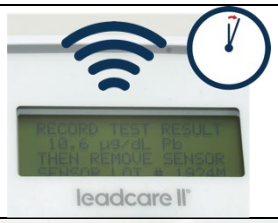
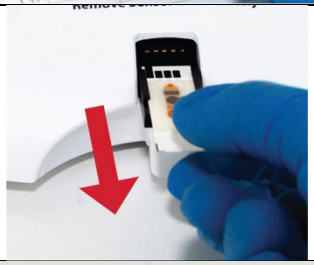
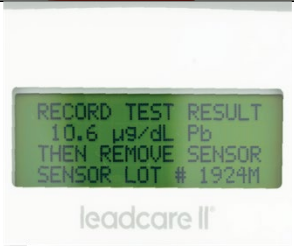
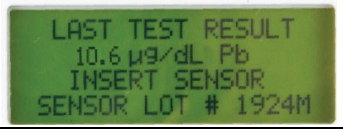


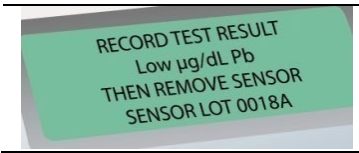
⚠ **CAUTION:** ***Make sure the message to the right is displayed on the screen before adding the sample.***

ADD SAMPLE
TO X ON SENSOR

SENSOR LOT 0018A

6. Touch the dropper tip to the X on the sensor and squeeze the walls to dispense the sample.

	7. The analyzer will beep when it has enough sample. It will display the message to the right. After 3 minutes (180 seconds) the analyzer will beep again to indicate that the test is done.	TESTING XXX SECONDS TO GO SENSOR LOT 0018A
	8. Record the test results.	RECORD TEST RESULT 7.5 µg/dL Pb THEN REMOVE SENSOR SENSOR LOT 0018A
	9. Remove the used sensor immediately after recording the result.	
	10. Discard the used materials in an appropriate biohazard container.	
	11. If you do not remove the sensor after recording your last result, within one minute the analyzer will sound two short warning beeps every 15 seconds until the sensor is removed or until the unit powers down.	
	Once the warning beep begins the message on the screen changes to “RECORD TEST RESULT XXXX µg/dL Pb PLEASE REMOVE SENSOR IMMEDIATELY”. The beep stops when the sensor is removed.	RECORD TEST RESULT XXXX µg/dL Pb PLEASE REMOVE SENSOR IMMEDIATELY
	12. The analyzer is ready for the next sample when the “LAST TEST RESULT” message appears on the screen.	LAST TEST RESULT 7.5 µg/dL Pb INSERT SENSOR SENSOR LOT 0018A



NOTE: The analyzer displays "Low" when it detects a blood lead level below 3.3 µg/dL. "Low" results should be recorded as "<3.3 µg/dL". It is not uncommon to obtain patient results that read "Low".

If you do not run another test within 60 minutes (15 minutes when using batteries), the analyzer will automatically go into "sleep" mode. If you have not recorded your test result, it will be lost. You will have to repeat the analysis.

Interpreting Patient Test Results

The analyzer's display window shows the blood lead result. The result is in micrograms (µg) of lead per deciliter (dL) of whole blood. No calculation is needed. Results are displayed to one decimal place. The reportable range of the LeadCare II system is 3.3 to 65 µg/dL.

"Low" in the display window indicates a blood lead test result less than 3.3 µg/dL. When this occurs, report the blood lead result as less than (<) 3.3 µg/dL.

"High" in the display window indicates a blood lead test result greater than 65 µg/dL. When this occurs, report the blood lead result as greater than (>) 65 µg/dL. **"High" results on LeadCare II should be followed up immediately as an emergency laboratory test.**

Follow-up Testing

Blood Lead test results should be shared with the patient's physician for interpretation and to determine when retesting and follow-up care are necessary. A capillary blood sample that generates an elevated lead level should be confirmed with a venous sample. The venous sample should be run at a reference laboratory using a high complexity testing method.

In cases where the capillary specimen demonstrates an elevated lead level but the confirmation venous sample does not, it is important to recognize that the child may live in a lead-contaminated environment that resulted in contamination of the fingertip. Efforts should be made to identify and eliminate the source of lead in these cases.

Report all blood lead test results to the appropriate local, state or federal agency.

Printing Test Results

You can print the results by connecting the analyzer to a compatible label printer. Refer to Appendix A: Connecting a Printer.

References

Additional information about lead poisoning is available through the Centers for Disease Control and Prevention at www.cdc.gov/nceh/lead/

Chapter 5 Troubleshooting and Maintenance

Several factors contribute to inaccurate blood lead testing and control testing. This chapter provides steps you can take if your patient blood lead tests or control tests are out of range. This chapter contains the following topics:

Calling LeadCare Product Support

If you cannot determine why your system is giving you a problem, call LeadCare Product Support at 1-800-275-0102 or email LeadCareSupport@magellandx.com.

Please collect this information and have it ready before you call:

- Serial No. of LeadCare II (on bottom of analyzer) _____
- Test kit lot number (on end of box) _____
- Calibration code on calibration button * _____
- When did you last test with controls? Date: _____
- Control results last recorded: Level 1 ____ Level 2 ____
- Control lot number * _____
- Control expiration date _____
- Sensor lot number * _____

***NOTE:** **Calibration code, control lot number and sensor lot number should all be the same.**

Troubleshooting Results Below the Target or Expected Value

Possible causes include:

- Less than 50 µL of blood was transferred to the treatment reagent tube.
- Analyzer is not calibrated properly.
- The sample is cold.
- The sensor is not inserted properly.

See detailed precautions below:

Blood Sampling

- Less than 50 µL in the capillary tube will lower blood lead level results.
- Make sure that there are no clots or bubbles in the tube.
- Use only fresh, capillary whole blood from patients collected in heparin or EDTA. Do NOT use venous samples. Do NOT use plasma or serum.

Blood Sample Preparation

- Every sample must be mixed in treatment reagent. You cannot test untreated whole blood.

Equipment Setup, Calibration and Testing Materials

- Check the expiration date on the test kit box. Do NOT use a test kit that is beyond the expiration date. When calibrated properly, the analyzer will not initiate a test with expired sensors.
- Make sure the analyzer is calibrated properly. Use the calibration button supplied with the test kit you are using. When processing the sample verify the code on the analyzer screen matches the code of the of the sensor lot in use.

Testing Conditions

- Operate the analyzer only within the specified humidity range: (12 to 80% Relative Humidity).
- Avoid operating the LeadCare II System in drafts or in locations with low humidity.
- Make sure that the analyzer and the test kit are maintained at a constant temperature. If you move any part of the system from one place to another (for example, from outside into a laboratory) wait for the analyzer and kit components to reach a stable temperature.

User Technique

- Make sure the sample/treatment reagent mixture is room temperature before placing it onto a sensor. This is only relevant when testing samples that were previously mixed with treatment reagent and stored refrigerated.
- Make sure the blood and treatment reagent is thoroughly mixed before placing it onto the sensor. The mixture should appear brown, confirming that the red blood cells have been lysed.
- Make sure the sensor is inserted under the sensor guides and sits flush on the sensor deck.
- Do NOT touch the sensor while the analyzer is running a test.

Troubleshooting Results Above the Target or Expected Value

Possible causes include:

- Contamination of blood sample.
- Excess blood on the capillary tube.
- Sample not mixed properly.
- The analyzer is not calibrated properly.

See detailed precautions below:

Blood Sampling

- Lead is widespread in the environment. It is easy to contaminate a blood sample. Thoroughly clean the collection site with soap and water followed by a clean alcohol wipe prior to puncture. Use clean powder-free gloves during testing and keep your gloved hands clean.
- Make sure you are using lead-free collection devices.
- Make sure the capillary tube is filled properly. Be sure to wipe excess blood from the capillary tube with a downward motion. The accuracy of the test depends on filling the capillary tube with 50 µL. Excess blood on the outside of the capillary tube will tend to produce higher blood lead results.

Blood Sample Preparation

- Do NOT use clotted blood. If there are clots in the blood, obtain a new sample.
- Make sure to transfer 50 µL of blood into the treatment reagent. Wipe the end of the capillary tube with a gauze pad, using a downward motion before adding the blood to the treatment reagent.

Equipment Setup, Calibration and Testing Materials

- Check the expiration date on the test kit. Do NOT use test kit materials that are beyond the expiration date. When calibrated properly the analyzer will not initiate a test with expired sensors.
- Make sure the analyzer is calibrated properly. Use the calibration button supplied with the test kit in use. When processing the sample, check to make sure the code on the analyzer screen matches the code of the calibration button for the test kit.
- Make sure you are using lead-free collection devices.

Testing Conditions

- Operate the analyzer only within the specified humidity range: (12 to 80% Relative Humidity).
- Make sure that the analyzer and the test kit are maintained at a constant temperature. If you move any part of the system from one place to another, (for example, from outside into a laboratory) wait for the analyzer and components to reach a stable temperature.

User Technique

- Do NOT touch the black bars on the sensor. This could damage the sensor.
- Do NOT touch the ends of the capillary tubes or the plungers. This could cause contamination.
- Make sure to thoroughly mix patient blood with the treatment reagent. The mixture should turn brown.
- Do NOT leave the treatment reagent tube uncapped other than to add the whole blood sample or to remove the sample for testing.
- Do NOT touch the sensor while running a test.

Control Test Results Below the Target Range: Possible Causes

Possible causes of low control test results include:

- Control lot number does not match the sensor lot and calibration code.
- Less than 50 µL of control material was transferred to treatment reagent
- The test sample is colder than detected by the analyzer.
- The analyzer is not calibrated properly.
- The sensor is not inserted properly.

See detailed precautions below:

Control Sample Preparation

- Use the capillary tubes and plungers provided with the test kit to transfer 50 µL of control into the treatment reagent tube.
- Always mix the control material with treatment reagent. Control material delivered directly to the sensor will not yield an accurate result.

Equipment Setup, Calibration and Testing Materials

- Make sure the controls were properly stored: Room temperature storage is considered 15 - 27ºC (59 - 80ºF).
- Check the expiration date on the control vial to verify the controls have not expired.
- Check the expiration on the test kit box to make sure the test kit materials have not expired.

NOTE:	**The controls are only intended for use with the test kit in which they come. When the other reagents included in the test kit are used up, discard the controls.**

- Make sure the analyzer is calibrated properly. Use the calibration button supplied with the test kit in use. When processing the sample, check to make sure the code on the analyzer screen matches the code of the calibration button for the test kit.

Testing Conditions

- Do NOT operate the LeadCare II System in drafty locations.
- Make sure that the analyzer and the test kit are maintained at a constant temperature. If you move any part of the system from one place to another, (for example, from outside into a laboratory) wait for the analyzer and components to reach a stable temperature.

User Technique

- Do NOT touch the black bars on the sensor.
- Make sure the sensor is inserted under the sensor guides and sits flush on the sensor deck.
- Do NOT touch the sensor while the analyzer is running a test.
- Make sure the control and treatment reagent is thoroughly mixed before placing onto the sensor. The mixture will appear red.

Control Test Results Above the Target Range: Possible Causes

Possible causes of high control test results include:

- Control lot number does not match the sensor lot and calibration code.
- More than 50 µL of control material was transferred to treatment reagent.
- The test sample is warmer than detected by the analyzer.
- The analyzer is not properly calibrated.

See detailed precautions below:

Control Sample Preparation

- Use the capillary tube and plunger to transfer 50 µL of blood into the treatment reagent vial.
- Wipe excess sample off the outside of the capillary tube with a clean gauze pad or laboratory wipe before adding the control to treatment reagent.

Equipment Setup, Calibration and Testing Materials

- Make sure the controls were properly stored: Room temperature storage is considered 15 - 27ºC (59 - 80ºF).
- Check the expiration date on the control vial to verify the controls have not expired.
- Make sure that the lot number of the control matches the lot number on the sensor container and the lot number on the display screen.

NOTE: **The controls are only intended for use with the test kit in which they come. When the other reagents included in the test kit are used up, discard the controls.**

- Make sure the analyzer is calibrated properly. Use the calibration button supplied with the test kit. When processing the sample, check to make sure the code on the analyzer screen matches the code of the calibration button for the test kit.

Testing Conditions

- Do NOT operate the LeadCare II System in drafty locations.
- Make sure that the analyzer and the test kit are maintained at a constant temperature. If you move any part of the system from one place to another (for example, from outside into a laboratory) wait for the analyzer and components to reach a stable temperature.

User Technique

- Do NOT leave the treatment reagent tube uncapped other than to add the control sample or to remove the sample for testing.
- Do NOT touch the black bars on the sensor.
- Do NOT touch the sensor while the analyzer is running a test.
- Make sure the control and treatment reagent is thoroughly mixed before placing onto the sensor. The mixture will appear red.

Screen Display Messages

There are a number of standard screen display messages that appear during the routine testing procedure. However, other messages may appear if the analyzer detects a condition that prevents normal operation. The following table shows some of the display messages.

NOTE: Occasionally, error messages not noted in this guide may appear on the display. Please note what error message was displayed and call Product Support for additional instructions. New users may want to check that the sensor was completely inserted into the analyzer first. Product Support can be reached at 1-800-275-0102.

Screen Display Messages

Message	Definition	What to Do
PLEASE CALIBRATE ANALYZER WITH BUTTON	The analyzer must be calibrated the first time you use it and for each new sensor lot.	Calibrate the analyzer. Refer to the calibration instructions in Chapter 2.
ELECTRONIC QC CHECK FAILED CALL TECH SERVICE ERROR X	The internal quality control check failed.	Record the error number & call Product Support at 1-800-275-0102.
TEMP IS TOO HOT PLEASE WAIT UNTIL ANALYZER IS IN TEMP RANGE	The temperature is too hot for testing.	Wait until the screen display the PREPARE SAMPLE message.
TEMP IS TOO COLD PLEASE WAIT UNTIL ANALYZER IS IN TEMP RANGE	The temperature is too cold for testing.	Wait until the screen display the PREPARE SAMPLE message.
WARNING TEMP IS UNSTABLE TEST MAY FAIL	The temperature is too unstable for testing.	Wait until the screen display the PREPARE SAMPLE message.
THIS IS A USED SENSOR PLEASE REMOVE SENSOR	The sensor in the analyzer is wet or previously used.	Remove the used sensor and insert a new sensor COMPLETELY into the analyzer to retest.
PLEASE REMOVE SENSOR	A sensor was left in the analyzer.	Remove the sensor.
SENSOR OUT OF VIAL TOO LONG PLEASE REMOVE SENSOR	The sensor in the analyzer has been out of the tube too long and cannot be used.	Remove the sensor and insert a new sensor.
TEST FAILED PLEASE REMOVE SENSOR	There is not enough sample on the sensor or the sensor failed.	Remove the sensor, discard it, and insert a new sensor. When adding the sample to the sensor, make sure the sample completely covers the X area.
SENSOR REMOVED TOO SOON	The sensor was removed from the analyzer before the end of the test.	Remove the sensor. Insert a new sensor and add another drop of sample. Wait 180 seconds (3 minutes) for the test to finish.
TEMP IS UNSTABLE RESULT DISCARDED PLEASE REMOVE SENSOR	The temperature in the room is too unstable to yield accurate test results.	Move the analyzer to an area where there are fewer temperature changes (away from sources of cold or heat). The temperature is stable enough when the PREPARE SAMPLE message indicates that the analyzer is ready.
PLEASE RECALIBRATE	There was a problem transferring the calibration data from the calibration button to the analyzer.	Repeat the calibration procedure. Refer to Chapter 2, Calibrating the analyzer.
SENSOR LOT TOO OLD PLEASE RECALIBRATE	The sensor is from a lot that has expired.	Discard the sensor and the expired lot. Use a sensor from a new lot and recalibrate the analyzer.
SYSTEM FAILURE CALL TECH SERVICE	One of the main system components failed.	Power analyzer off & on. If error persists, call Product Support at 1-800-275-0102.
CHANGE BATTERIES SOON (Message flashes before or after a test)	Voltage too low for the analyzer to run a test.	Change the batteries. Use four 1.5 V AA alkaline or lithium batteries.
PLEASE CHANGE BATTERIES	The battery voltage is too low.	Change the batteries. Analyzer uses four 1.5 V AA alkaline or lithium batteries.
LOW POWER CHECK POWER CORD	This message flashes for 2 seconds if the voltage from the AC adapter is low.	You can run a test.
LOW POWER CHECK POWER CORD OR CALL TECH SERVICE	The voltage from the AC adapter is too low. The lead test is NOT allowed.	Call Product Support at 1-800-275-0102.

***If an error message is encountered repeatedly, contact Product Support at 1-800-275-0102.**

Maintaining the Analyzer

Cleaning the Analyzer

- Remove used sensors from the analyzer as soon as a result is recorded.
- Clean the analyzer with a damp cloth and warm, soapy water. Do NOT immerse in water.
- Disinfect with dilute (10%) bleach solution.
- Do NOT leave any soap film on the analyzer.
- Do NOT allow liquid of any kind into the sensor connector.
- Do NOT get the metal pins in the sensor connector wet.
- Do NOT wash the inside of the calibration button reader.

Chapter 6 LeadCare II Blood Lead Testing System Limited Warranty

Magellan Diagnostics, Inc. (Magellan) warrants that each product manufactured and sold by it will be free from defects in material and workmanship in normal use and service from the date of delivery to you as the original purchaser for the following periods: Magellan Instruments - one year; Sensors and Electrodes - 90 days. This warranty does not cover, and no warranty is provided for, consumables and parts that by their nature are normally required to be replaced periodically consistent with normal maintenance. If any product covered by this warranty is returned to the original shipping point, transportation charges prepaid, within the applicable warranty period set forth above and upon examination Magellan determines to its satisfaction that such product was defective in material or workmanship Magellan will, at its option, repair or replace the product or defective part thereof or refund the original purchase price of the product to you. The foregoing notwithstanding, Magellan will not be responsible for damage to any product resulting from misuse, negligence or accident or resulting from repairs, alterations or installation made by any person or firm not duly authorized by Magellan in writing.

If, at any time during the period ending ninety (90) days after delivery of any product to you, you report and document any error in any software provided with the product and developed by Magellan or any failure of any such software substantially to conform to Magellan's software documentation that limits or prevents use of the software by you, Magellan, at its option, will use reasonable efforts to correct any such error or failure, will replace such software, or will terminate your license to use the software and refund the price of the related product. In connection with any such termination and refund, you will return the related product to Magellan forthwith upon request. This warranty shall apply only to those portions of the software that were developed by Magellan and that incorporate all program corrections and modifications, if any, delivered to you. It shall not apply to any error or failure due to machine error or to the misuse by or negligence of any person or entity other than Magellan or to any software which is modified by any person or entity other than Magellan.

With respect to products sold to you but not manufactured by Magellan, MAGELLAN MAKES NO WARRANTY OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, but will make available to you, to the extent permitted, the warranties of the manufacturer of the relevant products .

THIS LIMITED WARRANTY IS THE ONLY WARRANTY GIVEN BY MAGELLAN WITH RESPECT TO THE PRODUCTS AND SOFTWARE AND IS GIVEN IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. YOUR EXCLUSIVE REMEDIES AND MAGELLAN'S SOLE LIABILITY FOR ANY NON-CONFORMITY OR DEFECT IN THE PRODUCTS AND SOFTWARE WILL BE THOSE EXPRESSED HEREIN. UNDER NO CIRCUMSTANCES WILL MAGELLAN'S LIABILITY ARISING FROM THE PERFORMANCE OR FAILURE TO PERFORM OF ANY PRODUCT OR SOFTWARE IN CONTRACT, IN TORT (INCLUDING NEGLIGENCE), OR OTHERWISE, EXCEED THE PURCHASE PRICE OF THE PRODUCT. IN NO EVENT WILL MAGELLAN BE LIABLE FOR SPECIAL, INCIDENTAL, CONSEQUENTIAL, OR ANALOGOUS DAMAGES, INCLUDING, WITHOUT LIMITATION, DAMAGES RESULTING FROM LOSS OF USE, LOSS OF PROFITS, LOSS OF BUSINESS OR LOSS OF GOODWILL, EVEN IF MAGELLAN HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

This warranty shall be governed by and construed and enforced in accordance with, the substantive laws of the Commonwealth of Massachusetts, excluding its conflict of law principles. This warranty shall be non-transferable and shall run to the benefit of the original purchaser only.

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Appendix A Connecting a Compatible Serial Printer

CAUTION: The LeadCare® II Analyzer must run on AC power in order to generate a label. Battery power is insufficient to generate a label.

The LeadCare II Analyzer has printing capabilities. After a result is generated the information is transmitted via a serial connection to a label printer. The USB connection cannot be utilized for printing purposes.

Connections

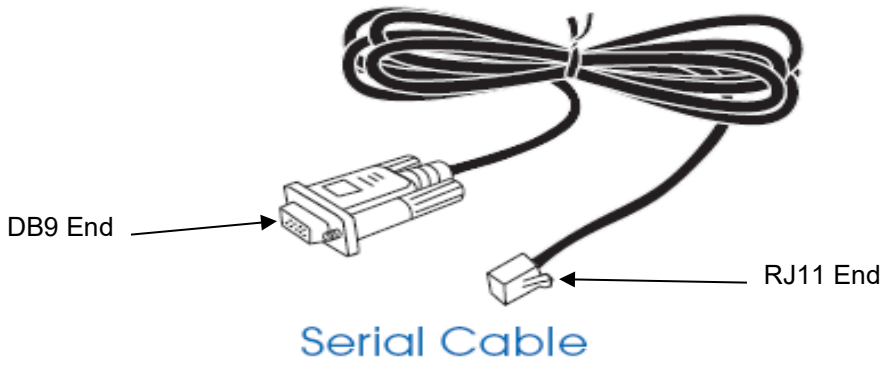

Figure A-1 Serial Cable

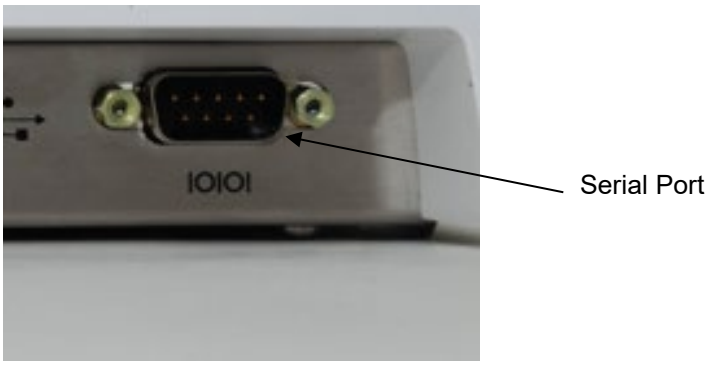

Figure A-2 Rear Panel of the LeadCare II

1. Using the serial cable supplied with the printer, connect the DB9 end to the LeadCare II's serial port.
2. Connect the RJ11 end of the cable to the printer's serial (telephone jack) connection port.
3. Plug the printer's AC adapter into a power outlet. Label the adapter so it only gets plugged into the SLP printer.
4. Ensure the LeadCare II is plugged into a power outlet with its appropriate adapter. Note: Battery operation is insufficient to generate a label.

NOTE: **The USB port cannot be used for printing LeadCare II results.**

Power On Cycle

1. Turn on the printer. A steady green light indicates ready mode.
2. Turn on the LeadCare II Analyzer.
3. Analyze a sample. The result will generate a label with the following information: :

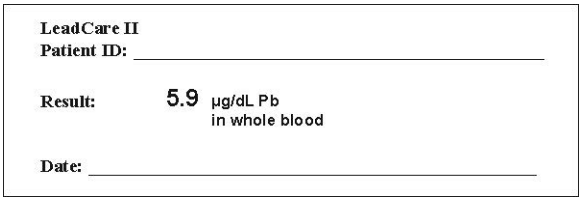

Figure A-3 LeadCare II Label

Power Off Cycle

1. Turn off the LeadCare II.
2. Turn off the printer.

Note on Labels: The SmartLabels have a mark on the backing of each label that the SLP 650SE and future models use for top of label alignment. Check to be sure the labels have this mark before loading them into the printer.

Loading Labels

1. Power on the printer. The green status light will flash until labels are loaded.
2. Lift the left side of the roll cover to open. Remove the spindle and place a roll of labels on the spindle. (The LeadCare II utilizes shipping labels: 2 1/8" W X 4" L label stock.) Adjust the guides to fit the labels (see below).

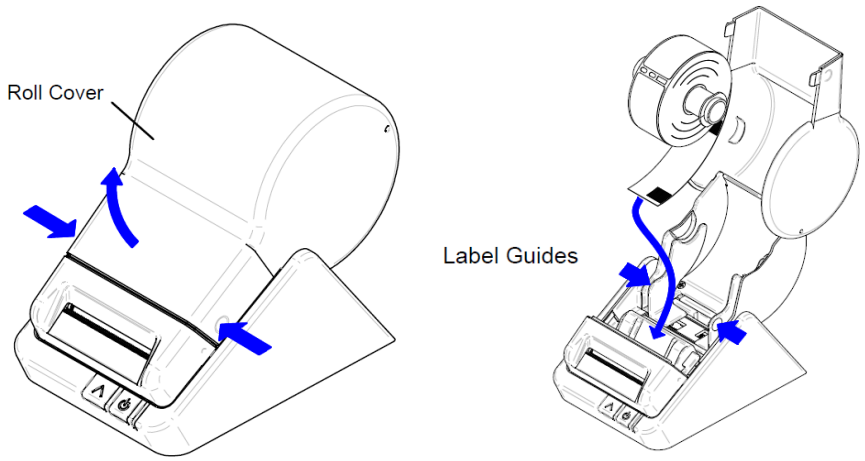

Figure A-4 Label Placement

3. Feed the labels into the entrance slot, label side down. The labels will automatically feed and align the end in the exit slot.
4. Close the roll cover.

Troubleshooting Information

- Steady green light indicates the printer is on-line.
- Blinking green light indicates the printer is awaiting labels.
- Blinking yellow indicates a label jam.
- Blinking red indicates a voltage error or print head error.
- Steady yellow light indicates the printer is off-line.

Call LeadCare Product Support for additional assistance: 1-800-275-0102.

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Appendix B Specifications, Operating Requirements, and Performance Characteristics

Specifications

Table B-1 Physical Dimensions	
Dimensions (Approximate, Analyzer Only)	Height 9 cm (3.5 in.) Width 17 cm (6.5 in.) Depth 23 cm (9 in.)
Weight (Approximate, Analyzer with Batteries)	1.13 kg (2.5 lb)

Table B-2 Electrical Specifications	
Power Requirements	Switching power supply (AC input 100-240 V, 0.25 A, 50-60 Hz, DC output +3.3 V-1.2 A) or 1.5 V AA alkaline or lithium batteries (4 each) The correct power adapter is included in the analyzer kit.
DC Input Power (External Mode)	Less than 600 mA
DC Input Power (Battery Mode)	Less than 400 mA
Battery Life	Up to 80 tests (7 hours)
Automatic Shutoff	15 minutes after last use with batteries 60 minutes after last use with AC adapter

Table B-3 Other Specifications	
CPT Code	83655 (Quantitative Blood Lead Analysis)
CLIA Complexity	Waived
Reportable Range	3.3 - 65.0 µg/dL Note: Displays "Low" below 3.3 µg/dL Displays "High" above 65.0 µg/dL
Sample Volume	50 µL
Test Time	3 minutes (180 seconds)
Calibration	Electronic calibration; calibration button included with each test kit

Operating Requirements

Table B-4 Storage and System Operating Ranges

Storage Ranges	
Analyzer	15°C to 30°C (59°F to 86°F) Up to 80% Relative humidity
Test Kit	15°C to 27°C (59°F to 80°F)
Capillary Whole Blood Sample (human) EDTA or Heparin are the anticoagulants of choice	Store at room temperature (RT) prior to mixing with Treatment Reagent. RT is 10°C to 32°C (50°F to 90°F)

System Operating Ranges	
Temperature	15°C to 27°C (59°F to 80°F)
Relative Humidity	12%-80%, non-condensing
Altitude	Operating up to 2,440 meters (8,000 feet) above sea level does not affect results.

Interference Substances

Tests were conducted by adding the potential interferences at the concentrations listed below to bovine blood with elevated lead levels. Lead results for samples with each potential interference did not differ statistically from lead results obtained on unadultered samples.

The following substances at the following concentrations do NOT affect the results of the LeadCare® II System:

- 5,5-Diphenylhydantoin (phenytoin), 100 µg/mL
- Acetominophen, 500 µg/mL
- Amoxicillin, 100 µg/mL
- Amphotericin, 50 µg/mL
- Arsenic III, 0.01 µg/mL
- Arsenic V, 0.005 µg/mL
- Carboplatin, 0.25 µg/mL
- Cephalexin (Keflex), 60 µg/mL
- Ciprofloxacin, 100 µg/mL
- Clondine, 100 µg/mL
- Cyclophosphamide, 500 µg/mL
- d-Amphetamine Sulfate, 100 µg/mL
- Diphenylhydramine Hydrochloride, 100 µg/mL
- Doxorubicin, 100 µg/mL
- Doxycycline, 100 µg/mL
- Erythromycin, 100 µg/mL
- Ferric chloride, 100 µg/mL
- Ferrous sulfate, 100 µg/mL
- Fexofenadine HCl (Allegra), 50 µg/mL
- Fluconazole (Diflucan), 100 µg/mL
- Gabapentin (Neurontin), 100 µg/mL
- Ganciclovir (AZT), 100 µg/mL
- Glyburide, 100 µg/mL
- Guanfacine, 100 µg/mL
- Hydroxyurea, 250 µg/mL
- Ibuprofen, 500 µg/mL
- Indinavir Hydrate, 100 µg/mL
- Isoniazid, 100 µg/mL
- Loratadine, 100 µg/mL
- Methyl Phenidate (Ritalin) HCl, 100 µg/mL
- Methotrexate, 60 µg/mL
- Metronidazole, 100 µg/mL
- Niacin, 100 µg/mL
- Nicotine , 10 µg/mL
- Nystatin, 100 µg/mL
- Penicillamine, 25 µg/mL
- Phenylephrine, 100 µg/mL
- Piperazine, 100 µg/mL
- Pseudoephedrine (guiafenesin), 100 µg/mL
- Pyridoxine, 100 µg/mL
- Riboflavin, 0.5 µg/mL
- Rifampicin, 100 µg/mL
- Sitagliptin, 100 µg/mL
- Thiamine, 50 µg/mL
- Trimethoprim, 100 µg/mL
- Valproic Acid, Na salt, 500 µg/mL
- Vitamin D3, 100 µg/mL

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Appendix C Steps for Collecting Fingerstick Blood Samples in Micro-Vials for Lead Testing

The following references provide additional information about blood sample collection, blood lead testing, and Magellan Diagnostics LeadCare II products.

Blood Sample Collection

Information about sample collection is available from the Clinical Laboratory Standards Institute (CLSI) or the Centers for Disease Control (CDC).

- CLSI (Clinical and Laboratory Standards Institute) GP44-A4: Procedures for the Handling and Processing of Blood Specimens; Approved Guideline – 4th ed. (ISBN 1-56238-724-3). www.clsi.org
- CDC Guidelines for Collecting and Handling Blood Lead Samples – 2004 - Video presentation describes how to collect and handle samples that will be used for blood lead testing. www.cdc.gov/nceh/lead/training/blood_lead_samples.htm

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Appendix D Safety Data Sheets (SDS)

This chapter contains the following LeadCare® II Safety Data Sheets:

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Attachment D2: Venipuncture Collection Process

Venipuncture Specimens for Blood Lead Collection and Transport

Lead confirmatory testing will be offered when results from the blood lead analyzer LeadCare® II capillary test are ≥ 5 µg/dL.

***The Venipuncture Collection Kit includes*:**

- One (1) sterile alcohol prep
- One (1) needle and holder or one (1) needle and syringe
- One (1) transport zip lock bag
- One (1) dry sterile gauze pad
- One (1) Vacutainer EDTA tube (purple top)

Personal Protective Equipment:

- Powder free gloves
- Eye protection
- Face mask

Preparation of the Puncture Site:

1. Thoroughly wash hands and don powder free gloves.
2. Expose the selected antecubital fossa and apply tourniquet to mid-biceps. Scrub the puncture site briskly with the alcohol pad to remove any environmental contamination and to increase blood flow.
3. Allow the site to air dry or use the sterile gauze to dry the area.

Collection of the Sample:

1. Prepare needle assembly, either needle and vacutainer holder, or needle and syringe.
2. Perform venipuncture per standard operating procedures. Make sure the vacutainer tube is completely filled before stopping collection. If using a needle and syringe, obtain a minimum of 2 mL of whole blood.
3. Remove tourniquet first, then needle from arm.
4. Apply pressure to the puncture site with a gauze pad to stop the patient's bleeding. parent/guardian or child may continue holding direct pressure on the puncture site.
5. If drawn directly into vacutainer tube, immediately mix the specimen manually by inverting a minimum of 10 times.
6. If drawn with a needle into the syringe, immediately inject the blood from the syringe into the vacutainer tube, gently mixing while filling. Continue to mix the specimen by inverting 10 times.
7. Dispose of used needle and syringe equipment into puncture proof sharps container.
8. Identify each skin puncture specimen with the patient's name, at a minimum, and collection date.

Submitting Specimens to the State Laboratory for Testing:

1. Specimens should be clearly labeled with two patient identifiers (name, DOB) and collection date.
2. Complete a Public Health Laboratory Request Form to include the patient's name, date of birth, gender, collection date, and submitter information.

3. Place the well mixed, un-clotted blood specimen in an individual biohazard zip lock bag containing absorbent material and seal bag tightly. Fold the requisition form and place in sleeve of the bag.
4. Store specimen(s) in the refrigerator until brought to St. James Community Hospital Laboratory the same day to coincide with the courier schedule. Specimens are stable for 7 days at refrigeration temperatures.

Results:

1. After test results are received from the state lab, the patient will be contacted to discuss the results and any next steps if applicable.

Attachment E: Montana Public Health Laboratory Request Form

MONTANA DEPARTMENT OF PUBLIC HEALTH & HUMAN SERVICES

Public Health Laboratory Request Form

P.O. Box 4369, Helena, MT 59604-4369
(406) 444-3444 (800) 821-7284 CLIA ID # 27D0652531

DPHHS PHL 0117

PATIENT INFORMATION (please PRINT legibly)

LAST NAME

FIRST NAME

PATIENT ID #

PATIENT ADDRESS

PATIENT CITY OF RESIDENCE

STATE ZIP CODE DATE OF BIRTH / /

GENDER
☐ Male
☐ Female

PROVIDER INFORMATION

LS470015
LABORATORY
BUTTE SILVERBOW HEALTH
25 W FRONT STREET
BUTTE MT 59701

PHYSICIAN / CLINICIAN NAME

NATIONAL PROVIDER IDENTIFIER (NPI)

MTPHL USE ONLY

TEST(S) REQUESTED INFORMATION

Serology:

- ☐ Blood Lead
- ☐ Brucella Antibody
- ☐ CTFV IgG Serology
- ☐ Hantavirus IgG & IgM Serology
- ☐ Hepatitis - Acute Panel
- ☐ Hepatitis A IgM Antibody
- ☐ Hepatitis B Surface Antigen
- ☐ Hepatitis B Surface Antibody
- ☐ Hepatitis B Total Core Antibody
- ☐ Hepatitis B Core IgM Antibody
- ☐ Hepatitis C Ab with Reflex as needed
- ☐ Herpes Simplex Virus IgG Serology
- ☐ HIV Ab/Ag Combo with Reflex Confirmation
- ☐ ~~Legionella IgG Serology~~
- ☐ Lyme Total Abs with Reflex Confirmation
- ☐ Mumps IgG Serology
- ☐ Q Fever IgG Serology
- ☐ RMSF IgG Serology
- ☐ Rubella IgG
- ☐ Rubeola (Measles) IgG
- ☐ Syphilis Screen with Reflex Confirmation
- ☐ Syphilis Confirmation (TP-PA)
- ☐ TB - QuantiFERON Gold In-Tube Testing
  Time Collected: _____
  Incubated 16 - 24 hrs? **Yes** **No**
- ☐ Tick Borne Disease Panel + Lyme
- ☐ Tick Borne Disease Panel
- ☐ Tularemia Antibody
- ☐ Varicella Zoster Virus IgG
- ☐ West Nile Virus IgM
- ☐ West Nile Virus IgG

Molecular Testing:

- ☐ Adenovirus PCR
- ☐ Bordetella pertussis multitarget PCR
- ☐ C difficile/NAP1 PCR
- ☐ Enterovirus PCR
- ☐ Enterovirus D68 PCR
- ☐ Herpes Simplex Virus PCR
- ☐ Influenza A and B PCR
- ☐ Measles (Rubeola) PCR
- ☐ Mumps PCR
- ☐ Norovirus PCR
- ☐ Varicella Zoster PCR

STD Testing (APTIMA): (Use cervical swab for chlamydia on eye)

☐ Chlamydia and Gonorrhea ☐ Chlamydia Only ☐ Gonorrhea Only

Sterilizer Monitoring:

- ☐ Autoclave Monitoring-BT Test

Microbiology

- ☐ Bacteriology Culture/ID, Aerobic
- ☐ Bacteriology Culture/ID, Anaerobic
- ☐ BT Agent Rule Out (list in Comments)
- ☐ EHEC (STEC) Toxin Test
- ☐ Enteric Panel Culture, includes EHEC
- ☐ Fungus Culture/ID
- ☐ Legionella Direct Detection/Culture/ID
- ☐ Malaria Screen
- ☐ Modified Acid Fast Stain
- ☐ Neisseria gonorrhoeae Culture/ID
- ☐ Vibrio screen
- ☐ Yersinia screen
- ☐ Cryptosporidium/Giardia EIA screen
- ☐ Cryptosporidium/Cyclospora Detection
- ☐ Ova and Parasite Exam

Chlamydia Culture

No longer available. See STD Testing.

Zika Testing (Is the patient pregnant? Y / N)

- ☐ Zika Serology (IgM)
- ☐ Zika Trioplex PCR Serum
- ☐ Zika Trioplex PCR Serum/Urine Combo
  (Trioplex PCR Includes Dengue and Chikangunya)

Surveillance Cultures:

Type of Isolate: _____

- ☐ CRE Confirmation
- ☐ ESBL Confirmation
- ☐ GC Confirmation/Susceptibility
- ☐ Influenza Confirmation
- ☐ MRSA Confirmation
- ☐ Salmonella/Shigella/E. coli/Campy
- ☐ VRE Confirmation
- ☐ Other Surveillance Confirmation

Virus Culture:

MT PHL is no longer performing viral culture. There are several Moleclar Testing methods available for viral testing.

TB/Mycobacteriology:

- ☐ TB Mycobacteria Smear/Culture/ID
- ☐ M. tuberculosis NAAT (Molecular)
  (Should be ordered on all highly suspect specimens)

SPECIMEN COLLECTION DATE / /

DATE OF ONSET (if applicable) / /

Medicaid / Medicare Billing Information:

☐ Bill MEDICAID ☐ Inpatient
☐ Bill MEDICARE ☐ Outpatient

MEDICAID ( ) or MEDICARE ( ) NUMBER

ICD DIAGNOSIS CODE

SPECIMEN SOURCE

- ☐ Bronchial Washings
- ☐ Buccal Swab
- ☐ Cervical Swab
- ☐ CSF
- ☐ EDTA Blood (Capillary)
- ☐ EDTA Blood (Venous)
- ☐ Heparanized Blood
- ☐ Lesion Swab (Site: _____)
- ☐ Nasal Swab
- ☐ Nasal Washings
- ☐ Other *(Specify)* _____
- ☐ NP Swab
- ☐ Pleural Fluid
- ☐ Rectal Swab
- ☐ Serum
- ☐ Sputum
- ☐ Stimulated Plasma (QFT)
- ☐ Stool
- ☐ Throat Swab
- ☐ Urethral Swab
- ☐ Urine
- ☐ Vaginal Swab

Other Test(s) Requested/ Pertinent Information / Comments

Do not photocopy. Please call for more forms if needed.

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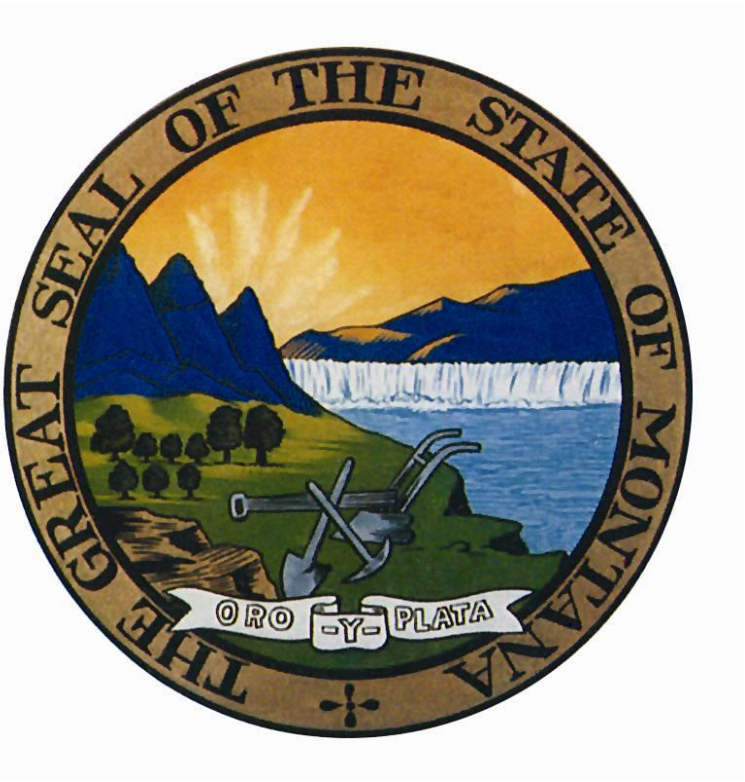
Attachment F: Montana Public Health Laboratory Services Manual



MONTANA
DPHHS
Healthy People. Healthy Communities.
Department of Public Health & Human Services

MONTANA PUBLIC HEALTH LABORATORY

LABORATORY SERVICES MANUAL

Updated April 2020

MONTANA LABORATORY SERVICES BUREAU Contact Information

1400 BROADWAY

W. F. COGSWELL BUILDING

1400 E. Broadway, P.O. BOX 4369

HELENA, MONTANA 59604-4369

CLIA ID. # 27D0652531

PHONE: 406-444-3444

800-821-7284 (24 hour)

MAIN FAX: 406-444-1802

****

LABORATORY SERVICES BUREAU LEADERSHIP

Laboratory Services Bureau Chief,

Ron Paul, 444-5559 or rpaul@mt.gov

Laboratory Systems Improvement Section Supervisor and Deputy Laboratory Director

Deborah Gibson 444-5970 or debgibson@mt.gov

LABORATORY SERVICES BUREAU SUPERVISORS

Laboratory Business Operations Manager,

Danielle Lindeman, 444-5246 or

DLindeman@mt.gov

Serology & Newborn Screening Laboratory

Manager, Angela Dusko,

444-3040 or adusko@mt.gov

Micro & Molecular Laboratory Manager,

Carrie Biskupiak, 444-5526 or cbiskupiak@mt.gov

Environmental Laboratory Supervisor,

Russ Leu, 444-5259 or rleu2@mt.gov

****

For most up-to-date contact information and testing information, see our website:

http://dphhs.mt.gov/publichealth/LaboratoryServices

The Eleven Core Functions of Public Health Laboratories (courtesy of APHL)

1. Disease Prevention, Control and Surveillance—Provide accurate and precise analytical data in a timely manner
2. Integrated Data Management—Serve as the conduit for scientific data and information in support of public health programs
3. Reference and Specialized Testing—Serve as centers of excellence using their expertise, reference and resources in the areas of biological, chemical and radiologic issues of public health importance
4. Environmental Health and Protection—Collaborate with partners to coordinate and ensure scientific analysis of environmental and human samples to identify, quantify and monitor potential threats to health
5. Food Safety—Collaborate in the detection, monitoring and response to food safety issues
6. Laboratory Improvement and Regulation—Provide leadership for laboratory improvement in areas of public health importance
7. Policy Development—Play a role in the development of state and federal health policy
8. Public Health Preparedness and Response—Fulfill a key partnership role in local, state and national disaster preparedness and response
9. Public Health Related Research—Engage in research to improve and expand the scientific and policy bases of public health laboratory practice and assure their optimal application in support of the public health system
10. Training and Education—Facilitate access to training and education
11. Partnerships and Communication—Support their respective state public health laboratory systems

The Montana Laboratory Services Bureau and its sentinel laboratories are part of the CDC's Laboratory Response Network (LRN)

LRN Mission: The LRN and its partners will maintain an integrated national and international network of laboratories that are fully equipped to respond quickly to acts of chemical or biological threats, emerging infectious diseases, and other public health threats and emergencies.

Sentinel laboratories play a key role in the early detection of biological agents. Sentinel laboratories provide routine diagnostic services, rule-out, and referral steps in the identification process. While these laboratories may not be equipped to perform the same tests as LRN reference laboratories, they can test samples.

Montana Sentinel Laboratories

"In the broadest sense, all laboratories capable of analyzing or referring specimens or samples that may contain microbial agents, biological toxins, chemical agents, chemical agent metabolites, or radiological agents function as sentinels in the public health laboratory system. This includes environmental, food, veterinary, agriculture, military, public health and clinical laboratories. Because of their routine activities, all these laboratories have the potential to encounter samples that may contain agents that threaten the public's health. While all these laboratories are sentinel laboratories, they may have different roles within the public health laboratory system.

Role of Sentinel Clinical Laboratories in the Public Health Laboratory System

Clinical laboratories testing human and animal samples are often the first interface with patients and the public health system. These laboratories perform a variety of critical tests, providing timely results to impact patient care. Optimally, these laboratories also work with local and state health departments to provide information on nationally notifiable diseases and other threats. While reporting of nationally notifiable diseases to the Centers for Disease Control and Prevention (CDC) is not federally mandated, it is currently required by legislation or regulation at the state or local levels. As such, the list of reportable diseases varies slightly by jurisdiction. Ongoing communications and trainings from public health staff, including laboratorians and epidemiologists, help to assure that clinical laboratories are integrated into the public health laboratory system. This coordination is vital to the surveillance and responses for endemic and emerging pathogens, including identification of novel threats such as pandemic influenza and the development of appropriate countermeasures such as vaccines.

Role of Sentinel Clinical Laboratories in the LRN for Biological Threat Preparedness

In addition to their broad role in the public health laboratory system, clinical laboratories work closely with local and state public health and federal laboratories to recognize potential biological threat agents and other emerging threats to public health. Such laboratories are part of the nation's Laboratory Response Network (LRN) founded by the CDC, the Federal Bureau of Investigation (FBI) and the Association of Public Health Laboratories (APHL). The strength of the LRN lies in its standardized approach and its tiered capability construct—with sentinel clinical laboratories serving at the foundation to quickly recognize, rule-out or refer potential biothreat agents to the LRN Reference Laboratories." (excerpt taken from "Definition of LRN Sentinel Laboratories" on the ASM website)

We would like to recognize Montana's 18 sentinel laboratories for serving in this role:

Benefis East Health Services, Great Falls
Big Horn County Memorial Hospital, Hardin
Billings Clinic, Billings
Bozeman Health, Bozeman
Clark Fork Valley Hospital, Plains
Community Medical Center, Missoula
Frances Mahon Deaconess Hospital, Glasgow
Glendive Medical Center, Glendive
Holy Rosary Hospital, Miles City
IHS Fort Belknap Hospital, Harlem
Kalispell Regional Hospital, Kalispell
Livingston Memorial Hospital, Livingston
Madison Valley Hospital, Ennis
Sidney Health Center, Sidney
St. Patrick's Hospital, Missoula
St. Peter's Hospital, Helena
St. Vincent's Hospital, Billings
VA Medical Center, Ft. Harrison, Helena

For more information on sentinel laboratories and rule-out testing, see the American Society for Microbiology website, https://www.asm.org/Articles/Policy/Laboratory-Response-Network-LRN-Sentinel-Level-C

Laboratory Outreach

The Montana Laboratory Services Bureau offers not only testing, but also consultation and outreach in several different areas.

One of our most recent outreach programs is biosafety. The Ebola crisis of 2014 revealed that, on a national level, there are gaps in laboratory biosafety programs. Measures that can be put in place to protect ourselves and the public from laboratory acquired infections include risk assessments, standardized training, and non-punitive systems for reporting incidents and near misses, to name a few. The Association of Public Health Laboratories, with funding by the CDC, has developed tools and provided training and other programs to enhance biosafety in each state. Public Health laboratories have been tasked with passing these resources on to clinical partners in their jurisdictions. Part of our outreach is to provide copies of our newly updated Laboratory Services Manual.

Please contact our program managers and subject matter experts for any assistance you may need. If you need assistance with a topic not listed below, please give one of us a call, and we can find someone to help.

For assistance with biosafety, packaging and shipping, biopreparedness training, jurisdictional transport plans (county level), Copia accounts, and Portacount requests or technical assistance, contact: **Biosafety Officer and Laboratory Training Specialist, Crystal Fortune, 444-0930 or cfortune@mt.gov**

For assistance with biopreparedness, jurisdictional sample transport plans (county level), CAP LPX facility feedback, and sentinel laboratory outreach, contact: **Bioterrorism Specialist, Lana Moyer, 444-0944 or lmoyer@mt.gov**

For assistance with chemical terrorism preparedness, including rapid toxic screening questions or training, contact: **Chemical Terrorism Specialist, Joel Felix, 444-9653 or jfelix@mt.gov**

For assistance with Copia, contact: **Data Coordinator, Kim Varvel, 444-4115 or kvarvel@mt.gov**

For assistance with laboratory safety/biosafety; quality assurance, including rapid HIV/HCV; and Portacount requests, contact: **Quality Assurance and Safety Specialist, Donna Jo Hosmer, 444-5941 or dhosmer@mt.gov**

Clinical Testing List of Services

For most up-to-date manual, refer to our website. For tests not listed, please contact the laboratory (800-821-7284) for availability.

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Summary of Changes:

Some serology reference testing removed
Additional testing such as HCV and HIV quantitation added
Changes made to Syphilis screening, HIV screening per CDC algorithm
QuantiFERON updated to four-tube method
Added instructions for Blood Parasite Screen Thick EDTA Blood Smear Preparation
Microbiology testing updated to include MALDI-TOF technology, where applicable
Updates to specimen requirements and shipment temperatures

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Note: *To avoid rejection,* ***all patient specimens should be clearly marked with two identifiers (name, DOB, medical record number, etc.) and collection date.*** *Additionally, specimens should be submitted, with absorbent material, inside a biohazard transport bag and the corresponding requisition in the outer pouch of the transport bag. Please do not submit more than one patient or more than one specimen type (example, culture and blood) per transport bag or allow requisitions to be in contact with specimens.*
Call the laboratory (800) 821-7284 with any questions regarding safe transport.

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Table of Contents

Tests in Alphabetical Order

A

Acid Fast Bacilli (AFB) (see *Mycobacterium spp*. Culture/Identification)

Actinomyces spp. Culture Isolation/ Identification (see Bacterial Culture, Anaerobic)

Adenovirus Direct Detection by Real Time PCR

Specimen Requirements: Respiratory specimen in Universal Viral Transport Media**.** See Molecular (Nucleic Acid Amplification) Testing Collection and Transport instructions.

Transport Temperature: 2-8°C

Turn-around Time: 1 to 3 working days. Results are telephoned to the submitter.

CPT Code:
87798
Price: $107.00

Amebiasis Detection (see Ova and Parasite Exam)

Anthrax (see *Bacillus anthracis Culture Isolation/ Identification/Rapid Test Methods*)

Antimicrobial Resistant Bacteria Confirmation

Confirmation testing for an isolate that demonstrates a resistance pattern with high epidemiologic significance such as potential Vancomycin Intermediate or Resistant *Staphylococcus aureus*, Methicillin Resistant *Staphylococcus aureus*, Vancomycin Resistant Enterococci, ESBL producing *Enterobacteriaceae*, or resistant *Streptococcus pneumoniae*.

Specimen Requirements: Pure culture isolate submitted in Cary-Blair transport or on solid media.

Transport Temperature: Ambient

Turn-around Time: 2 to 4 working days. May be referred to the Centers for Disease Control in Atlanta, Georgia.

CPT Code:
87081 (ESBL, MRSA, VRE, VISA/VRSA)
Price: $38.00

CPT Code:
None (Streptococcus pneumoniae)
Price: Fee Waived

Arbovirus Serology by ELISA

Specimen Requirements: 1 mL serum or CSF; Paired acute and convalescent serum recommended. Date of onset must be included on requisition form.

Transport Temperature: 4-30°C (Refrigeration preferable)

Referred to the Centers for Disease Control, Fort Collins, CO.

Turn-around Time: 4 weeks

CPT Codes:
86654 (Western Equine Encephalitis)
86651 (California Group)

Total Price: $30.00

Aspergillus spp. **Culture Isolation/ Identification** **(see Fungal Culture)**

Autoclave Monitoring

Specimen Requirements: EZ Test vials containing Geob*acillus stearothermophilus* are obtained by contacting the laboratory. Place the EZ Test vial in center of the load to be sterilized, then autoclave using normal procedures.

Transport Temperature: Ambient

Turn-around Time: 2 working days from receipt of specimen

CPT Code:
No code
Price: $23.00

B

Babesia **Detection** **(see Blood Parasite Screen)**

Babesiosis Serology by IFA

Specimen Requirements: 1.5 mL serum

Transport Temperature: 4-30°C (Refrigeration preferable)

Referred to the Centers for Disease Control, Atlanta, Georgia

Turn-around Time: 18 days

CPT Code:
86256
Price: $38.00

Bacillus anthracis **Culture Isolation/ Identification/Rapid Test Methods**

Specimen Requirements: Lesion swab, clinical specimen or pure culture isolate on solid media or in Cary-Blair transport.

Note: A suspected B. anthracis *culture requires Category A Infectious Disease packaging (Class 6.2) and trackable shipping.* ***Please notify the laboratory by telephone at time of shipment.***

Please contact the laboratory prior to submission regarding environmental samples, rapid test methods, and transport instructions.

Transport Temperature: Ambient

Turn-around Time: Rapid test methods are performed in Molecular Diagnostics and are available within 6 - 8 hours of specimen receipt. A positive or negative PCR result is a CONFIRMATORY result. Results are telephoned to the submitter as soon as testing is complete.

CPT Codes:
87081 (Culture screen)
Price: Fee Waived

87798 (PCR)
Price: Fee Waived

Bacterial Culture Identification, Aerobic

Specimen Requirements: Send non-fastidious Gram negative or Gram-positive isolates on solid media or on swab in Cary-Blair, Stuart's, or Amies transport medium. Fastidious or slow growing organisms require careful transport on an enriched agar medium.

Transport Temperature: Ambient

Turn-around Time: Normally 3 to 14 working days, depending on the purity and the growth rate of the isolate.

CPT Codes:
87070 (culture, presumptive ID)
Price: $25.00

87077 (Each add'l ID)
Price: $25.00

Bacterial Culture Identification, Anaerobic

Specimen Requirements: Send pure culture isolate in an anaerobic transport system.

Transport Temperature: Ambient

Turn-around Time: Normally 3 to 14 working days, depending on the growth rate of the isolate.

CPT Codes:
87075 (culture, presumptive ID)
Price: $25.00

87076 (Each add'l ID)
Price: 25.00

Bartonella spp. (formerly *Rochalimaea spp*.) Serology by IFA

Specimen Requirements: 2 mL serum, plus completed cat scratch fever disease history form. The laboratory will fax you a form upon request.

Referred to the Centers for Disease Control, Atlanta, Georgia

Transport Temperature: 2-8°C

Turn-around Time: 2 weeks

CPT Code:
86256
Price: $30.00

***Blastomyces, Histoplasma, Coccidoides* Identification by Nucleic Acid Probe**

Specimen Requirements: Isolates sent on Sabouraud's slants or as reflex testing on positive primary specimens submitted for culture.

Transport Temperature: Ambient

Turn-around Time: 1 to 3 working days for submitted isolates, others dependent on growth rate.

CPT Code:
87149 (each)
Price: $35.00 each

***Blastomyces spp.* Culture Isolation/ Identification** **(see Fungal Culture)**

Blastomyces Serology **(see Fungal Serology)**

Blood Borne Pathogen Exposure - Exposed Worker (HBsAb, HIV, HCV) by EIA

Specimen Requirements: 1 mL serum

Transport Temperature: 2-8°C

Turn-around Time: Routinely batch tested once per week. Positive results are telephoned to the submitter. These tests may be ordered as a panel but are billed individually.

CPT Codes:
86706 (HBsAb)
Price: $30.00

87389 (HIV)
Price: $31.00

86803 (HCV)
Price: $40.00

Total Price: $101.00

Blood Borne Pathogen Exposure - Source Patient (HBsAg, HIV, HCV) by EIA

Specimen Requirements: 2 mL serum

Transport Temperature: 2-8°C

Turn-around Time: Routinely batch tested once per week. Positive results are telephoned to the submitter. These tests may be ordered as a panel but are billed individually.

CPT Codes:
87340 (HBsAg)
Price: $25.00

87389 (HIV)
Price: $31.00

86803 (HCV)
Price: $40.00

Total Price: $96.00

Blood Lead by Anodic Stripping Voltometry

Specimen Requirements: 1 mL venous or 0.3 mL capillary whole blood, EDTA (purple top). Adult and child specimen collection kits are available through the laboratory. See Blood Lead Collection and Transport instructions on the collection and transport of capillary and venous specimens.

Transport Temperature: 2-30°C (Refrigeration preferable)

Note: Venous specimens are referred to South Dakota Public Health Laboratory for testing.

Turn-around Time: 1-2 days for capillary specimens; 1 week for venous specimens.

CPT Code:
83655
Price: $23.00

Blood Parasite Screen

Analysis includes *Plasmodium* spp. (Malaria), *Babesia* spp., *Trypanosoma* spp., and Filarial nematodes (*Brugia malayi*, *Loa loa*, *Mansonella* spp., *Onchocera* volvulus, and *Wuchereria bancrofti*).

Specimen Requirements: Two sets of thick and thin EDTA Blood smears; one set of thick and thin smears stained with Giemsa or Wright's Stain, and 1-5 ml whole blood in EDTA tube (for possible PCR testing). See Blood Parasite Screen Thick EDTA Blood Smear Preparation Instructions for correct preparation and RBC lysing of thick blood smears.

Please contact the laboratory prior to submission of specimen. Patient travel history is required.

Transport Temperature: Ambient

Turn-around Time: 1 to 2 working days. Positive samples for confirmation and specimens for PCR testing are referred to the Centers for Disease Control, Atlanta, Georgia.

CPT Code:
87207
Price: $38.00

Bordetella pertussis/B. parapertussis/B. holmesii Direct Detection by Real Time PCR

Specimen Requirements: Nasopharyngeal (NP) swab in a sterile container without transport media. Do not submit a throat or nares specimen or a specimen submitted in Regan Lowe Media. See Molecular (Nucleic Acid Amplification)

Testing Collection and Transport instructions.

Turn-around Time: 1 to 2 working days. Positive results are telephoned to the submitter.

NOTE: PCR testing should be performed only on symptomatic patients; a positive PCR in an asymptomatic patient does not meet the standard CDC case definition and cannot be considered a case of pertussis. PCR testing may be able to detect *B. pertussis* 3 to 4 weeks post onset.

CPT Code:
87801
Price: $107.00

Transport Temperature: Ambient or 2-8°C

***Borrelia burgdorferi* Culture**

Specimen Requirements: Skin punch biopsy, synovial fluid, CSF, 0.5 ml EDTA whole blood, or blood smears (unstained or stained with Wright's or Giemsa). *Contact the laboratory prior to collection for special instructions and transport media requirements.*

Referred to the Centers for Disease Control, Fort Collins, Colorado

Transport Temperature: Ambient

Turn-around Time: 8 weeks

CPT Code:
87081
Price: $30.00

***Borrelia burgdorferi* Serology Total Antibody by EIA with reflex Western Blot confirmation**

Specimen Requirements: 2 mL serum

Transport Temperature: 2-30°C (Refrigeration preferable)

Turn-around Time: Routinely batch-tested once per week. Specimens that test positive or equivocal are referred to South Dakota Public Health Laboratory in Pierre, SD, for Lyme IgG and IgM Western Blot confirmation.

CPT Code:
86618 (Screen)
Price: $40.00

86617 (Western Blot)
Price: $100.00

***Borrelia hermsii* Serology (Tick Borne Relapsing Fever) by IgM/IgG ELISA**

Specimen Requirements: 2 mL serum; Paired acute and convalescent serum recommended. Date of onset, signs, symptoms, and antibiotic treatment information must be included on requisition form.

Referred to the Centers for Disease Control, Fort Collins, Colorado

Transport Temperature: 2-30°C or frozen (Refrigeration preferable)

Turn-around Time: 3 weeks

CPT Code:
86619
Price: $30.00

Brucella spp. **Culture Isolation/ Identification/Rapid Test Methods**

Specimen Requirements: EDTA whole blood (PCR) or pure culture isolate on solid medium.

Note: A suspected Brucella spp. *culture requires Category A Infectious Disease packaging (Class 6.2) and trackable shipping. Please notify the laboratory by telephone at time of shipment.*

Please contact the laboratory prior to submission regarding environmental samples, rapid test methods, and transport instructions.

Transport Temperature: Ambient

Turn-around Time: Cultures will be held for five (5) working days before reporting as negative. Results are telephoned as soon as possible to the submitter.

Rapid test methods (PCR) are performed in Molecular Diagnostics and are available within 6 - 8 hours of specimen receipt. Culture is considered CONFIRMATORY for specimens that are PCR PRESUMPTIVE Positive. Further confirmatory testing at the CDC may be needed.

CPT Codes:
87081 (Culture screen)
Price: Fee Waived

87798 (PCR)
Price: Fee Waived

Brucella **Serology by Bacterial Agglutination**

Specimen Requirements: 2 ml. Serum; Paired acute and convalescent serum recommended.

Transport Temperature: 2-30°C (Refrigeration preferable)

Turn-around Time: Routinely batch tested once per week.

NOTE: Tularemia serology will be automatically performed on all requests for Brucella serology due to antigen cross reactivity.

CPT Codes:
86622 (Brucella) 86668 (Tularemia)

Price: $25.00 (each)

Total Price: $50.00

***Burkholderia mallei*, *B. pseudomallei* Culture Isolation / ID / Rapid Test Methods**

Specimen Requirements: EDTA whole blood (PCR) or pure culture isolate submitted in Cary-Blair transport or on solid medium.

Note: A suspected Burkholderia mallei *or* B. pseudomallei *culture requires Category A Infectious Disease packaging (Class 6.2) and trackable shipping. Please notify the laboratory by telephone at time of shipment.*

Please contact the laboratory prior to submission regarding environmental samples, rapid test methods, and transport instructions.

Transport Temperature: Ambient

Turn-around Time: Cultures will be held for five (5) working days before reporting as negative. Results are telephoned as soon as possible to the submitter.

Rapid test methods (PCR) are performed in Molecular Diagnostics and are available within 6 - 8 hours of specimen receipt. CONFIRMATION requires a combination of culture, biochemical, and PCR results. Presumptive Positives may need additional testing at the CDC.

CPT Codes:
87081 (Culture screen)
Price: Fee Waived

87798 (PCR)
Price: Fee Waived

C

***Campylobacter spp.* Culture Isolation/Identification**

Specimen Requirements: Stool in submitted in Cary-Blair transport or pure culture isolate on solid media sent in a *Campylobacter* transport system.

Transport Temperature: 2-8°C for stool specimens, ambient for isolates

Turn-around Time: 3 to 5 working days. Positive results from a primary culture are telephoned to the submitter.

CPT Codes:
87046 (Culture ID)
Price: $18.00

87077 (Each add'l ID)
Price: $25.00

***Candida albicans* Culture Isolation/Identification** (see Fungal Culture)

***Candida auris* Identification/Antifungal Susceptibility Testing**

Specimen requirements: Send a pure culture isolate on solid medium - Sabouraud's Dextrose, blood, or chocolate agar slants.

Please contact the laboratory prior to submitting the isolate.

Transport Temperature: Ambient

Referred to the regional ARLN Laboratory

Turn-around Time: 2-4 days

CPT Code:
None
Price: Fee waived

Carbapenem-Resistant Organisms Direct Detection by Real-Time PCR (including Carbapenem-Resistant *Enterobacteriaceae* (CRE) and Carbapenem-Resistant Pseudomonas aeruginosa (CRPA)

Detects and differentiates KPC, NDM, VIM, OXA-48, and IMP gene sequences associated with Carbapenem non-susceptibility in gram-negative bacteria.

Specimen requirements: Pure culture isolate on solid media or in Cary-Blair transport or direct rectal swab collection. Rectal swabs specific to this test are provided by MTPHL. Store the collection swabs at room temperature. For collection of a paired rectal swab, See Molecular (Nucleic Acid Amplification) Testing Collection and Transport instructions.

Please contact the laboratory prior to submission regarding surveillance (fee waived) criteria. Isolates that do not meet the surveillance criteria can be tested for a fee.

Transport Temperature: Ambient

Turn-around Time: Routinely tested each working day. Positive results are telephoned to the submitter.

CPT Code:
None (Surveillance)
Price: Fee Waived

CPT Code:
87184 (mCIM)
Price: $38.00

CPT Code:
87801 (Carba-R)
Price: $107.00

Cat Scratch Fever (see *Bartonella spp.* Serology)

Chagas Disease (see *Trypanosomiasis* Detection)

Chikungunya Virus by PCR (see Zika Trioplex PCR)

Chlamydia trachomatis Direct Detection by Nucleic Acid Amplification

Specimen Requirements: Endocervical or male urethral swab in APTIMA Uni-Sex Swab Specimen Collection Tube; throat, rectal, or vaginal swab in APTIMA Multitest Specimen Collection Tube; or urine in APTIMA Urine Specimen Collection Tube. See Chlamydia/Gonorrhea Amplified Testing Collection and Transport instructions.

Transport Temperature: 2-30°C

Turn-around Time: Routinely tested daily (Monday through Friday). Positive results are telephoned to the submitter.

NOTE: Can be run in tandem with *Neisseria gonorrhoeae* Direct Detection by APTIMA Amplification (see Combination Amplification Test below)

CPT Code:
87491
Price: $44.00

***Chlamydia trachomatis/Neisseria gonorrhoeae* Direct Detection by NAAT (Combo Test)**

Specimen Requirements: Endocervical or male urethral swab in APTIMA Uni-Sex Swab Specimen Collection Tube; throat, rectal or vaginal swab in APTIMA Multitest Specimen Collection Tube; or urine in APTIMA Urine Specimen Collection Tube. See Chlamydia/Gonorrhea Amplified Testing Collection and Transport instructions.

Transport Temperature: 2-30°C

Turn-around Time: Routinely tested daily (Monday through Friday). Positive results are telephoned to the submitter. These tests can be ordered as a panel but will be billed individually.

CPT Codes:
87491 (Chlamydia) 87591 (GC)

Price: $44.00 (each)

Total Price: $88.00

Cholera (see *Vibrio spp*. Culture Isolation/ Identification)

***Clostridium botulinum* (Botulism) Bacterial ID, Toxin, and Serology Testing**

Call the Montana Public Health Laboratory at (800)821-7284 for consultation on sending specimens; an epidemiologic consultation is also required for preapproval of testing, and for making arrangements to receive antitoxin.

Specimen Requirements: 10 mL serum, and 25 gm stool. Special requirements for infants are a stool sample only, serum will not be accepted.

Food testing is not performed at MTPHL. Human testing referred to the Utah State Public Health Laboratory in Salt Lake City, UT

Transport Temperature: 2-8°C

Turn-around Time: Preliminary results in 2 to 4 working days.

CPT Code:
None
Price: Fee Waived*

***Clostridium difficile* PCR, including NAP1**

Specimen Requirements: Liquid or unformed stool in a sterile container

Transport Temperature: 2-8°C (Stable for up to 5 days when stored at 2-8°C)

Turn-around Time: 1 to 2 working days. Positive results are telephoned to the submitter.

CPT Code:
87493
Price: $107.00

Clostridium spp. **(except *C. botulinum*) Culture Isolation/ ID** **(see Bacterial Culture, Anaerobic)**

Coccidioides spp**. Culture Isolation/ Identification** **(see Fungal Culture)**

Coccidioides Serology **(see Fungal Serology)**

Colorado Tick Fever Virus (CTFV) Serology, IgG by Indirect Immunofluorescence

Specimen Requirements: 1 mL serum; Paired acute and convalescent serum recommended.

Transport Temperature: 2-30°C (Refrigeration preferable)

Referred to the Centers for Disease Control, Fort Collins, Colorado

Turn-around Time: 6 weeks

NOTE: Rocky Mountain Spotted Fever testing will automatically be performed on all requests for Colorado Tick Fever.

CPT Codes:
86790 (CTFV)
Price: $30.00

86757 (RMSF)
Price: $25.00 (each)

Total Price: $55.00

Corynebacterium diphtheriae **Culture Isolation/ Identification**

Specimen Requirements: Throat, nasal, and wound swabs, pseudo-membrane, and sputum. Swabs may be placed in Amies or Stuart transport medial. Pseudo-membrane should be sent in leak proof container with saline (not formalin).

Please contact the State Epidemiology Department (406)-444-0273) for consultation prior to submission of specimens.

Transport Temperature: 2-8°C

Referred to the Centers for Disease Control, Atlanta, Georgia.

Turn-around Time: One week. Positive results are telephoned to the submitter.

CPT Code:
87081
Price: $30.00

Corynebacterium spp. **(not *C. diphtheriae)* Culture Isolation/ Identification** **(see Bacterial Culture, Aerobic)**

Coxiella burnetii **by Real-Time PCR**

Specimen Requirements: EDTA whole blood or environmental samples

Please contact the Montana Public Health Laboratory prior to submission regarding sample collection and transport instructions.

Transport Temperature: Ambient

Turn-around Time: Rapid test methods are performed in Molecular Diagnostics and are available within 6 - 8 hours of specimen receipt. Results are telephoned as soon as possible to the submitter.

NOTE: This is a presumptive assay. Confirmation for *Coxiella burnetii* is performed at the Centers for Disease Control and Prevention (CDC).

CPT Code:
87798
Price: Fee Waived

Coxiella burnetii **Serology** **(see Q fever Serology)**

Cryptococcus spp**. Culture Isolation/ Identification** **(see Fungal Culture)**

Cryptosporidium / Cyclospora / Cystoisospora **Detection by Fluorescent Stain**

Specimen Requirements: Stool in Total-Fix preservative or 10% Formalin

Transport Temperature: Ambient

Turn-around Time: Performed each working day. Positive results are telephoned to the submitter.

CPT Code:
87207
Price: $35.00

Culture for Storage

Specimen Requirements: Pure culture isolate submitted in Cary-Blair transport or on solid media.

Submit organisms that are of epidemiologic interest and need to be stored for molecular comparison to other strains. Laboratories are encouraged to submit organisms which may be part of an outbreak or which demonstrate a significant antibiotic resistance, i.e. *E. coli O157*, Toxigenic *E. coli, Salmonella spp., Shigella spp., Legionella spp., Listeria monocytogenes, Vibrio spp., Yersinia enterocolitica, N. gonorrhoeae*, *N. meningitidis* from a sterile site, *H. influenzae* from a sterile site, resistant *Streptococcus pneumoniae*, CRE, CRPA, KPC, and potential VISA or VRSA.

Transport Temperature: Ambient

CPT Code:
None
Price: Fee Waived

***Cyclospora* Detection (see *Cryptosporidium / Cyclospora / Cystoisospora* Detection by Fluorescent Stain)**

***Cystoisospora* Detection (see *Cryptosporidium / Cyclospora / Cystoisospora* Detection by Fluorescent Stain)**

D

Dengue Fever Serology by ELISA IgM and IgG

Specimen Requirements: 2 mL serum

Transport Temperature: 2-30°C or frozen (refrigeration or frozen specimens preferred)

Referred to the Centers for Disease Control, San Juan, Puerto Rico. An additional form must be filled out.

Turn-around Time: 7 days

CPT Code:
86790
Price: $30.00

Dengue Fever Virus by PCR (see Zika Trioplex PCR)

Dermatophytes Culture Isolation/ Identification (see Fungal Culture)

Diphtheria (see *Corynebacterium diphtheriae* Culture Isolation)

E

Ebola Virus

Specimen Requirements: Whole blood, serum, or plasma. Urine may be submitted, but only when accompanied by a blood specimen.

NOTE: Contact your local health department or the State Epidemiology Department (406-444-0273) to ensure the patient meets criteria for testing.

A specimen SUSPECTED of containing *Ebola Virus requires Category A Infectious Disease packaging (Class 6.2) and trackable shipping. Please contact the Montana Public Health Laboratory prior to submission regarding sample collection and transport instructions.*

Transport Temperature: Whole blood: 2-8°C
Serum, plasma, or urine: 2-8°C or frozen

Turn-around Time: Rapid test methods are performed in Molecular Diagnostics and are available within 6 - 8 hours of specimen receipt. Samples that yield positive, equivocal, or inconclusive results will be forwarded to CDC for additional evaluation.

Note: Negative EBOV rRT-PCR results do not preclude Ebola virus infection and should not be used as the sole basis for patient management decisions. The level of Ebola virus that would be present in whole blood, serum or plasma specimens from individuals with early systemic infection is variable but generally positive at the time of symptom onset. In asymptomatic individuals or individuals within 72 hours of symptom onset, a negative result does not

exclude the possibility of Ebola virus infection and does not demonstrate that an individual is not infectious. If negative results are obtained for an individual with 72 hours of symptom onset, testing should be repeated at or after the 72-hour time point.

CPT Code:
87798
Price: Fee Waived

Echinococcosis Serology by Western Blot or Immunoblot

Specimen Requirements: 2 mL serum

Transport Temperature: 2-30°C (Refrigeration preferable)

Referred to the Centers for Disease Control, Atlanta, Georgia

Turn-around Time: 18 days

CPT Code:
84182
Price: $30.00

EHEC, Enterohemorrhagic *E. coli* (see *Escherichia coli* Shiga-Like Toxin Assay or Enteric Panel)

Ehrlichia spp. Serology by Indirect Immunofluorescence

Specimen Requirements: 2 mL serum

Transport Temperature: 2-30°C (Refrigeration preferable)

Referred to the Centers for Disease Control, Atlanta, Georgia

Turn-around Time: 6 weeks

CPT Code:
86682
Price: $30.00

Entamoeba histolytica Serology by EIA

Specimen Requirements: 2 mL serum Include documentation of negative stool examinations for *E. histolytica*.

Referred to the Centers for Disease Control, Atlanta, Georgia

Transport Temperature: 2-30°C (Refrigeration preferable)
Turn-around Time: 3 to 6 weeks

CPT Code:
86753
Price: $30.00

Enteric Isolate Surveillance

Specimen Requirements: All isolates of *Campylobacter* spp., Shiga-toxin producing *Escherichia coli* (STEC including

serotype O157:H7), *Salmonella spp., Shigella spp*., *Vibrio*, *Yersinia* spp., and *Listeria* should be referred for surveillance purposes. All stools that are positive by Culture-Independent Testing (e.g. PCR, EIA) for the listed organisms should be sent for surveillance purposes.

Confirmation of isolates is performed are reported to submitter. In addition, Whole Genome Sequencing will be performed to determine strain-relatedness on certain organisms of interest; results are compared to other strain patterns in Montana and across the nation using the CDC PulseNet database. Results are communicated to the DPHHS Epidemiology staff for follow up.

Transport Temperature: 2-8°C for stool, ambient for isolates

Turn-around Time: Routinely tested each week.

CPT Code:
none
Price: Fee Waived

Enteric Panel Culture Isolation/ Identification

Includes screens for Salmonella, Shigella, Campylobacter, E. coli O157, EHEC, Aeromonas, and Plesiomonas

Specimen Requirements: Stool in Cary-Blair transport, or other commercial enteric transport media. Collect stool directly from patient into a clean specimen container. Do not collect from toilet bowl or use stool contaminated with urine. Use a sterile swab to collect a portion of the stool (collect from bloody or mucous-containing areas if present) and insert swab to the lower part of a Cary-Blair transport tube and break or cut the swab stick. A rectal swab is also acceptable if there is evidence of fecal staining on the swab. Cary-Blair transport tubes are supplied upon request.

Escherichia coli Shiga-Like Toxin Assay will be performed on all specimens. Stools with positive toxin tests will be further cultured to isolate and identify the toxin-producing organism.

Transport Temperature: 2-8°C

Turn-around Time: 2 to 4 working days. Positive test results are telephoned to the submitter.

CPT Codes:
87045 (*Salmonella* and *Shigella* culture)
87046 (*E. coli* culture)
87046 (*Campy* culture)
87046 (*Aeromonas* culture)
87046 (*Plesiomonas* culture)

87449 (EHEC)
Price: $30.00

Total Price: $84.00

87077 (Each add'l ID)
Price: $25.00

Enterovirus (D68) Detection by Real-Time PCR

Specimen Requirements: CSF in a sterile transport container without transport media, respiratory specimens (NP swab) in Universal Viral Transport Media. See Molecular (Nucleic Acid Amplification) Testing Collection and Transport

instructions.

Transport Temperature: 2-8°C

Turn-around Time: 1 to 3 working days. Positive results are telephoned to the submitter.

CPT Code:
87498
Price: $107.00

Enterovirus (Pan-Enterovirus) Detection by Real-Time PCR

Specimen Requirements: CSF in a sterile transport container without transport media, respiratory specimens (NP swab) in Universal Viral Transport Media. See Molecular (Nucleic Acid Amplification) Testing Collection and Transport instructions.

Transport Temperature: 2-8°C

Turn-around Time: 1 to 3 working days. Positive results are telephoned to the submitter.

CPT Code:
87498
Price: $107.00

ESBL (see Antimicrobial Resistant Bacteria Confirmation)

Escherichia coli O157 Culture Isolation/Identification

Specimen Requirements: Stool specimen in Cary-Blair transport, or other commercial enteric transport media, or pure culture isolate submitted in Cary Blair transport or on solid media.

Note: A suspected E. coli O157 *culture requires Infectious Disease packaging (Class 6.2) and trackable shipping. Please notify the laboratory by telephone at time of shipment.*

For public health surveillance, please submit all isolates of *E. coli* O157 to the laboratory. See Enteric Isolate Surveillance.

Transport Temperature: 2-8°C for stool, ambient for isolates

Turn-around Time: 2 to 4 working days. Positive results are telephoned to the submitter.

CPT Codes:
87046 (Culture ID)
Price: $18.00

87077 (Each add'l ID)
Price: $25.00

Escherichia coli Shiga-Like Toxin Assay (Enterohemorrhagic *E. coli*, EHEC or STEC) by EIA

Specimen Requirements: Stool specimen in Cary-Blair transport, or other commercial enteric transport media, or pure culture *Escherichia coli* isolate submitted in Cary Blair transport or on solid media.

EHEC is also performed on all routine enteric panels.

Transport Temperature: 2-8°C

Turn-around Time: 2 to 4 working days. Positive results are telephoned to the submitter. Stools with positive toxin tests will be further cultured to isolate and identify the toxin-producing organism.

CPT Code:
87449
Price: $30.00

F

Francisella tularensis **Culture Isolation/ Identification/Rapid Test Methods**

Specimen Requirements: Clinical specimen in sterile container or pure culture isolate on solid medium.

Note: A suspected F. tularensis *culture requires Category A Infectious Disease packaging (Class 6.2) and trackable shipping. Please notify the laboratory by telephone at time of shipment.*

Please contact the laboratory prior to submission regarding environmental samples, rapid test methods, and transport instructions.

Transport Temperature: Ambient

Turn-around Time: Cultures will be held for five (5) working days before reporting as negative. Results are telephoned as soon as possible to the submitter.

PCR testing methods are performed in Molecular Diagnostics and are available within 6 - 8 hours of specimen receipt. Culture is considered confirmatory for specimens that are PCR-positive.

CPT Codes:
87081 (Culture screen)
Price: Fee Waived

87798 (PCR)
Price: Fee Waived

Francisella tularensis **Serology by Bacterial Agglutination**

Specimen Requirements: 2 mL serum; Paired acute and convalescent specimens recommended.

Transport Temperature: 2-30°C (Refrigeration preferable)

Turn-around Time: Routinely batch tested once per week.

NOTE: *Brucella* serology testing will be automatically performed on all requests for Tularemia serology due to antigen cross reactivity.

CPT Codes:
86668 (Tularemia) 86622 (*Brucella*)

Price: $25.00 (each)

Total Price: $50.00

Fungal Culture Isolation/ Identification

Specimen Requirements: Send original specimens in a sterile container. Send cutaneous specimens dry. Send pure fungal isolates (molds or yeasts) on an agar slant. See Mycology (Fungal) Culture Collection and Transport instructions.

Transport Temperature: Ambient

Turn-around Time: Primary specimen cultures are monitored for 4 weeks prior to a negative report.

CPT Codes:

87101 (culture, skin)
87102 (culture, other)
87103 (culture, blood)

Price: $42.00 Each

87106 (ID, yeast)
Price: $22.00 Each

87107 (ID, mold)
Price: $22.00 Each

Fungal Serology (Histo, Cocci, Blasto) by Complement Fixation & Immunodiffusion

Specimen Requirements: 1.5 mL serum or CSF. Serum cannot be hemolyzed and plasma is not accepted.

Transport Temperature: 2-8°C

Referred to the Centers for Disease Control, Atlanta, Georgia

Turn-around Time: 4 weeks

CPT Codes:

86698 (Histoplasma)
86612 (Blastomyces)
86635 (Coccidioides)

Price: $30.00

G

***Gardnerella vaginalis* Culture Isolation/ Identification (see Bacterial Culture, Aerobic)**

***Giardia* Detection (see Ova and Parasite Exam)**

Gonococcal Infections (see *Neisseria gonorrhoeae* Culture Isolation)

H

***Haemophilus influenzae* Culture Isolation/ Identification**

Specimen Requirements: Primary specimen or pure culture isolate on chocolate media.

Transport Temperature: Ambient

Turn-around Time: 2 to 4 working days. Positive *H. influenzae* results from sterile sites are telephoned to the submitter.

NOTE: Serogrouping is routinely performed on *H. influenzae* isolates from sterile body sites such as blood or cerebral spinal fluid. Please submit all *H. influenzae* isolates from sterile body sites to the laboratory for serogrouping and storage for future epidemiologic purposes.

CPT Codes:
87081 (culture)
Price: $38.00

87185 (beta lactamase)
Price: $9.00

***Haemophilus spp*. Culture Isolation/ Identification** **(see Bacterial Culture, Aerobic)**

Hantavirus IgM Serology by EIA, capture EIA
Specimen Requirements: 3 mL serum

Transport Temperature: 2-30°C (Refrigeration preferable)

Turn-around Time: Routinely batch tested once per week. STAT testing is available each working day, or on weekends and holidays as needed. *Call ahead to notify the laboratory and to make arrangements.*

Positive and STAT results are telephoned to the submitter. Specimens that yield a positive result are referred to the Centers for Disease Control, Atlanta, Georgia for IgG and IgM testing. Confirmation testing turn-around time is 10 days.

To qualify for STAT testing, all the following criteria must be met:

1. The patient is hospitalized with an acute respiratory illness, typical of Hantavirus Pulmonary Syndrome (HPS).
2. The patient is critically ill.
3. The patient does not have any relevant underlying medical condition that could account for the symptoms (COPD, malignancy, immunosuppression, diabetes)
4. The onset of illness (date when prodromal symptoms such as low-grade fever and myalgia were noted) is three (3) or more days prior to serum sample collection. IgM antibody to SNV is usually not detectable until the patient develops shortness of breath.

CPT Codes:
86790 (IgM)

Price: $ 100.00

Hepatitis A IgM Antibody (HAV IgM) by EIA
Specimen Requirements: 1 mL serum

Transport Temperature: 2-30°C (Refrigeration preferable)

Turn-around Time: Testing is routinely batch tested once per week but may be available each working day as needed. *Call ahead to notify the laboratory and to make arrangements if immediate testing is needed.*

CPT Code:

86709
Price: $35.00

Hepatitis, Acute Panel by EIA (HAV IgM Ab, HBsAg, HBc IgM Ab, HCV)

Specimen Requirements: 2 mL serum

Transport Temperature: 2-30°C (Refrigeration preferable)

Turn-around Time: Testing is routinely batch tested once per week but may be available each working day as needed. *Call ahead to notify the laboratory and to make arrangements if immediate testing is needed.*

CPT Codes:
80074 (entire panel)
Total Price: $135.00

Hepatitis B Core IgM (HBc IgM) Antibody by EIA

Specimen Requirements: 1 mL serum

Transport Temperature: 2-30°C (Refrigeration preferable)

Turn-around Time: Testing is routinely batch tested once per week but may be available each working day as needed. *Call ahead to notify the laboratory and to make arrangements if immediate testing is needed.* Positive and STAT results are telephoned to the submitter.

CPT Code:
86705
Price: $35.00

Hepatitis B Core Total Antibody (HBc Total) by EIA

Specimen Requirements: 1 mL serum

Transport Temperature: 2-30°C (Refrigeration preferable)

Turn-around Time: Testing is routinely batch tested once per week. Positive results are telephoned to the submitter.

CPT Code:
86704
Price: $40.00

Hepatitis B Post-Vaccination Panel with Reflex Confirmation (Infants Only)

Specimen Requirements: 2 mL serum

Transport Temperature: 2-30°C (Refrigeration preferable)

Turn-around Time: Testing is routinely batch tested once per week.

NOTE: **This test is only for post-vaccination serologic testing for infants born to Hepatitis B-infected women.** Confirmatory Neutralization testing will be automatically performed on all repeat reactive HBsAg.

CPT Code:

86706 (HBsAb)
Price: $30.00

87340 (HBsAg)
Price: $25.00

Total Price: $55.00

87341 (HBsAg Neutralization)
Price: $31:00

Hepatitis B Surface Antibody (HBsAb) by EIA (Quantitation)

Specimen Requirements: 1 mL serum

Transport Temperature: 2-30°C (Refrigeration preferable)

Turn-around Time: Testing is routinely batch tested once per week.

CPT Code:
86706
Price: $30.00

Hepatitis B Surface Antigen (HBsAg) by EIA with Reflex Confirmation

Specimen Requirements: 2 mL serum

Transport Temperature: 2-30°C (Refrigeration preferable)

Turn-around Time: Routinely batch tested once per week. *Call ahead to notify the laboratory and to make arrangements if immediate testing is needed.* Positive and STAT results are telephoned to the submitter.

NOTE: Confirmatory Neutralization testing will be automatically performed on all repeat reactive screens.

CPT Code:

87340 (HBsAg)
Price: $25.00

87341 (HBsAg Neutralization)
Price: $31.00

Hepatitis C (HCV) Antibody Screen by EIA

Specimen Requirements: 2 mL serum

Transport Temperature: 2-30°C (Refrigeration preferable)

Turn-around Time: EIA screens routinely batch tested twice per week. Positive results are telephoned to the submitter.

NOTE: Repeat positive samples will automatically reflex to HCV RNA for confirmation and quantitation.

CPT Code:

86803 (Screen)
Price: $40.00

Hepatitis C (HCV) RNA Quantitation

This CONFIRMATORY testing is a reflex test for repeat positive HCV specimens.

Specimen Requirements: 2 mL serum or plasma (EDTA, anticoagulant citrate dextrose solution or plasma preparation tubes). Whole blood can be stored at 2-30°C and must be centrifuged within 6 hours of specimen collection. Separate the plasma or serum from the pelleted red blood cells following the manufacturer's instruction for the tube used.

Transport Temperature: 2-8°C. Ship specimen within 5 days of collection.

Turn-around Time: 3-5 days. Positive results are telephoned to the submitter.

CPT Code:
87522
Price: $107.00

Herpes Simplex Virus (HSV), Type 1 and 2, Direct Detection by NAAT

Specimen Requirements: Cervical Swab or Lesion swab in Aptima Multitest Specimen collection tube. See Chlamydia/Gonorrhea Amplified Testing Collection and Transport instructions.
Note: CSF in a sterile container without transport media is sent to North Dakota Public Health Laboratory for testing.

Transport Temperature: 2-8°C

Turn-around Time: 1 to 3 working days. Positive results are telephoned to the submitter.

CPT Code:
87529
Price: $107.00

Herpes Simplex Virus (HSV), Type 1 and 2, IgG Serology by type specific EIA

Specimen Requirements: 1 mL serum; Screen or paired acute and convalescent specimens

Transport Temperature: 2-30°C (Refrigeration preferable)

Turn-around Time: Routinely batch tested once per week.

CPT Codes:
86695 (HSV 1) 86696 (HSV 2)

Price: $25.00 (each)

Total Price: $50.00

Herpes Zoster Virus IgG Serology by EIA (see Varicella Zoster Virus Serology)

***Histoplasma* Culture Isolation/ Identification** (see Fungal Culture)

***Histoplasma* Serology** (see Fungal Serology)

HIV 1/2 Ab/p24 Ag by EIA, with Reflex Confirmation

Specimen Requirements: 1 mL K_2 EDTA or serum (note that plasma is required for HIV RNA quantitation).

Transport Temperature: 2-8°C or frozen

Turn-around Time: EIA screens routinely tested at least two (2) days each week. Specimens sent for confirmation will be tested the day they are received.

NOTE: Reflex supplemental testing is performed on all repeat reactive EIA screens using the CDC HIV testing algorithm.

HIV-1/HIV-2 Geenius testing will be performed to confirm the presence of HIV antibody and to differentiate HIV-1 and HIV-2.

HIV NAT testing will be performed to confirm the presence of HIV p24 antigen (acute infection) when the HIV Ab/Ag Combo test is repeat reactive and the HIV-1/HIV-2 Geenius test is negative. It will also be performed for any newly detected cases.

CPT Codes:
87389
Price: $31.00

HIV-1/HIV-2 Geenius

This test is used to differentiate HIV-1 and HIV-2 and is used in an algorithm when the HIV Combo Ag/Ab EIA is repeat-reactive. Repeat reactive EIA screens with inconclusive or conflicting Geenius results are reflexed to HIV RNA Quantitation testing.

Specimen Requirements: 1 mL K_2 EDTA or serum (note that plasma is required for HIV RNA quantitation).

Transport Temperature: 2-8°C or frozen

Turn-around Time: Within 1 to 2 working days of repeat reactive HIV Combo Ag/Ab EIA

CPT Code:
86703
Price: $55.00

HIV RNA Quantitation

Per CDC recommendations for HIV testing: Specimens that are positive by the HIV EIA method and negative by the HIV supplemental test will be reflex tested for HIV RNA Quantitation.

Specimen Requirements: 2 mL plasma obtained by K_2 EDTA or Acid Citrate Dextrose (ACD) anticoagulants or Plasma Preparation tubes (PPTs). Whole blood can be stored at 2-30°C and must be centrifuged within 24 hours of specimen collection. Separate the plasma from the pelleted red blood cells following the manufacturer's instructions for the tube used. Ship the separated plasma.

Transport Temperature: 2-8°C. Ship specimen within 3 days of collection.
Turn-around Time: 3-5 days

CPT Code:
87536
Price: $107.00

I

Influenza A and B Direct Detection by Real Time PCR

Specimen Requirements: Respiratory specimen in Universal Viral Transport Media. See Molecular (Nucleic Acid Amplification) Testing Collection and Transport instructions.

This test detects Influenza B and all subtypes of Influenza A. All specimens positive for Influenza A will be reflexed to real-time PCR subtyping. Specimens positive for Influenza B will be reflexed to real-time PCR genotyping.

Transport Temperature: 2-8°C

Turn-around Time: 1 to 3 working days. Positive results are telephoned to the submitter.

CPT Code:
87502
Price: $55.00

Influenza A Sub-typing by Real Time PCR

Detects Influenza A subtypes H3N2, H1N1 2009 pdm, H5, H7, or variant subtypes.

Note: if H5 or H7 is suspected, call the laboratory for a consultation prior to submission. The individual case must meet Epidemiological testing criteria.

Specimen Requirements: Nucleic acid derived from a PCR specimen screened positive for Influenza A. Reflex testing is performed on all Influenza A positive specimens.

Transport Temperature: 2-8°C

Turn-around Time: Sub-typing is performed each working day. Results are telephoned to the submitter.

CPT Code:
87503
Price: $33.00

Influenza B Genotyping by Real Time PCR

Detects Yamagata and Victoria lineage genotypes

Specimen Requirements: Nucleic acid derived from a PCR specimen screened positive for Influenza B. Reflex testing is performed on all Influenza B positive specimens.

Transport Temperature: 2-8°C

Turn-around Time: Sub-typing is performed each working day. Results are telephoned to the submitter.

CPT Code:
87503
Price: $33.00

Influenza Isolate Susceptibility Testing and Characterization

Specimen Requirements: Influenza A isolate in Universal Transport Media. The laboratory routinely selects significant isolates for susceptibility testing and characterization.

*Testing is performed at no cost for epidemiological purposes.

Transport Temperature: 2-8°C

Referred to the Centers for Disease Control, Atlanta, Georgia

Turn-around Time: 6 to 8 weeks

Price: Fee Waived

J

K

KPC (*K. pneumoniae* Carbapenemase) (see Carbapenem-Resistant Organisms Direct Detection by Real-Time PCR)

L

Lead Testing (see Blood Lead)

Legionella pneumophila Groups 1-6 Direct Detection by Immunofluorescence

Specimen Requirements: Submit fresh or frozen lung tissue, pleural fluid, bronchial washings, trans-tracheal aspirates, chest drainage, BAL, or sputum. Put a minimum of 1 mL specimen in a sterile, leak-proof container, and transport on ice in an insulated container.

Transport Temperature: 2-8°C

Turn-around Time: Performed each working day. Positive results are telephoned to the submitter.

CPT Code:
87278
Price: $29.00

Legionella spp. Culture Isolation/ Identification

Specimen Requirements: Submit fresh or frozen lung tissue, pleural fluid, bronchial washings, trans-tracheal aspirates, chest drainage, BAL, or sputum. Put a minimum of 1 mL specimen in a sterile, leak-proof container, and transport on ice in an insulated container. A suspect pure culture isolate submitted on BCYE medium may be submitted.

Transport Temperature: 2-8°C for specimen, ambient for isolate

Turn-around Time: DFA test performed each working day. Positive test results are telephoned to the submitter. Cultures are monitored for 14 working days before reporting as negative.

NOTE: Both a DFA test and culture is performed on each primary specimen received.

CPT Codes:
87081 (Culture screen)
Price: $38.00

87278 (DFA)
Price: $29.00

Leishmania **Detection**

Specimen Requirements: Tissue, 1-5 ml of whole EDTA blood, or bone marrow.

Please contact the laboratory prior to submission regarding proper CDC-provided transport medium for tissue specimens.

Transport Temperature: 2-8°C for whole blood and bone marrow, ambient for inoculated culture medium

Referred to the Centers for Disease Control, Atlanta, Georgia

Turn-around Time: 3 to 6 weeks

CPT Code:
87207
Price: $30.00

Leishmaniasis **Serology by IFA**

Specimen Requirements: 2 mL serum

Transport Temperature: 2-30°C (Refrigeration preferable)

Referred to the Centers for Disease Control, Atlanta, Georgia

Turn-around Time: 3 weeks

CPT Code:
86717
Price: $30.00

Leptospira **Serology by INDX Dip-S-Ticks or IgM EIA**

Specimen Requirements: 2 mL serum; Paired acute and convalescent serum specimens are recommended.

Transport Temperature: 4°C; ambient specimens not accepted

Referred to the Centers for Disease Control, Atlanta, Georgia

Turn-around Time: 18 days

CPT Code:
86720
Price: $30.00

Listeria Culture Isolation/ Identification (see Bacterial Culture, Aerobic)

Lyme Disease Culture (see _Borrelia burgdorferi_ culture)

Lyme Disease Serology (see _Borrelia burgdorferi_ serology)

M

Malaria Detection/ Identification (see _Blood Parasite Screen_)

Malaria Serology (see _Plasmodium_ Serology)

Measles PCR (see Rubeola (Measles) Direct Detection by Real Time PCR)

Measles Serology (see Rubeola Serology)

Meningococcal Infection (see _Neisseria spp._ including _N. meningitidis_ Culture)

MERS Co-V

Detects Middle Eastern Respiratory Syndrome Virus from individuals meeting MERS-CoV clinical and/or Epidemiological criteria. History of travel to a geographic location where MERS-CoV cases have been detected, contact with a probable or confirmed MERS-CoV case, or other epidemiologic links for which MERS-CoV testing may be indicated as part of a public health investigation.

Note: Call the laboratory for a consultation prior to submission. The individual case must meet Epidemiological testing criteria.

Specimen Requirements: Respiratory specimens; Nasopharyngeal or oropharyngeal swabs, lower respiratory aspirates/washes.

Transport Temperature: 2-8°C

Turn-around Time: 1 to 3 working days. Results are telephoned to the submitter.

CPT Code:
87798
Price: Fee Waived

Methicillin Resistant _Staphylococcus aureus_ (MRSA) (see Antimicrobial Resistant Bacteria Confirmation)

Modified Acid-Fast Stain

Specimen Requirements: Send specimens in sterile container. Add 1.0 ml sterile saline or broth to tissues or other non-liquid specimens. Send isolates on LJ medium.

Transport Temperature: Ambient

Turn-around Time: 1 to 2 working days. Positive results will be called to the submitter.

CPT Code:
87206 (smear)
Price: $18.00

Mold Culture Isolation/ Identification (see Fungal Culture)

Mumps Direct Detection by Real Time PCR

Specimen Requirements: Oral/buccal or oropharyngeal Dacron swabs in viral transport media and/or 50 ml minimum of urine.
Urine should be centrifuged at 2500xg for 15 min at 4° C. Resuspend sediment in 2 ml viral transport media. Swabs are the preferred specimen.

Note: Urine may not be positive until 4 days after symptom onset.
CSF may be submitted in meningitis/encephalitis-suspect cases with prior consult.

Transport Temperature: 2-8° C within 24 hours or freeze at -70° C and transport on dry ice.

Turn-around Time: 1 to 2 working days. Positive results are telephoned to the submitter.

CPT Code:
87798
Price: $107.00

Mumps IgG Serology by EIA

Specimen Requirements: 1 mL serum; Screen or paired acute and convalescent specimens

Transport temperature: 2-30°C (Refrigeration preferable)

Turn-around Time: Routinely batch tested once per week.

CPT Code:
86735
Price: $25.00

Mumps IgM Serology by IFA

Specimen Requirements: 1 mL serum; collect acute phase serum only and include an immunization history.

Transport Temperature: Frozen

Turn-around Time: Testing performed at North Dakota Public Health Laboratory as needed. Results are available within 2-3 days. Results are telephoned to the submitter.

CPT Code:
86735
Price: $22.00

Mycobacterium spp. **Culture Isolation/ Identification**

Specimen Requirements: Send specimens in sterile container. **Add 1.0 ml sterile saline or broth to tissues or other non-liquid specimens**. Send isolates on LJ medium or in liquid media vials. See *Mycobacterium spp.* (AFB or TB) Testing Collection and Transport instructions.

Note: The specimen must be received within 5 days of collection.

Transport Temperature: Ambient for Heparinized blood or bone marrow; 2-8°C for all other specimens

Turn-around Time: Smear reports are faxed to submitter by 5 p.m. the same day that the specimen is processed. Positive results are telephoned to the submitter; cultures are monitored for 6 weeks prior to issuing a negative report. Cultures positive for Mycobacterium tuberculosis complex will be reflexed for *Mycobacterium tuberculosis* complex Antimicrobial Susceptibility Testing.

NOTE: After a patient has tested positive for *M. tuberculosis*, no more than three specimens per week from the same body site will be processed to determine response to therapy and infectious status, without prior consultation. To determine response to therapy, specimens should be obtained no sooner than 7 days post initiation of therapy.

CPT Codes:
87206 (smear)
Price: $18.00

87015 (concentration)
Price: $20.00

87116 (culture)
Price: $38.00

87176 (tissue digestion)
Price: $12.00

Mycobacterium spp. **Identification by Nucleic Acid Probe/MALDI-TOF MS Identification**

Specimen Requirements: Isolates sent on LJ slants or in liquid media vials, or as reflex testing on positive primary specimens submitted for culture.

Transport Temperature: Ambient

Turn-around Time: 1 to 3 working days for submitted isolates, others dependent on growth rate.

NOTE: On initial isolation of an AFB from a new patient, both *M. tuberculosis* complex and *M. avium* complex probes will be run on the isolate. After *M. tuberculosis* complex has been confirmed in the patient, subsequent cultures received during the next six weeks will only be probed for *M. tuberculosis* complex.

CPT Codes:
87555 (*M. tuberculosis* probe*)*
87560 (*M. avium* probe)
87550 (*M. gordonae* probe)

Price: $35.00 each probe

83789 (MALDI-TOF MS Identification)
Price: 38.00 MALDI-TOF MS ID

***Mycobacterium tuberculosis* complex Antimicrobial Susceptibility Testing**

Specimen Requirements: Isolates sent on LJ slants or in liquid media vials, or primary specimens submitted for culture. Reflex testing is performed on *Mycobacterium tuberculosis* complex isolates identified in this laboratory.

Agents tested include Isoniazid, Rifampin, Ethambutol and PZA.

Transport Temperature: Ambient for isolates or liquid media vials; 2-8°C for primary specimens

Turn-around Time: 14 to 21 working days from date susceptibility testing is begun.

NOTE: Susceptibility testing for *M. tuberculosis* will be performed only on the first isolate from the patient and will be repeated as requested by the MT TB Program director. Other susceptibility testing including molecular drug susceptibility testing or second line drug testing is available upon consultation.

CPT Code:
None
Price: Fee Waived

***Mycobacterium tuberculosis* Nucleic Acid Amplification Testing (NAAT) with Rifampin resistance marker**

Specimen Requirements: Processed concentrated respiratory specimen or primary respiratory specimen. See *Mycobacterium spp.* (AFB or TB) Testing Collection and Transport instructions.

Transport Temperature: 2-8°C

Turn-around Time: 1 to 2 working days. *Call ahead to make testing arrangements.* Results are telephoned to the submitter.

NOTE: Nucleic acid amplification testing (NAAT) is recommended on specimens of patients highly suspected or known to have TB.

If NAAT is not ordered and an AFB smear is positive, the laboratory will contact the submitter to offer NAAT testing for *M. tuberculosis* complex.

CPT Code:
87556
Price: $107.00

Mycology Culture (see Fungal Culture)

N

***Neisseria gonorrhoeae* Culture Isolation/ Identification**

Specimen Requirements: Primary culture or pure culture isolate on MTM or chocolate media; identification performed by MALDI-TOF.

Transport Temperature: Ambient

Turn-around Time: 2 to 3 working days. Positive results are telephoned to the submitter.

NOTE: For public health surveillance, please submit all *N. gonorrhoeae* isolates to the laboratory. This is at no cost to the submitter (See Culture for Storage).

CPT Codes:

87081 (Culture screen)
Price: $38.00

87590 (ID)
Price: $38.00

87185 (Beta-lactamase)
Price: $9.00

***Neisseria gonorrhoeae* Direct Detection by Nucleic Acid Amplification**

Specimen Requirements: Endocervical or male urethral swab in APTIMA Uni-Sex Swab Specimen Collection Tube; throat, rectal, or vaginal swab in APTIMA Multitest Specimen Collection Tube; or urine in APTIMA Urine Specimen Collection Tube. See Chlamydia/Gonorrhea Amplified Testing Collection and Transport instructions.

Transport Temperature: 2-30°C

Turn-around Time: Routinely tested daily (Monday through Friday). Positive results are telephoned to the submitter.

NOTE: Can be run in tandem with *Chlamydia trachomatis* Direct Detection by Amplification (see Combination Amplification Test).

CPT Code:
87591
Price: $44.00

***Neisseria spp*. (including *N. meningitidis*) Culture Isolation /Identification/Typing**

Specimen Requirements: Primary specimen or pure culture isolate on chocolate media

Transport Temperature: Ambient

Turn-around Time: 2 to 4 working days. Positive *N. meningitidis* results are telephoned to the submitter.

NOTE: Serogrouping is routinely performed on *N. meningitidis* isolates from sterile body sites such as blood or cerebral spinal fluid. Please submit all *N. meningitidis* isolates from sterile body sites to the laboratory for serogrouping and storage for future epidemiologic purposes.

CPT Codes:
87081 (Culture screen)
Price: $38.00

87185 (Beta-lactamase)
Price: $9.00

Newborn Screening Panel

Specimen Requirements: Dried Blood Spots. See Newborn Screening Collection and Transport instructions.

Transport Temperature: Ambient

Turn-around Time: 3 to 5 working days. Abnormal results are telephoned to the submitter. Contact the laboratory for further information.

Total Price: $134.00

Screening Tests	CPT Code	Price
Acylcarnitine Disorders by Tandem Mass Spectrometry (MS/MS) * Fatty Acid Oxidation Disorders Carnitine Uptake Defect Long Chain L-3-Hydroxyacyl CoA Dehydrogenase Deficiency (LCHAD) Medium Chain Acyl-CoA Dehydrogenase Deficiency (MCAD) Trifunctional Protein Deficiency (TFP) Very Long Chain Acyl-CoA Dehydrogenase Deficiency (VLCAD) Organic Acidemia Disorders 3-OH 3-CH3 Glutaric Aciduria 3-Methylcrotonyl-CoA Carboxylase Deficiency β-ketothiolase Deficiency Glutaric Acidemia Type I Isovaleric Acidemia Methylmalonic Acidemia (Cbl A and B) Methylmalonic Acidemia (mutase deficiency) Multiple CoA Carboxylase Deficiency (MCD) Proprionic Acidemia	82017	$11.75
Amino Acid Disorders by Tandem Mass Spectrometry (MS/MS) * Argininosuccinic acidemia Citrullinemia Homocystinuria (due to CBS deficiency) Maple syrup urine disease Tyrosinemia type I	82136	$4.65
Biotinidase*	82261	$6.00
Classic Galactosemia	82775	$28.90
Congenital Adrenal Hyperplasia (CAH)* 21 hydroxylase deficiency	83498	$11.50
Congenital Hypothyroidism (CH) Thyroxine (T4) testing, TSH reflex testing	84437 (T4) 84443 (TSH)	$20.41 $23.05
Cystic Fibrosis (IRT) Confirmatory DNA Mutational Analysis* as warranted	83516	$15.97
Phenylketonuria (PKU)	84030	$19.06

Hemoglobinopathies by Isoelectric Focusing Hb **S/B**-thalassemia Hb **SC** disease Hb **SS** disease (Sickle cell anemia) HPLC reflex testing*	83020 87143 (HGB Confirmation)	$17.66 $12.00
Severe Combined Immunodeficiency (SCID Immunodeficiency: TREC) *	TBD	$6.00

* Tests referred to the Wisconsin State Newborn Screening Laboratory

The cost of reflex confirmatory testing (TSH, Hemoglobinopathies by HPLC and Cystic Fibrosis DNA Mutational Analysis) has been incorporated into the cost of the Newborn Screening panel, and no additional charges will be assessed.

Norovirus Direct Detection by Nucleic Acid Amplification

Specimen Requirements: 2 mL stool in a sterile container. See Molecular (Nucleic Acid Amplification) Testing Collection and Transport instructions.

Transport Temperature: 2-8°C

Turn-around Time: 1 to 3 working days. Positive results are telephoned to the submitter.

CPT Code:
87798
Price: $107.00

O

Orthopoxvirus, including Variola (Smallpox), Direct Detection by Real Time PCR

Specimen Requirements: Lesion swab in Universal Viral Transport Media plus an additional lesion swab transported dry in a sterile container.

NOTE: Contact your local health department or the State Epidemiology Department (406-444-0273) to ensure the patient meets criteria for testing. Please contact the Montana Public Health Laboratory prior to submission regarding sample collection and transport instructions.

A suspect Orthopoxvirus requires Category A Infectious Disease packaging (Class 6.2) and trackable shipping. Please notify the laboratory by telephone at time of shipment.

Transport Temperature: 2-8°C

Turn-around Time: 1 to 3 working days. Results are telephoned to the submitter.

CPT Code:
87798
Price: Fee Waived

Orthopoxvirus, Other Than Variola, Direct Detection by Real Time PCR

Specimen Requirements: Lesion swab in Universal Viral Transport Media plus an additional lesion swab transported dry in a sterile container. See Molecular (Nucleic Acid Amplification) Testing Collection and Transport instructions.

Transport Temperature: 2-8°C

Turn-around Time: 1 to 3 working days. Results are telephoned to the submitter.

CPT Code:
87798
Price: Fee Waived

Ova and Parasite Exam

Specimen Requirements: Stool transported in a vial of Total-Fix preservative. Collect stool into a clean specimen container. Using the spoon inside the transport vial, immediately transfer stool to the vial until the liquid level reaches the red fill line. Stool should be emulsified into the transport media with the spoon. Recap the vial tightly and shake the vial until the contents are well mixed. Total-Fix transport kits are available from the laboratory upon request.

For optimal recovery, a series of three (3) specimens should be submitted.

Transport Temperature: Ambient

Turn-around Time: 1 to 2 working days. Positive results are telephoned to the submitter.

CPT Codes:
87177 (concentration/ID)
87209 (Trichrome stain)

Price: $27.00 (each)
Total Price: $54.00

P

Parasite Detection (see Ova and Parasite Exam)

Paratyphoid Fever (see *Salmonella spp.*)

Pasteurella spp. Culture Isolation/ Identification (see Bacterial Culture, Aerobic)

Pertussis (see *Bordetella pertussis*)

Phenylalanine (PKU) Monitor by Fluorescent Immunoassay

Used to monitor levels in patients diagnosed with phenylketonuria (PKU) only.

Specimen Requirements: Dried Blood Spots. See Newborn Screening Collection and Transport instructions.

Transport Temperature: Ambient

Turn-around Time: 1 to 2 working days.

CPT Code:
84030
Price: Fee Waived. Phone the laboratory for more information 1-406-444-2930.

Pinworm Examination (*Enterobius vermicularis*)

Specimen Requirements: Microscopic identification of eggs collected in the perianal area is the method of choice for

diagnosing enterobiasis. In the morning, before defecation and washing, press transparent adhesive tape ("Scotch test") on the perianal skin and then place the tape sticky side down on a slide. Alternatively, the tape can be attached to the glass slide in a loop, and then folded over the glass surface after application to the perianal skin.

Transport Temperature: Ambient

Turn-around Time: 1 to 2 working days. Positive results are telephoned to the submitter.

CPT Code:
87172 (concentration/ID)
Price: $27.00

Plague (see *Yersinia pestis* Culture Isolation)

***Plasmodium* Detection (see Blood Parasite Screen)**

Pneumococcal Infection (see *Streptococcus pneumoniae*)

***Pseudomonas spp*. Culture Isolation/ Identification (see Bacterial Culture, Aerobic)**

Q

Q-Fever (*Coxiella burnetii*) Phase 1 and 2 IgG Serology by Indirect Immunofluorescence
Specimen Requirements: 1 mL serum; Paired acute and convalescent serum specimens are recommended.

Transport Temperature: 2-30°C (Refrigeration preferable)

Turn-around Time: Routinely batch tested once per week.

CPT Code:
86638
Price: $25.00

QuantiFERON – Gold (QFT – Gold) In-Tube Testing
Specimen Requirements: Stimulated plasma, obtained from vacutainer tubes specifically coated with antigens. Requires access to a 37°C incubator. See QuantiFERON®-TB Gold In-Tube Testing Collection and Transport instructions.

Transport Temperature: Ambient

Turn-around Time: Routinely batch tested twice a week.

CPT Code:
86480 (Single Test)
Price: $90.00

R

Rabies Detection for Diagnostic Purposes (Animal Testing)
Animal testing is not performed by our laboratory.

Refer specimens to the Veterinary Diagnostic Laboratory in Bozeman, (406) 994-4885

Rabies Detection for Diagnostic Purposes (Human Testing)

Human Testing for Diagnostic Purposes: *Consult with the Epidemiology Section (406) 444-0273 for pre-approval prior to testing. Consult the laboratory for specific sampling requirements and proper handling and transport.*

Human Diagnostic Testing is referred to the Centers for Disease Control, Atlanta, Georgia.

Transport Temperature: Call for instructions
Turn-around Time: Preliminary results (PCR) are available as soon as possible, usually the same day as receipt.

CPT Code:
None
Price: Fee Waived

Rabies Serology for Immune Status Antibody Testing by RFFIT

Testing not available through this laboratory

Testing available from
Atlanta Health Associates, Alpharetta, Georgia (770) 667-8023
http://www.atlantahealth.net

Kansas State University, Manhattan, KS (785) 532-4483
http://www.ksvdl.org/rabies-laboratory/rffit-test/

Rapid Toxic Screen, (for Chemical Exposure)

Consult with the Epidemiology Section (406) 444-0273 for pre-approval prior to testing. Arrangements must be made with the laboratory regarding proper collection, packaging, and transport of blood and urine specimens.

Transport Temperature: 2-8°C for whole blood, -70°C for urine (call for instructions)

Referred to the Centers for Disease Control, Atlanta, Georgia

Turn-around Time: 36 hours

CPT Code:
None
Price: Fee Waived

Retail Meat Testing (*E. coli*)

Specimen Requirements: 325g minimum of ground beef or beef trim, and 400ml poultry rinse samples. **Must be received within 24 hours of collection**.

Transport Temperature: 2-8°C within 24 hours

Turn-around Time: 2 to 3 working days for negative samples; up to 5 days for a positive sample. Positive results are telephoned to the submitter.

CPT Code:
None

Price: $70.00

Retail Meat Testing (*Listeria*)

Specimen Requirements: 25g minimum of ground beef, poultry, or ready-to-eat meat samples, and environmental swabs or sponges. **Must be received within 24 hours of collection**. **Ready-to-eat samples should be submitted by Wednesday;** samples submitted on Thursday or Friday will not be processed until the following Monday.

Transport Temperature: 2-8°C within 24 hours

Turn-around Time: 2 to 3 working days for negative samples; up to 5 days for a positive sample. Positive results are telephoned to the submitter.

CPT Code:
None
Price: $75.00

Retail Meat Testing (*Salmonella*)

Specimen Requirements: 25g minimum of ground beef or beef trim, 325g minimum of ready-to-eat meats, 50 ml whole-bird poultry rinse, carcass sponges and environmental swabs. **Must be received within 24 hours of collection**.

Transport Temperature: 2-8°C within 24 hours

Turn-around Time: 2 to 3 working days for negative samples; up to 5 days for a positive sample. Positive results are telephoned to the submitter.

CPT Code:
None
Price: $70.00

Ricin Rapid Tests

Specimen Requirements: Environmental samples only

NOTE: Contact your local health department or the State Epidemiology Department (406-444-0273) to ensure the sample meets criteria for testing. Please contact the Montana Public Health Laboratory prior to submission regarding sample collection and transport instructions.

Transport Temperature: Ambient

Turn-around Time: 1 to 3 working days. Results are telephoned to the submitter.

CPT Code:
None
Price: Fee Waived

Rickettsial Serology (see Rocky Mountain Spotted Fever, Typhus Fever Serology)

***Rochalimea spp*. Serology (see *Bartonella* Serology)**

Rocky Mountain Spotted Fever (RMSF)

Specimen Requirements: 1 mL serum; Paired acute and convalescent serum recommended.

Transport Temperature: 2-30°C (Refrigeration preferable)

Turn-around Time: Routinely batch tested once per week. Positive results are telephoned to the submitter.

NOTE: Colorado Tick Fever testing will be automatically performed on all requests for Rocky Mountain Spotted Fever.

CPT Codes:
86757 (RMSF)
Price $25.00

86790 (CTFV)
Price: $30.00

Total Price: $55.00

Rubella IgG Serology by EIA

Specimen Requirements: 1 mL serum; Screen or paired acute and convalescent specimens

Transport Temperature: 2-30°C (Refrigeration preferable)

Turn-around Time: Routinely batch tested once per week.

CPT Code:
86762
Price: $25.00

Rubella IgM Serology by EIA

Specimen Requirements: 1 mL serum; Collect acute phase serum only and include an immunization history.

Collect specimen at least two (2) days after onset of rash and include date of onset.

Transport Temperature: Frozen

Turn-around Time: Testing performed at North Dakota Public Health Laboratory as needed. Results are available within 2-3 days.

CPT Code:
86762
Price: $39.00

Rubeola (Measles) Direct Detection by Real Time PCR

Specimen Requirements: Throat, nasopharyngeal or nasal Dacron swabs in viral transport media and/or 50 ml minimum of urine.

Urine should be centrifuged 2500xg for 15 min at 4° C. Resuspend sediment in 2 ml viral transport media. Swabs are the preferred specimen.
CSF may be submitted in meningitis/encephalitis-suspect cases with prior consult

Note: Collect specimens as soon after the rash as possible. Detection is optimum with a collection the day one (1) through 3 (three) of rash onset.

Transport Temperature: 2-8° C within 24 hours or freeze at -70° C and transport on dry ice.

Turn-around Time: 1 to 2 working days. Positive results are telephoned to the submitter.

CPT Code:
87798
Price: $107.00

Rubeola (Measles) IgG Serology by EIA

Specimen Requirements: 1 mL serum; Screen or paired acute and convalescent specimens.

Transport Temperature: 2-30°C (Refrigeration preferable)

Turn-around Time: Routinely batch tested once per week. Significant results are telephoned to the submitter.

CPT Code:
86765
Price: $25.00

Rubeola (Measles) IgM Serology

Specimen Requirements: 1 mL serum; Collect specimen at least two (2) days after onset of rash and include date of onset.

Transport Temperature: Frozen

Turn-around Time: Testing performed at North Dakota Public Health Laboratory as needed. Results are available within 2-3 days. Results are telephoned to the submitter.

CPT Code:
86765
Price: $30.00

S

Salmonella spp. (including *S. typhi*) Culture Isolation/Identification

Specimen Requirements: Stool in Cary-Blair transport or other commercial enteric transport media, or pure culture isolate in Cary Blair transport or on solid media. See Enteric Panel for specific instructions.

Biochemically confirmed *Salmonella spp.* will be serotyped for epidemiologic purposes at no additional cost.

For public health surveillance, please submit all isolates of *Salmonella spp.* to the laboratory. See Enteric Isolate Surveillance.

Transport Temperature: 2-8°C for stool, ambient for isolates

Turn-around Time: 2 to 4 working days. Positive identification results of primary cultures or test of cure cultures are telephoned to the submitter.

CPT Codes:
87045 (Culture ID)
Price: $18.00

87077 (Each add'l ID)
Price: $25.00

Shigella spp. **Culture Isolation/ Identification**

Specimen Requirements: Stool in Cary-Blair Transport or other commercial enteric transport media, or pure culture isolate in Cary Blair transport or on solid media. See Enteric Panel for specific instructions.

For public health surveillance, please submit all isolates of *Shigella spp.* to the laboratory. See Enteric Isolate Surveillance.

Transport Temperature: 2-8°C for stool, ambient for isolates

Turn-around Time: 2 to 4 working days. Positive results of primary cultures or test of cure cultures are telephoned to the submitter.

CPT Codes:
87045 (Culture ID)
Price: $18.00

87077 (Each add'l ID)
Price: $25.00

Sporothrix **Culture Isolation/ Identification** **(see Fungal Culture)**

Staphylococcus **spp. Culture Isolation/ Identification** **(see Bacterial Culture, Aerobic)**

STEC (see *Escherichia coli* Shiga-Like Toxin Assay or Enteric Panel)

Stool Culture (see Enteric Panel)

Streptococcus pneumoniae **Culture Isolation/ ID** **(see Bacterial Culture, Aerobic)**

Streptococcus spp**. Culture Isolation/ Identification** **(see Bacterial Culture, Aerobic)**

Strongyloides **Detection** **(see Ova and Parasite Exam)**

Strongyloides **Serology**

Specimen Requirements: 2 mL serum or plasma

Transport Temperature: 4-8°C

Referred to the Centers for Disease Control, Atlanta, Georgia

Turn-around Time: 18 days

CPT Code:
86317
Price: $30.00

Syphilis IgG Antibody Screen - Serum

Specimen Requirements: 2 mL serum

Transport Temperature: 2-30°C

Turn-around Time: Routinely batch tested twice per week. Positive results are reflexed to a quantitative Syphilis VDRL Titer Monitor. A positive IgG Antibody screen with a negative Syphilis VDRL Titer Monitor result is reflexed to a *Treponema pallidum* Particle Agglutination Assay.

CPT Code:
86592
Price: $16.00

Syphilis VDRL Titer Monitor - Serum

This test is for testing known positive Syphilis patients who are currently or recently have received treatment.

Specimen Requirements: 2 mL serum

Transport Temperature: 2-30°C

Turn-around Time: Routinely batch tested twice per week.

CPT Code:
86593
Price: $16.00

Syphilis Serology Screen - CSF (Qualitative) by VDRL

Specimen Requirements: 1 mL CSF

Transport Temperature: 2-30°C (Refrigeration preferable)

Turn-around Time: Routinely batch tested twice per week. Positive results are reflexed to quantitative VDRL.

CPT Code:
86592
Price: $15.50

Syphilis Serology Screen - CSF (Quantitative) by VDRL

Specimen Requirements: 1 mL CSF

Transport Temperature: 2-30°C (Refrigeration preferable)

Turn-around Time: Routinely batch tested twice per week. Significant results are telephoned to the submitter.

NOTE: Reflex confirmatory TP-PA testing is performed on all positive serum VDRL specimens.

CPT Code:
86593
Price $16.00

T

Tick-borne Disease IgG Serology Panel by IFA, Bacterial Agglutination

Includes RMSF, CTFV, Q-Fever, Tularemia and Brucella antibodies. The panel can be ordered with or without Lyme Disease antibodies.

Specimen Requirements: 3 mL serum; Paired acute and convalescent serum recommended.

Transport Temperature: 2-30°C (Refrigeration preferable)

Turn-around Time: Routinely batch tested once per week. Positive results are telephoned to the submitter. These tests may be ordered as a panel but will be billed individually.

Note: Although not a tick-borne disease, Brucella testing is performed on all requests for Tularemia due to antigen cross reactivity.

CPT Codes:
86622 (Brucella)
86757 (RMSF)
86790 (CTFV)
86638 (Q-Fever)
86668 (Tularemia)

Total Price: $125.00

86618 Lyme Screen
Total Price w/Lyme: $165.00

Tick-borne Relapsing Fever (see *Borrelia hermsii* Serology)

Treponema pallidum Particle Agglutination Assay

This test is not available as a stand-alone test to be ordered. Please refer to the Syphilis IgG Antibody Screen – Serum for the testing algorithm.

Specimen Requirements: 2 mL serum

Transport Temperature: 2-30°C (Refrigeration preferable)

Turn-around Time: Routinely batch tested once per week. Positive results are telephoned to the submitter.

CPT Code:
86780
Price: $38.00

Trypanosomiasis Detection (including *Trypanosoma cruzi* / Chagas Disease) (see Blood Parasite Screen)

Tuberculosis (See *Mycobacterium spp.*)

Tularemia Culture (See *Francisella tularensis* culture)

Tularemia Serology (See *Francisella tularensis* serology)

Typhoid Fever (see Enteric Panel or *Salmonella spp.*)

Typhus Fever IgG Serology by Indirect Immunofluorescence

Specimen Requirements: 2 mL serum; Paired acute and convalescent serum specimens are recommended.

Transport Temperature: 2-30°C (Refrigeration preferable)

Referred to the Centers for Disease Control, Atlanta, Georgia

Turn-around Time: 3 to 6 weeks

CPT Code:
86256
Price: $30.00

U

V

Vancomycin Resistant Enterococci (VRE) (see Antimicrobial Resistant Bacteria Confirmation)

Vancomycin Intermediate/ Resistant Staphylococcus aureus (see Antimicrobial Resistant Bacteria Confirmation)

Varicella Zoster Virus (VZV) (Herpes Zoster Virus) Direct Detection by Real Time PCR

Specimen Requirements: Vesicular lesion swab in Universal Viral Transport Media. See Molecular (Nucleic Acid Amplification) Testing Collection and Transport instructions.

Transport Temperature: 2-8°C

Turn-around Time: 1 to 3 working days. Positive results are telephoned to the submitter.

CPT Code:
87798
Price: $107.00

Varicella Zoster Virus (VZV) (Herpes Zoster Virus) IgG Serology by EIA

Specimen Requirements: 1 mL serum; Screen or paired acute and convalescent specimens.

Transport Temperature: 2-30°C (Refrigeration preferable)

Turn-around Time: Routinely batch tested once per week; available each working day, as needed. Significant and STAT results are telephoned to the submitter.

CPT Code:
86787
Price: $25.00

VDRL Serology (see Syphilis VDRL Titer Monitor or Syphilis Serology Screen-CSF)

***Vibrio spp.* Culture Isolation/ Identification**

Specimen Requirements: Stool in Cary-Blair transport or other commercial enteric transport media, or pure culture isolate submitted in Cary-Blair transport or on solid media. Specify species on request form.

Transport Temperature: 2-8°C for stool, ambient for isolates

Turn-around Time: 2 to 4 working days. Positive results are telephoned to the submitter.

CPT Codes:
87046 (Culture ID)
Price: $18.00

87077 (Each add'l ID)
Price: $25.00

W

West Nile Virus (WNV) IgG Serology by EIA

Specimen Requirements: 1 mL serum. Paired acute and convalescent specimens recommended.
Date of onset is required, and the city or county of patient's residence is requested.

Transport Temperature: 2-30°C (Refrigeration preferable)

Turn-around Time: Routinely batch tested once per week; during seasonal outbreaks, testing may be performed each working day, depending on workload. Positive results are telephoned to the submitter.

CPT Code:
86789
Price: $25.00

West Nile Virus (WNV) IgM Serology by EIA

NOTE: Serology is the recommended method of testing for WNV in both serum and cerebral spinal fluid (CSF), because viremia (as detected by PCR) is very transient.

Specimen Requirements: 1 mL serum and/or 1 mL CSF
Date of onset is required, and the city or county of patient's residence is requested.

NOTE: Negative results on specimens drawn less than 9 days from date of onset should have a convalescent serum tested if active disease is suspected.

Transport Temperature: 2-30°C (Refrigeration preferable)

Turn-around Time: Routinely batch tested once per week; during seasonal outbreaks, testing may be performed each working day, depending on workload. Positive results are telephoned to the submitter. Certain specimens may be referred to the Centers for Disease Control in Fort Collins, Colorado for confirmation using more specific Plaque Reduction Neutralization tests, and equivocal (borderline) results may be reflexed to St. Louis Encephalitis IgM Serology.

CPT Code:
86788
Price: $25.00

X

Y

Yeast Culture (see Fungal Culture)

Yersinia enterocolitica Culture Isolation/Identification

Specimen Requirements: Stool in Cary-Blair transport or other commercial enteric transport media, or pure culture isolate submitted in Cary-Blair transport or on solid media.

Transport Temperature: 2-8°C for stool, ambient for isolates

Turn-around Time: 2 to 4 working days. Positive results are telephoned to the submitter.

CPT Codes:
87046 (Culture ID)
Price: $18.00

87077 (Each add'l ID)
Price: $25.00

Yersinia pestis Culture Isolation/ Identification/Rapid Test Methods

Specimen Requirements: Pure culture isolate submitted on solid medium or clinical respiratory specimens transported cold in sterile saline.

Note: A suspected Y. pestis *culture requires Category A Infectious Disease packaging (Class 6.2) and trackable shipping. Please notify the laboratory by telephone at time of shipment.*

Please contact the laboratory prior to submission regarding environmental samples, rapid test methods, and transport instructions.

Transport Temperature: 2-8°C for tissue, ambient for isolates

Turn-around Time: Cultures will be held for five (5) working days before reporting as negative. Results are telephoned as soon as possible to the submitter. Rapid test methods are performed in Molecular Diagnostics and are available within 6 - 8 hours of specimen receipt.

CPT Codes:

87081 (Culture screen)
Price: Fee Waived

87798 (PCR)
Price: Fee Waived

***Yersinia pestis* Serology by Passive Hemagglutination**

Specimen Requirements: 2 mL serum

Referred to the Centers for Disease Control, Fort Collins, Colorado

Transport Temperature: 2-30°C (Refrigeration preferable)
Turn-around Time: 4 to 6 weeks

CPT Code:
86793
Price: $30.00

Z

Zika Virus Testing by CDC Trioplex Real-Time PCR Assay

This PCR assay detects Zika, Chikungunya, and Dengue Virus

Specimen Requirements: Serum only **or** serum and urine. **Urine must be submitted with serum.**
*Serum should be collected within <= 14 days of symptom onset in a separator (gold or tiger top tube) or decanted into a sterile screw-capped vial **(labeled "serum")** and secured with parafilm
*1 ml **aliquot** of urine poured off into a sterile screw-capped vial **(labeled "urine")** and secured with parafilm. **Do not submit urine in its original collection container (i.e. urine cup)**

Additional specimen types that are accepted **with a consult** include CSF and amniotic fluid.

Transport Temperature: Store at 4°C and ship in a biohazard bag with cold packs within 48 hours of collection.

Turn-around Time: Specimens are tested on the day of arrival and reported within 24 hours

CPT Code:
Urine and Serum:
Price: $175.00

Serum only:
Price: $107.00

Collection and Transport of Specimens

Chlamydia/Gonorrhea Amplified Testing Collection and Transport

The Unisex Swab Specimen Collection Kit, Multitest Swab Specimen Collection Kit, and Urine Specimen Collection Kit are stored at room temperature.

Eye Swab Collection

1. **Use the Unisex Swab Specimen Collection Kit (white label) or Viral Transport Medium.**
2. Gently rotate the blue-shafted collection swab clockwise across the surface of the eye to ensure adequate sampling.
3. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
4. Carefully break the blue swab shaft at the score line; use care to avoid splashing of contents.
5. Re-cap the swab specimen transport tube tightly.
6. Specimens should be clearly labeled with two patient identifiers (name, DOB, medical record number, etc.) and the collection date.

Endocervical Swab Collection

1. **Use the Unisex Swab Specimen Collection Kit (white label).**
2. Remove excess mucus from the cervical os and surrounding mucosa using the white shafted cleansing swab. Discard the white shafted swab.
3. Insert the blue-shafted specimen collection swab into the endocervical canal.
4. Gently rotate the swab clockwise for 10 to 30 seconds in the endocervical canal to ensure adequate sampling.
5. Withdraw the swab carefully; avoid any contact with the vaginal mucosa.
6. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
7. Carefully break the blue swab shaft at the score line; use care to avoid splashing of contents.
8. Re-cap the swab specimen transport tube tightly.
9. Specimens should be clearly labeled with two patient identifiers (name, DOB, medical record number, etc.) and the collection date.

Vaginal Swab Collection

1. **Use the Multitest Swab Specimen Collection Kit (orange label).**
2. Patient can collect own specimen in a health care facility. Vaginal swab collection is preferred over urine collection in women when a pelvic examination is not performed.
3. Insert the specimen collection swab into the vagina about two inches inside the opening of the vagina.
4. Gently rotate the swab clockwise for 10 to 30 seconds touching the walls of the vaginal to ensure adequate sampling.
5. Withdraw the swab carefully; avoid any contact with skin.
6. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
7. Carefully break the swab shaft at the score line; use care to avoid splashing of contents.
8. Re-cap the swab specimen transport tube tightly.
9. Specimens should be clearly labeled with two patient identifiers (name, DOB, medical record number, etc.) and the collection date.

Male Urethral Swab Collection

1. **Use the Unisex Swab Specimen Collection Kit (white label).**
2. The patient should not have urinated for at least one hour prior to sample collection.
3. Insert the blue-shafted specimen collection swab 2 – 4 cm into the urethra.
4. Gently rotate the swab clockwise for 2 to 3 seconds in the urethra to ensure adequate sampling.

5. Withdraw the swab carefully.
6. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
7. Carefully break the blue swab shaft at the score line; use care to avoid splashing of contents.
8. Re-cap the swab specimen transport tube tightly.
9. Specimens should be clearly labeled with two patient identifiers (name, DOB, medical record number, etc.) and the collection date.

Penile Meatal Swab Collection

1. **Use the Multitest Swab Specimen Collection Kit (orange label).**
2. Use the small blue-shafted collection swab, **not the larger white shafted cleansing swab**.
3. For uncircumcised males roll the foreskin down before staring collection.
4. Roll the swab on the tip of the penis, outside the opening of the urethra, ensuring to roll the swab all the way around the opening to obtain the best sample.
5. Withdraw the swab carefully without touching any other area of the skin.
6. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
7. Carefully break the blue swab shaft at the score line; use care to avoid splashing of contents.
8. Re-cap the swab specimen transport tube tightly.
9. Specimens should be clearly labeled with two patient identifiers (name, DOB, medical record number, etc.) and the collection date.

Rectal Swab Collection

1. **Use the Multitest Swab Specimen Collection Kit (orange label).**
2. Use the small blue-shafted collection swab, **not the larger white shafted cleansing swab**.
3. Insert the small blue-shafted collection swab approximately 3 – 5 cm into the rectum and rotate against the rectal wall several times (at least 3 times).
4. Swabs that are grossly contaminated with feces should be discarded and the collection repeated.
5. Withdraw the swab carefully without touching the skin.
6. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
7. Carefully break the blue swab shaft at the score line; use care to avoid splashing of contents.
8. Re-cap the swab specimen transport tube tightly.
9. Specimens should be clearly labeled with two patient identifiers (name, DOB, medical record number, etc.) and the collection date.

Throat Swab Collection

1. **Use the Multitest Swab Specimen Collection Kit (orange label).**
2. Use the small blue-shafted collection swab, **not the larger white shafted cleansing swab.**
3. Using a tongue depressor, insert the small blue shafted collection swab and vigorously rub the tonsils and the posterior pharynx.
4. Carefully remove the swab, not touching any area of the mouth.
5. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube.
6. Carefully break the blue swab shaft at the score line; use care to avoid splashing of contents.
7. Re-cap the swab specimen transport tube tightly.
8. Specimens should be clearly labeled with two patient identifiers (name, DOB, medical record number, etc.) and the collection date.
9. Complete the requisition form; be sure to record the specimen source.

Urine Collection

1. **Use the Urine Specimen Collection Kit (yellow label).**
2. The patient should not have urinated for at least one hour prior to sampling.
3. Direct patient to provide a first-catch urine (approximately 20 to 30 mL of the initial urine stream) into a urine collection cup. Collection of larger volumes of urine may reduce test sensitivity. Female patients should not cleanse the labial area prior to providing the specimen. This is NOT a clean-catch urine – we want the initial urine stream, which contains sloughed cells.
4. Remove the cap and transfer 2 mL of urine into the urine specimen transport tube using the disposable pipette provided. The correct volume of urine has been added when the fluid level is between the black lines on the urine specimen transport tube label.
5. Re-cap the urine specimen transport tube tightly. This is now known as the processed urine specimen.
6. Specimens should be clearly labeled with two patient identifiers (name, DOB, medical record number, etc.) and the collection date.

Swab and Urine Specimen Transport

After collection, ensure that specimens are properly labeled.
Fill out the Public Health Laboratory Request Form.
Place the corresponding transport tube in an individual zip lock bag containing absorbent material and seal the bag tightly. Place the form in the sleeve of the zip lock bag; DO NOT put the request form inside the zip lock bag.
Store swab specimen transport tubes and processed urine specimens (those in urine specimen transport tubes) at 2°C to 30°C. Place transport tubes in white mailing canisters and send to the laboratory by mail or courier.

NOTE: Although swab specimens in the specimen transport tube must be tested within 60 days of collection and urine specimens in the specimen transport tube must be tested within 30 days of collection, we advise you to submit specimens in a timely manner so that test results can be obtained as soon as possible.

Utilize the MTPHL courier service if available, or ship specimens to the following address:
Montana Public Health Laboratory
(Street Address)
1400 Broadway
Helena, MT 59601

Or

PO Box 4369
Helena, MT 59604-4369

Result Reporting

Positive results are telephoned to the provider; additionally, positive GC results are notified electronically to the DPHHS STD Program.

Specimen Rejection

Specimens with unresolved labeling issues, leaking containers, expired containers, or with insufficient volume may be rejected. The provider will be notified and asked to resubmit.

Requests for Additional Information or Specimen Collection Questions:

For additional information or questions, or to order collection kits, contact the laboratory at 800-821-7284 or 406-444-3444.

Molecular (Nucleic Acid Amplification) Testing Collection and Transport

For technical assistance in determining proper specimen selection for specific agents, call the laboratory at 800-821-7284.

Universal Viral Transport Media for Viral Agents is supplied by the laboratory. Store the kits at room temperature.

Specimen Type	Instructions
Bronchial Alveolar Lavage (BAL) /Bronchial Washings	For Viral Agents, mix an equal portion of the BAL with Universal Viral Transport Media. Store in cold conditions and ship on cold packs. For Bacterial Agents, collect in sterile container. Store in cold conditions and ship on cold packs.
Cerebral Spinal Fluid (CSF)	Place 1 – 2 mL in sterile container **without viral transport media**. Store in cold conditions and ship on cold packs.
Lesion swab (HSV)	Use the Aptima Multitest Swab Specimen Collection Kit (orange label). If needed, expose the base of the lesion to access fluid. Vigorously swab the base of the lesion to absorb fluid, being careful not to draw blood. Withdraw the swab without touching any other site outside the lesion. Remove the cap from the swab specimen transport tube and immediately place the specimen collection swab into the transport tube. Carefully break the swab shaft at the score line; use care to avoid splashing of contents. Re-cap the swab specimen transport tube tightly. *Store and transport at ambient temperature.*
Nasopharyngeal Aspirate	Introduce 1-2 mL of sterile saline into the nasopharyngeal cavity, aspirate into sterile vial. Store in cold conditions and ship on cold packs. ***Note: If the specimen is also being submitted for viral agents, please submit in Universal Viral Transport Media. Store in cold conditions and ship on cold packs.*
Nasopharyngeal Wash	Use only sterile saline to collect the NP wash. Instruct the patient to sit with head slightly tilted backwards, and to hold the sterile collection cup. Instruct the patient on how to constrict the muscles at the back of the throat by saying the "K" sound rapidly and repetitively. Inform the patient that this process may prevent the saline from draining down the throat. Fill a 5-cc syringe with warm sterile saline. Gently push the tip of the patient's nose back with your thumb, and quickly inject 1 – 2 mL of sterile saline into each nostril. Instruct the patient to contain the saline in the nostrils for approximately 10 seconds while repetitively saying the "K" sound. After 10 seconds, ask the patient to tilt their head forward and collect the saline in the sterile cup. Cap the washings tightly. Refrigerate the nasopharyngeal washings until transport and ship on cold packs. *Store in cold conditions and ship on cold packs.*
Nasopharyngeal Swab	Use a flexible wire Dacron or polyester swab. Do not use Calcium Alginate swabs or swabs with wooden shafts. Instruct the patient to sit with head slightly tilted backwards. Bend the flexible wire in a small arc and insert the swab into the nostril back to the nasopharyngeal cavity. The patient's eyes will momentarily tear. Slowly rotate the swab as it is being withdrawn. For Viral Agents, place swab into Universal Viral Transport Media, trim swab shaft, and tightly cap. Store in cold conditions and ship on cold packs. For Pertussis and other Bacterial Agents, place swab in sterile tube without transport.

Rectal swabs (for CRE)	Collection of paired rectal swab: Carefully insert both swab tips approximately one (1) cm beyond the anal sphincter and rotate gently. Do not collect highly soiled swabs. Place swab pair back in original transport tube. Swabs in the transport tube can be stored at 15-28°C for up to five days and transported at ambient temperature.
Serum	Collect 5-10 mL of whole blood in serum separator tube. Allow blood to clot, centrifuge and aliquot resulting sera. Store in cold conditions and ship on cold packs. If serum has already been frozen, ship on dry ice.
Stool	Collect at least 2 mL of stool in a leak-proof, clean, dry container. Do not add transport media. Store in cold conditions and ship on cold packs.
Throat Swab	Use a plastic-shafted Dacron swab. Do not use Calcium Alginate swabs or swabs with wooden shafts. Using a tongue depressor, insert the swab and vigorously rub the tonsils and the posterior pharynx. Carefully remove the swab, not touching any area of the mouth. For Viral Agents, place swab into Universal Viral Transport Media, trim swab shaft, and tightly cap. Store in cold conditions and ship on cold packs. For Bacterial Agents, place swab in sterile tube without transport.
Tissue Specimens Autopsy or Biopsy	For Viral Agents, place each specimen in separate sterile containers containing small amounts of Universal Viral Transport Media. Store and ship on cold packs or dry ice. *Do Not submit formalized tissue.* For Bacterial Agents, place each specimen in separate sterile containers containing small amounts of sterile saline or PBS. Store and ship on cold packs. *Do Not submit formalized tissue.*
Vesicles/Vesicular Fluid/ Scrapings	Aspirate fluid from multiple fresh unbroken vesicles and place into 1-2 mL of Universal Viral Transport Media. Remove the top of the vesicle and place the skin of the vesicle top into a sterile tube without transport. Store both samples in cold conditions and ship on cold packs.
Whole Blood	Collect 5 -10 mL whole blood in EDTA anticoagulant. Store in cold conditions and ship on cold packs.

Specimens should be clearly labeled with two patient identifiers (name, DOB, medical record number, etc.), collection date and specimen source. Place each specimen container in an individual biohazard zip lock bag containing absorbent material and seal bag tightly.

Fill out the Public Health Laboratory Request Form completely and place in the outer sleeve of the biohazard zip lock bag. Do not place the request form inside the biohazard zip lock bag.

Ship specimens promptly, maintaining cold temperature from collection until receipt at the laboratory. For those specimens that must be shipped in a cold condition, use cold packs and Styrofoam containers. Mailers will be returned for reuse. Transport by UPS, FedEx, mail or courier.

Mycobacterium spp. (AFB or TB) Testing Collection and Transport

All specimens are potentially infectious; handle carefully.

Specimen Type	Instructions
Sputum or Nebulized Sputum	Collect three early morning specimens on successive days (within 72 hours) and **submit daily** in separate containers. Good specimens are material brought up by the lungs after a productive cough or nebulization. Send a minimum of 5 mL in a sterile container.
Urine	Collect multiple first morning "clean catch" specimens on three successive days. Send a minimum of 40 mL in a sterile container.
Gastric	Collect three early morning fasting specimens on successive days. Send a minimum of 10 mL in a sterile container. Add 10 mg of sodium bicarbonate to neutralize the acidity. Send promptly after collection; these specimens should be processed as soon as possible.
Bronchial Washings	Submit first sputum specimen following bronchoscopy as well as the bronchial washings. Send a minimum of 5 mL in a sterile container.
Tissues	Collect aseptically and place in sterile container. Add 1 mL sterile broth or sterile saline to tissues to prevent dehydration.
CSF or Other Sterile Body Fluids	Submit in a sterile collection tube; at least 2 mL is needed for an adequate test.
Blood or Bone Marrow	Collect in heparinized tube or add sterile heparin (0.2 mg/mL) to prevent clotting. Send a minimum of 1 mL in a sterile container.
Stool	Submit 1 gram of raw stool in a sterile container. Send on ice.
Swab **(Not Optimal)**	Specimens submitted on swabs are **highly discouraged**. Please make every effort to submit tissue or aspirated fluid, as these are preferred sources. If swabs are submitted, add 1 ml of sterile saline or sterile broth to the swab to prevent dehydration.

Use only sterile materials in the collection of the specimen. Collect the specimen directly into the sterile bottle provided or into a sterile container. Screw the lid onto the specimen container tightly so specimen does not leak. Place each specimen container in an individual biohazard zip lock bag containing absorbent material and seal the bag tightly. Specimens should be clearly labeled with two patient identifiers (name, DOB, medical record number, etc.) and the collection date.

Refrigerate the specimen until transported and send as soon as possible. **Specimens must be received within 5 days of obtaining the specimen.**

Fill out the Public Health Laboratory Request Form. Place the form in outside sleeve of biohazard zip lock bag and put into TB mailing container. Respiratory specimens should be packaged and transported cold by mail or courier. All other specimens may be transported at ambient temperature.

Mycology (Fungal) Culture Collection and Transport

Specimen Type	Instructions
Tissue	Place tissue in a sterile screw cap container and cover with 1 mL of sterile saline or broth. Refrigerate until time of mailing.
Blood	Collect blood aseptically an automated blood culture system bottle. **If mold or yeast is suspected, submit blood culture bottle for culture identification.**
Bone marrow	Collect approximately 0.3 mL of bone marrow in a heparinized tube. Store specimen at room temperature or incubate until mailing. Ship in sterile screw cap container.
Bronchial wash, Pleural fluid, Joint fluid, Sputum	Send in sterile screw cap container. May be sent in TB transport container. Refrigerate specimen until mailing.
CSF	Send a minimum of 1.0 mL in sterile screw cap container. Store specimen at room temperature or incubate until mailing.
Hair	Remove about 10 hairs with roots using forceps and send in a sterile container. NOTE: Hairs that break off at scalp level when using forceps must be removed with a knife. Scraping the scalp rarely yields infected hairs. Store and transport at room temperature.
Skin	Wipe lesions well with alcohol sponge (cotton will leave too many fibers on skin). Scrape the entire periphery of the lesion(s) with a sterile scalpel. Send scrapings in a sterile container. Store and transport at room temperature.
Nails	Clean nail with alcohol sponge. Scrape and discard outer portion of nail. Collect scrapings from inner nail and send in a sterile screwcap container. Send an entire nail, if it has been removed, in a sterile screw cap container. Store and transport at room temperature.

Please Note: Both a TB culture and a fungal culture can be processed from a single specimen by request. Make certain that the test request form is clearly marked for both tests.

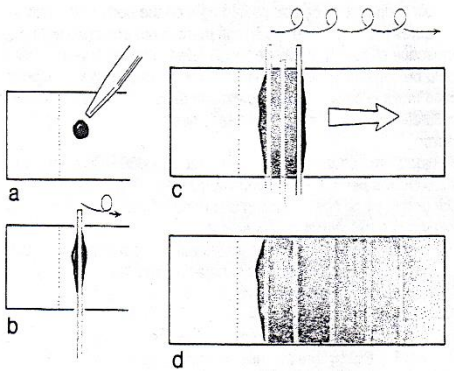
Place each specimen container in an individual biohazard zip lock bag containing absorbent material and seal the bag tightly. Specimens should be clearly labeled with **two patient identifiers** (name, DOB, medical record number, etc.) and the collection date.

Fill out the Public Health Laboratory Request Form. Place the form in the outside sleeve of biohazard zip lock bag and put into mailing container. Transport at ambient temperature by mail or courier.

Blood Parasite Screen Thick EDTA Blood Smear Preparation Instructions

1. Specimen: an EDTA-preserved tube of peripheral blood that has not cooled to room temperature nor had its lid removed prior to this sampling. **Make two thick smears per specimen** (one to be stained in-house and the other to be stained at MTPHL).
2. Wear gloves when performing this procedure.
3. Place a pre-cleaned 1 X 3" glass microscope slide on a horizontal surface.
4. Place a 30-40 µl drop of blood onto one end of the slide about 0.5 inches from the end.
5. Lay an applicator stick across the glass slide and contact the drop of blood. Allow the blood to spread along the applicator stick until it spreads from one side of the slide to the other.
6. Keeping the applicator in contact with the blood and glass, rotate (DO NOT "ROLL") the stick in a circular motion while moving the stick down the glass slide to the opposite end. See figure below.

Figure 1: Method of thick-thin combination blood film preparation. (a) Position of drop of EDTA blood; (b) position of applicator stick in contact with blood and glass slide; (c) rotation of applicator stick; and (d) completed thick-thin combination blood film prior to staining. (Illustration by Sharon Belkin)(From reference 2, with permission).



7. The appearance of the blood smear should be alternate thick and thin areas of blood that cover the entire slide.
8. Immediately place the slide over some small print and be sure that the print is just barely readable through the blood film.
9. Allow the film to air dry horizontally and protected from dust for **at least 30 min. to 1 hour**. DO NOT speed the drying process by applying any type of heat as the heat will fix the RBCs and they subsequently will not lyse in the staining process.
10. Dip the thick slides twice in acetone and allow them to air dry in a vertical position. This step improves the durability of the blood film and will prevent the blood from flaking off in transit.
11. Lyse the RBCs on the thick films by either:
    a. Dipping each slide in **Buffered Methylene Blue solution (0.65%)** for 1-2 seconds and allow the slides to air dry in a vertical position. **This is the preferred option** as RBCs are hemolyzed, color is introduced into the cytoplasm of the parasites, and prestaining with methylene blue helps to preserve the organisms on the smear. The formula for 0.65% Buffered Methylene Blue solution is as follows:

Methylene Blue	0.65 g.
Di-sodium hydrogen phosphate Na_2HPO4	2.0 g.
Potassium di-hydrogen phosphate KH_2PO_4	0.65 g.
Distilled water	1.0 L

       Mix and store the solution in a brown stoppered bottle.
    b. Alternatively, the slides may be placed in Buffered water (pH 7.0 to 7.2) for 10 min. and allow the slides to air dry in a vertical position.
12. Stain one thick smear with either Giemsa or Wright's Stain. Submit both slides to MTPHL.
13. Note on the Public Health Laboratory Request Form as to which method the thick smears were lysed.

Newborn Screening Collection and Transport

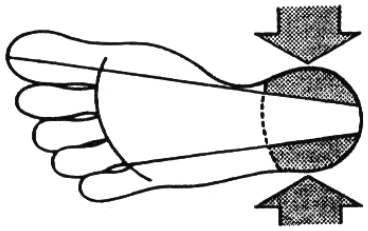
Newborn screening specimen cards for collection of dried blood spot samples are available from the laboratory. See Supply Request Form. These forms contain the requisition form along with the attached filter paper collection device.

Store specimen cards in a cool dry place on edge; flat stacking compresses the filter paper fibers. Do not handle the filter paper portion, as skin oils will prevent saturation.

Complete all the information on the requisition form legibly in block capital letters.

Sample Collection

The usual puncture site is illustrated below (shaded areas).



1. Sterilize and dry skin. Puncture heel with sterile lancet.
2. Allow large blood droplet to form.
3. Touch filter paper to blood and allow to soak through completely in each circle. Total saturation of the circles must be evident when the paper is viewed on both sides. Do not apply blood to both sides.
4. Be certain to properly fill all five (5) circles on the card. These need to all be satisfactory spots.
5. Use of capillary tubes is not recommended because they tend to roughen the filter paper and cause over absorption.
6. Allow blood spots to air dry thoroughly for 2-3 hours at room temperature. Keep away from direct sunlight and heat. Do not stack filter papers before thorough drying. Protective cover can be used to hold specimen while drying.
7. Cover with end flap only after specimen is completely dry.
8. Inspect the dried blood spots for adequacy prior to transport. Do not send unsatisfactory specimens.
9. Transport specimen by UPS or courier at ambient temperature within 24 hours of collection.

Note: Specimens may be UNSATISFACTORY if:

- All circles not completely filled (QNS)
- Blood is layered by application on both sides or by multiple spotting
- Filter paper is scuffed or torn
- Specimen is contaminated or improperly dried
- Information is incomplete

Capillary (Fingerstick Specimens) for Blood Lead Collection and Transport

Collection supplies are available free of charge by contacting the laboratory. Kits include:

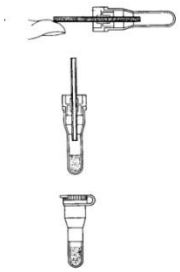
Two (2) Sterile Alcohol Preps	One (1) Capillary collection device	One (1) Transport zip lock bag
One (1) Lancet	One (1) Dry Sterile Gauze Pad	One (1) Instruction sheet

Performing the Skin Puncture:

1. Thoroughly wash hands and don powder free gloves.
2. Select the puncture site. Blood can be obtained from:
   - fingertip (for adults and children older than 1 year)
   - the bottom of the big toe (infants only)
   - the heel (infants only)
3. Clean the puncture site with alcohol pad. If the site is extremely soiled or very cold, wash with warm soapy water and towel dry. Use the alcohol swab to briskly scrub the puncture site to remove any environmental contamination and to increase blood flow.
4. Allow the site to air dry or use the sterile gauze to dry the area.
5. Puncture the skin with the lancet.

Collection of the Sample:

1. Use the gauze to wipe off the first drop of blood, which contains excess tissue fluid. A rounded drop of blood will form over the puncture site. When the tip of the collection device touches this drop, blood will flow by capillary action into the tube. Care should be taken that the tip of the collection device is in contact with the blood only, not skin. Gently apply continuous pressure to the surrounding tissue; avoid milking the site.



Important: The flow of blood must be adequate to fill the capillary rapidly. Do not stop to shake or tap the tube until the capillary is filled. Capillary must be held continuously in a horizontal position during the drawing of the blood.

2. After filling, turn the capillary device immediately to a vertical position to allow the blood to flow into the tube. Remove capillary with holder at the same time. Close tube with attached cap.
3. Apply pressure to the puncture site with a gauze pad to stop bleeding, while mixing the specimen by inverting a minimum of five times.
4. Identify each skin puncture specimen with the patient's name and collection date.

Submitting Specimens to the Laboratory for Testing:

1. Specimens should be clearly labeled with two patient identifiers (name, DOB, medical record number, etc.) and collection date.
2. Complete a Public Health Laboratory Request Form to include the patient's name, date of birth, gender, collection date, submitter information, and, if applicable, Medicaid billing information.
3. Place the well-mixed blood specimen container into the individual biohazard zip lock transport bag and seal bag tightly. Fold the requisition form and place in sleeve of the bag. Place the zip lock bag(s) into a preaddressed white mailing canister. Store the specimen(s) in the refrigerator until shipped. Specimens are stable for 7 days at refrigeration temperatures.
4. Specimens are transported at ambient temperature by mail or courier.

Results:

1. Laboratory test results will be mailed to the submitter upon completion of testing.
2. Should the initial test be elevated, a venous specimen will be requested for verification.

Venipuncture Specimens for Blood Lead Collection and Transport

Collection supplies are available free of charge by contacting the laboratory.

The Venipuncture Collection Kit includes:

One (1) sterile alcohol preps
One (1) needle and holder or one (1) needle and syringe
One (1) transport zip lock bag
One (1) dry sterile gauze pad
One (1) Vacutainer EDTA tube
One (1) instruction sheet

Preparation of the Puncture Site:

1. Thoroughly wash hands and don powder free gloves.
2. Expose the selected antecubital fossa and apply tourniquet to mid-biceps. Scrub the puncture site briskly with the alcohol pad to remove any environmental contamination and to increase blood flow.
3. Allow the site to air dry or use the sterile gauze to dry the area.

Collection of the Sample:

1. Prepare needle assembly, either needle and vacutainer holder, or needle and syringe.
2. Perform venipuncture per standard operating procedures. Make sure the vacutainer tube is completely filled before stopping collection. If using a needle and syringe, obtain a minimum of 2 mL of whole blood.
3. Remove tourniquet first, then needle from arm.
4. Apply pressure to the puncture site with a gauze pad to stop the patient's bleeding. Parent/guardian or child may continue holding direct pressure on the puncture site.
5. If drawn directly into vacutainer tube, immediately mix the specimen manually by inverting a minimum of 10 times.
6. If drawn with a needle into the syringe, immediately inject the blood from the syringe into the vacutainer tube, gently mixing while filling. Continue to mix the specimen by inverting 10 times.
7. Dispose of used needle and syringe equipment into puncture proof Sharps container.
8. Identify each skin puncture specimen with the patient's name, at a minimum, and collection date.

Submitting Specimens to the Laboratory for Testing:

1. Specimens should be clearly labeled with two patient identifiers (name, DOB, medical record number, etc.) and collection date.
2. Complete a Public Health Laboratory Request Form to include the patient's name, date of birth, gender, collection date, submitter information, and, if applicable, Medicaid billing information.
3. Place the well mixed, unclotted blood specimen in an individual biohazard zip lock bag containing absorbent material and seal bag tightly. Fold the requisition form and place in sleeve of the bag. Place the zip lock bag(s) into a preaddressed white mailing canister.
4. Store the specimen(s) in the refrigerator until shipped. Specimens are transported at ambient temperature by mail or courier. Specimens are stable for 7 days at refrigeration temperatures.

Results:

Laboratory test results will be mailed to the submitter upon completion of testing.

QuantiFERON®-TB Gold In-Tube Testing Collection and Transport

The QuantiFERON-TB Gold assay (QFT®) measures the Interferon-gamma (IFN-γ) response in whole blood stimulated with antigen. The kit uses specialized QFT blood collection tubes. The following is a guide for blood collection into these tubes.

Please read and follow the complete directions carefully!

Filling QuantiFERON®-TB Gold blood collection tubes

QuantiFERON®-TB Gold IT uses the following collection tubes; the set will be provided for you free of charge by calling 800-821-7284, or e-mailing mtphl@mt.gov.

1. Nil Tube (Grey cap with yellow ring). The yellow ring designates a high-altitude tube.
2. TB1 Tube (Green cap with yellow ring).
3. TB2 Tube (Yellow cap with yellow ring).
4. Mitogen Tube (Purple cap with yellow ring).

These procedures should be followed for optimal results:

1. Tubes should be at 17 - 25°C at the time of blood filling.
2. Collect 1 mL of blood by venipuncture directly into each QFT blood collection tube in the order Nil, TB1, TB2, and Mitogen. As 1 mL tubes draw blood relatively slowly, keep the tube on the needle for 2-3 seconds once the tube appears to have completed filling to ensure that the correct volume is drawn.
3. The black mark on the side of the tubes indicates the 1 mL fill volume. QFT blood collection tubes have been validated for volumes ranging from 0.8 to 1.2 ml. If the level of blood in any tube is not close to the indicator line, it is recommended to obtain another blood sample.
   •If a "butterfly needle" is used, prime tubing with a "purge" tube before filling the QFT tubes.

Mixing Tubes

1. Antigens have been dried onto the inner wall of the blood collection tubes. It is essential that the tubes' contents be thoroughly mixed with the blood. Thorough mixing will dissolve the heparin, preventing clotting, and allow resolubilization of the stimulating antigen. Mixing is performed by shaking, not just inverting, the tubes vertically ten (10) times, firmly enough to ensure that the entire inner surface of the tube is coated with blood. **Over-energetic shaking may cause gel disruption and could lead to aberrant results.**
2. Label tubes appropriately with two patient identifiers. Ensure each tube (Nil, TB1, TB2, Mitogen) is identifiable by its label or other means once the cap is removed.

Incubation of Tubes

1. Following filling, shaking and labeling, the tubes must be transferred to a 37°C ± 1°C incubator as soon as possible, and within 16 hours of collection. If the blood is not incubated immediately after collection, re-mixing of the tubes by inverting 10 times must be performed immediately prior to incubation.
2. Incubate the tubes **UPRIGHT** at 37°C ± 1ºC for 16 to 24 **consecutive** hours. The incubator does not require CO_2 or humidification.
3. If tubes are not incubated on site, maintain tubes at room temperature (22°C ± 5°C). Do not refrigerate or freeze the blood samples. Tubes must be received in the Public Health Laboratory within 16 hours of collection for incubation.
4. Following 37ºC ± 1ºC incubation, blood collection tubes may be transported between 2°C and 27°C. **Specimens must be received in the Public Health Laboratory within 3 days of incubation. If this is not possible, call MTPHL for direction.**
5. Complete a black and white Public Health Laboratory Request Form; **include date and TIME of draw,** and **whether the specimen(s) have been incubated** prior to shipment**.** Please note this information in the Comments/Pertinent Information section of the request form.

An illustrated Quick Guide for Blood Collection is available at http://www.cellestis.com/. Click on the links: QuantiFERON Products, QuantiFERON®-TB Gold In-Tube, Technical Resources, Technical Documents, and Blood Collection Quick Guide.

QUESTIONS? Contact the MTPHL at 800-821-7284 or mtphl@mt.gov

Serology Specimens Collection and Transport

TESTING POLICY: If a convalescent specimen is received, it will be tested in parallel with the original acute specimen, and only the convalescent specimen will be billed.

Specimen Type	Instructions
Acute serology specimen	The DATE OF ONSET of symptoms or disease is less than 7 days from the date serum is obtained, usually the first few days of the illness. IgG antibody titers are not elevated. Exceptions: Rubeola, Rubella, and Colorado Tick Fever and Rocky Mountain Spotted Fever may have a significant IgG titer in 7-10 days.
Convalescent serology specimen	The DATE OF ONSET of symptoms or disease is 2 weeks or greater from the date serum is obtained. IgG antibody levels should be at a significant level. Exception: Legionella sp. antibody levels may not be significant for 4-6 weeks.
Serology screen only Post-convalescent serology specimen	The patient has a chronic condition, with the DATE OF ONSET of symptoms or disease being a very long period (months to years, OR patient is being screened for antibodies to a certain infectious agent (HIV, Hepatitis B, Rubella, VZV, etc.) ALTERNATIVELY, IgM testing is available. Single specimen test results may be difficult to interpret, and an additional specimen may be requested if results warrant.

Submit approximately 2 - 4 mL of clear non-hemolyzed serum for testing. Contact the laboratory for exact volumes needed if serum is difficult to obtain. Serum separator tubes can be used. Spin the SST tubes well to separate the serum and cells and submit the whole tube. Serum does not have to be poured off. DO NOT submit unspun SST tubes. If serum is not submitted in the original SST tube, place in a leakproof container.

Cerebral Spinal Fluid (CSF) may also be submitted for serological testing in certain instances. A serum sample should also be submitted with the CSF for comparison testing.

Specimens should be clearly labeled with two patient identifiers (name, DOB, medical record number, etc.) and collection date. Completely fill out the Public Health Laboratory Request Form.

Place each specimen container in an individual biohazard zip lock bag containing absorbent material and seal bag tightly. Place the completed laboratory request form in the outer sleeve of the biohazard zip lock bag. Do not place the completed laboratory request form inside the zip lock bag.

If specimen is stored prior to shipment, store at 4°C. If storage is longer than 1 week, freeze the specimen. Specimens may be shipped at room temperature. Labeled pre-addressed mailing canisters are available from the laboratory. Transport by mail or courier.

Clinical Laboratory Requisition Forms

Request forms are available by calling the laboratory at 800-821-7284:

The Public Health Laboratory Request Form, preprinted with your account information; all clinical testing can be ordered with this form.

A Newborn Screening Panel Form; this form contains the dried blood spot collection kit.

Examples of each form are included on the following pages, as well as specific instructions on filling out the Newborn Screening Form.

General Instructions:

Please fill the forms out completely to include (at a minimum):

Patient Last Name or anonymous identifier (required)
Patient First Name
Patient ID #/ Medical Record #
Date of Birth
Gender
Medicaid # (if applicable)
NPI (or UPIN) # of Physician/Clinician (preferred)
Physician/Clinician Name (if NPI is not provided)
Specimen Collection Date (required)
Date of Onset of Illness (for serology and molecular testing)
Source of Specimen
Test(s) Ordered

There will need to be two forms of patient identification on both the requisition form and the submitted specimen for the submission to be acceptable.

NOTE: Forms are read using an optical scanning device. **Please PRINT information** clearly in boxes indicated. **Do not use preprinted labels or stamps.**

Public Health Laboratory Request Form

MONTANA DEPARTMENT OF PUBLIC HEALTH & HUMAN SERVICES

Public Health Laboratory Request Form

P.O. Box 4369, Helena, MT 59604-4369
(406) 444-3444 (800) 821-7284 CLIA ID # 27D0652531

DPHHS PHL 0117

PATIENT INFORMATION (please PRINT legibly)

LAST NAME

FIRST NAME

PATIENT ID #

PATIENT ADDRESS

PATIENT CITY OF RESIDENCE

STATE ZIP CODE DATE OF BIRTH / /

GENDER
☐ Male
☐ Female

PROVIDER INFORMATION

PHYSICIAN / CLINICIAN NAME

NATIONAL PROVIDER IDENTIFIER (NPI)

MTPHL USE ONLY

TEST(S) REQUESTED INFORMATION

Serology:

- ☐ Blood Lead
- ☐ Brucella Antibody
- ☐ CTFV IgG Serology
- ☐ Hantavirus IgG & IgM Serology
- ☐ Hepatitis - Acute Panel
- ☐ Hepatitis A IgM Antibody
- ☐ Hepatitis B Surface Antigen
- ☐ Hepatitis B Surface Antibody
- ☐ Hepatitis B Total Core Antibody
- ☐ Hepatitis B Core IgM Antibody
- ☐ Hepatitis C Ab with Reflex as needed
- ☐ Herpes Simplex Virus IgG Serology
- ☐ HIV Ab/Ag Combo with Reflex Confirmation
- ☐ Legionella IgG Serology
- ☐ Lyme Total Abs with Reflex Confirmation
- ☐ Mumps IgG Serology
- ☐ Q Fever IgG Serology
- ☐ RMSF IgG Serology
- ☐ Rubella IgG
- ☐ Rubeola (Measles) IgG
- ☐ Syphilis Screen with Reflex Confirmation
- ☐ Syphilis Confirmation (TP-PA)
- ☐ TB - QuantiFERON Gold In-Tube Testing
  Time Collected: _____
  Incubated 16 - 24 hrs? Yes No
- ☐ Tick Borne Disease Panel + Lyme
- ☐ Tick Borne Disease Panel
- ☐ Tularemia Antibody
- ☐ Varicella Zoster Virus IgG
- ☐ West Nile Virus IgM
- ☐ West Nile Virus IgG

Molecular Testing:

- ☐ Adenovirus PCR
- ☐ Bordetella pertussis multitarget PCR
- ☐ C difficile NAP1 PCR
- ☐ Enterovirus PCR
- ☐ Enterovirus D68 PCR
- ☐ Herpes Simplex Virus PCR
- ☐ Influenza A and B PCR
- ☐ Measles (Rubeola) PCR
- ☐ Mumps PCR
- ☐ Norovirus PCR
- ☐ Varicella Zoster PCR

STD Testing (APTIMA):

☐ Chlamydia and Gonorrhea ☐ Chlamydia Only ☐ Gonorrhea Only

Sterilizer Monitoring:

☐ Autoclave Monitoring-BT Test

Microbiology

- ☐ Bacteriology Culture/ID, Aerobic
- ☐ Bacteriology Culture/ID, Anaerobic
- ☐ BT Agent Rule Out (list in Comments)
- ☐ EHEC (STEC) Toxin Test
- ☐ Enteric Panel Culture, includes EHEC
- ☐ Fungus Culture/ID
- ☐ Legionella Direct Detection/Culture ID
- ☐ Malaria Screen
- ☐ Modified Acid Fast Stain
- ☐ Neisseria gonorrhoeae Culture/ID
- ☐ Vibrio screen
- ☐ Yersinia screen
- ☐ Cryptosporidium/Giardia EIA screen
- ☐ Cryptosporidium/Cyclospora Detection
- ☐ Ova and Parasite Exam

Chlamydia Culture

☐ Chlamydia Culture

Zika Testing

- ☐ Zika Serology (IgM)
- ☐ Zika Trioplex PCR Serum
- ☐ Zika Trioplex PCR Serum/Urine Combo
  (Trioplex PCR includes Dengue and Chikungunya)

Surveillance Cultures:

Type of Isolate: _____

- ☐ CRE Confirmation
- ☐ ESBL Confirmation
- ☐ GC Confirmation/Susceptibility
- ☐ Influenza Confirmation
- ☐ MRSA Confirmation
- ☐ Salmonella/Shigella/E. coli/Campy
- ☐ VRE Confirmation
- ☐ Other Surveillance Confirmation

Virus Culture:

- ☐ CNS Virus Isolation
- ☐ Cytomegalovirus Isolation
- ☐ Enteric Virus Isolation
- ☐ Herpes Simplex Virus (HSV) Isolation
- ☐ Respiratory Virus Isolation
- ☐ RSV Direct Detect
- ☐ Varicella Zoster Virus (VZV) Isolation
- ☐ Virus Isolation (Other)

TB/Mycobacteriology:

- ☐ TB Mycobacteria Smear/Culture/ID
- ☐ M. tuberculosis NAAT (Molecular)
  (Should be ordered on all highly suspect specimens)

SPECIMEN COLLECTION DATE / /

DATE OF ONSET / /

Medicaid / Medicare Billing Information:

☐ Bill MEDICAID ☐ Inpatient
☐ Bill MEDICARE ☐ Outpatient

MEDICAID ( ) or MEDICARE ( ) NUMBER

ICD DIAGNOSIS CODE

SPECIMEN SOURCE

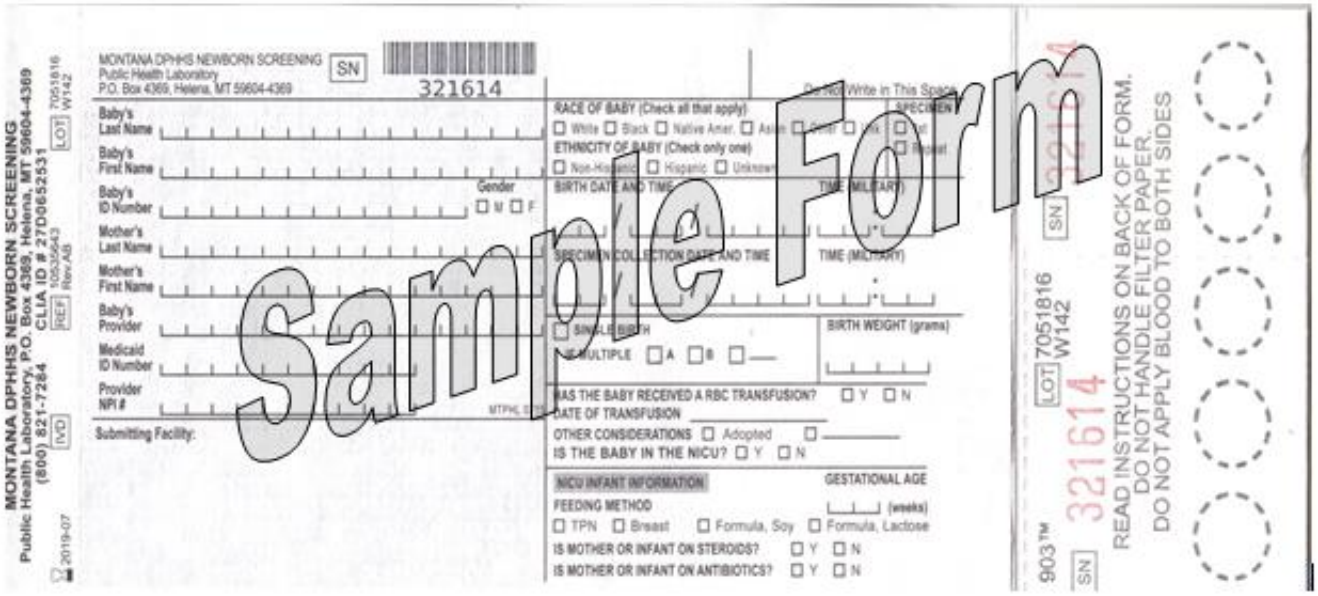
- ☐ Bronchial Washings
- ☐ Buccal Swab
- ☐ Cervical Swab
- ☐ CSF
- ☐ EDTA Blood (Capillary)
- ☐ EDTA Blood (Venous)
- ☐ Heparanized Blood
- ☐ Lesion Swab (Site: _____)
- ☐ Nasal Swab
- ☐ Nasal Washings
- ☐ Other (Specify) _____
- ☐ NP Swab
- ☐ Pleural Fluid
- ☐ Rectal Swab
- ☐ Serum
- ☐ Sputum
- ☐ Stimulated Plasma (QFT)
- ☐ Stool
- ☐ Throat Swab
- ☐ Urethral Swab
- ☐ Urine
- ☐ Vaginal Swab

Other Test(s) Requested/ Pertinent Information / Comments

17760

Newborn Screening Requisition Form

This form has attached special filter paper for collection of the blood spots.



All information contained on the form must be completed.

Complete the patient information (name, sex, ID#, race, and ethnicity) as well as the mother's name and baby's provider. It is important to specify the provider that will be providing care for the infant once he or she is released from the hospital. We will not accept hospitalists or obstetricians in this field.

Mark the specimen as to whether this is the first screen performed on the baby or repeat screen. If the baby was screened at the hospital, and then is followed up with a repeat test at the physician's office, mark the repeat box.

Accurately complete the birth date and time and the specimen collection date and time. Samples obtained from a child less than 24 hours old must be repeated.

Complete the birth weight in grams.

Answer the questions on transfusion history. In cases when the baby received a transfusion, please include the date of transfusion.

If the baby is on TPN (Total Parenteral Nutrition) at the time of collection, please indicate that on the form.

This same form can be used for monitoring Phenylalanine levels on patients with known PKU disease.

Supply Order Form

Supply Order Form

Toll Free 800-821-7284 or FAX 406-444-1802

Facility / ATTN: _____

Street Address _____

Account Number: _____ Order Date: _____

Phone No _____ Order Taken By _____

Quantity	Supplies	Revised 01/2020
	Kits Boxes	
_____	☐ ☐	Chlamydia/GC Aptima **Swab** Collection Kits (50/box) (for Cervical & Urethral)
_____	☐ ☐	Chlamydia/GC Aptima **Urine** Collection Kits (50/box)
_____	☐ ☐	Chlamydia/GC Aptima **Multitest** Collection Kits (50/box) (for Rectal, Throat & Penile) also for Herpes Simplex Virus
_____		Tuberculosis Transports
_____		Ova & Parasite Transports (Total-Fix)
_____		QuantiFERON Gold Plus Collection Tubes (4 tubes/set)
_____		Capillary Blood Lead Collection Kits
_____		Venous Blood Lead Collection Kits
_____		Cary-Blair Transport Medium (for stools and bacteriology cultures)
_____		Universal Transport Medium (for molecular testing)
_____		Polyester Flexible Wire Swabs for Nasopharyngeal Collection
_____		White Specimen Mailing Tubes _____ Petri Dish Mailers
_____		Specimen Bags 6"x9" or 2'x2' _____ Mailing Labels
_____		Autoclave Indicator Vials
	Meat Testing	
_____		Whirlpack Bags _____ Gloves _____ Ice Packs
_____		Listeria Swabs _____ Carcass Sampler _____ Box
	Forms	
_____		Public Health Laboratory Request Forms (black & white)
_____		Neonatal Screening Forms _____ Envelopes
_____		Meat Inspection Testing Request Forms

Please Note: These supplies are the property of the State of Montana and are to be used only for business with the Montana Department of Public Health and Human Services.

For more information visit: www.lab.hhs.mt.gov

Packaging and Shipping Guidelines

It is the responsibility of the facility to ensure proper packaging and shipping of all potentially infectious and biological substances. Listed below are some general guidelines and links to websites that will provide more detailed information.

Category A (UN2814 "Infectious Substance Affecting Humans"): "An infectious substance in a form capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. An exposure occurs when an infectious substance is released outside of its protective packaging, resulting in physical contact with humans or animals. Classification must be based on the known medical history or symptoms of the source patient or animal, endemic local conditions, or professional judgment concerning the individual circumstances of the source human or animal. Category A poses more risk than Category B."

Category B (UN 3373 "Biological Substance, Category B"): "An infectious substance NOT in a form generally capable of causing permanent disability or life-threatening or fatal disease in otherwise healthy humans or animals when exposure to it occurs. This includes Category B infectious substances transported for diagnostic or investigational purposes."

Exempt Human Specimens: Exempt Human Specimen label indicates there is no infectious substance in the package. (Examples include fecal occult blood and dried blood spots.)

For more information, please visit the following sites:

49 CFR PART 172—HAZARDOUS MATERIALS TABLE, SPECIAL PROVISIONS, HAZARDOUS MATERIALS COMMUNICATIONS, EMERGENCY RESPONSE INFORMATION, TRAINING REQUIREMENTS, AND SECURITY PLANS
http://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=44acea8f201b183f75c4e90179e00f56&n=49y2.1.1.3.9&r=PART&ty=HTML#se49.2.172_1704

49 CFR PART 173—SHIPPERS—GENERAL REQUIREMENTS FOR SHIPMENTS AND PACKAGINGS
http://www.ecfr.gov/cgi-bin/text-idx?SID=b939d5f0b1d7600fa4adf1a00c1f49d6&node=49:2.1.1.3.10&rgn=div5#49:2.1.1.3.10.2.25.8

A Guide for Shippers of Infectious Substances, 2015
http://www.who.int/ihr/infectious_substances/en/

Guidance on regulations for the Transport of Infectious Substances
http://www.who.int/ihr/publications/who_hse_ihr_2015.2/en/

International Air Transport Association (IATA) Dangerous Good Regulations:
https://store.iata.org/IEC_SearchResults?site-search=dangerous+goods+regulations

DOT: Transporting Infectious Substances Safely
https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/docs/Transporting_Infectious_Substances_brochure.pdf

ASM SENTINEL LEVEL CLINICAL LABORATORY GUIDELINES FOR SUSPECTED AGENTS OF BIOTERRORISM AND EMERGING INFECTIOUS DISEASES: Packing and Shipping Infectious Substances
https://asm.org/Articles/Policy/Laboratory-Response-Network-LRN-Sentinel-Level-C

CDC Packaging and Shipping Training Course
https://www.cdc.gov/labtraining/training-courses/packing-shipping-division-6.2-materials.html

Attachment G: Montana Public Health Laboratory Clinical Improvements Amendments

CENTERS FOR MEDICARE & MEDICAID SERVICES

CLINICAL LABORATORY IMPROVEMENT AMENDMENTS

CERTIFICATE OF WAIVER

LABORATORY NAME AND ADDRESS
MT STATE DEPT OF PUBLIC HEALTH & HUMAN
1400 E BROADWAY
ROOM C-211
HELENA, MT 59601

CLIA ID NUMBER
27D1013849

EFFECTIVE DATE
06/18/2021

LABORATORY DIRECTOR
JUDY NIELSEN DIRECTOR

EXPIRATION DATE
06/17/2023

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Monique Spruill

Monique Spruill, Director
Division of Clinical Laboratory Improvement & Quality
Quality & Safety Oversight Group
Center for Clinical Standards and Quality

1769 Certs1_051821

- If this is a Certificate of Registration, it represents only the enrollment of the laboratory in the CLIA program and does not indicate a Federal certification of compliance with other CLIA requirements. The laboratory is permitted to begin testing upon receipt of this certificate, but is not determined to be in compliance until a survey is successfully completed.
- If this is a Certificate for Provider-Performed Microscopy Procedures, it certifies the laboratory to perform only those laboratory procedures that have been specified as provider-performed microscopy procedures and, if applicable, examinations or procedures that have been approved as waived tests by the Department of Health and Human Services.
- If this is a Certificate of Waiver, it certifies the laboratory to perform only examinations or procedures that have been approved as waived tests by the Department of Health and Human Services.

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.GOV/CLIA
OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR
YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.