

| Sentinel Clinical Laboratories Criteria for Certification | | Currently in place | In Progress - 6 months | Planned within next 12 months | No Plans to Implement |
|--|---|--------------------|------------------------|-------------------------------|-----------------------|
| CONTACT INFORMATION | | | | | |
| 1 | Laboratory Name: | | | | |
| 2 | Laboratory Mailing Address: | | | | |
| 3 | Laboratory Physical Address: | | | | |
| 4 | Laboratory Manager Name: | | | | |
| 5 | Laboratory Manager Email: | | | | |
| 6 | Laboratory Manager Phone/Fax: | | | | |
| 7 | Microbiology Supervisor Name: | | | | |
| 8 | Microbiology Supervisor Email: | | | | |
| 9 | Microbiology Supervisor Phone/Fax: | | | | |
| 10 | 24/7 Emergency Contact (Phone/Pager/Answering Service): | | | | |
| 11 | List each method for receiving emergency alerts and communications (e.g., email, fax, phone) | | | | |
| CAPACITY | | | | | |
| 12 | Is certified to perform high complexity testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) by the Centers for Medicare & Medicaid Services (CMS) for the applicable Microbiology specialty or the laboratory is a Department of Defense (DoD) Laboratory certified under the DoD Clinical Laboratory Improvement Program or the laboratory is a veterinary medical diagnostic laboratory that is fully accredited by the American Association of Veterinary Laboratory Diagnosticians (AAVLD). Definition found at https://www.asm.org/Articles/CPHMC/Laboratory-Response-Network-LRN-Sentinel-Level-C | | | | |
| 13 | Is inspected successfully by CMS, a CMS agent, a CMS-approved accreditation organization, or, for a CLIA-exempt laboratory, by the State of Montana. | | | | |
| 14 | Laboratory CLIA number | | | | |
| 15 | In-house testing includes gram stains and at least one of the following: lower respiratory tract, wound, or blood cultures. | | | | |
| 16 | Additional Infectious Disease Testing capabilities (e.g., Molecular Biology, Sequencing, Mycobacteriology, Virology): | | | | |
| 17 | Is aware of and complies with Montana rules for reporting and referral of all diagnostic specimens/isolates of public health significance to the MTL SB. https://www.dphhs.mt.gov/publichealth/cdepi/reporting/index | | | | |

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| BIOSAFETY | | | | | |
| 18 | Highest Biosafety Level (BSL-2, BSL-3, Other/Don't Know): | | | | |
| 19 | Has a functioning, certified Class II or higher Biological Safety Cabinet (BSC) | | | | |
| 20 | Number of Class II Biological Safety Cabinets (If none, simply enter N/A): | | | | |
| 21 | Complies with Biosafety Level II (BSL-2) practices, as outlined in the Biosafety in Microbiological and Biomedical Laboratories guidelines (BMBL), available on the CDC website: https://www.cdc.gov/labs/bmbl/ | | | | |
| 22 | Complies with applicable Occupational Safety and Health Administration (OSHA) regulations for bloodborne pathogens and a respiratory protection program, including policies and procedures for use of additional respiratory protection, when such use is necessary, and documentation of safe use (e.g. N-95 fit-testing). | | | | |
| PERSONNEL | | | | | |
| 23 | How many personnel are trained to perform high complexity Microbiology testing? | | | | |
| 24 | Has policies and procedures that include the ASM Sentinel Level Clinical Microbiology Laboratory Guidelines for Suspected Agents of Bioterrorism and Emerging Infectious Diseases? <i>See link on line 12.</i> | | | | |
| 25 | How many personnel are trained to perform rule-out testing for a suspect biothreat agent as described in the ASM Sentinel Level Clinical Microbiology Laboratory Guidelines for Suspected Agents of Bioterrorism and Emerging Infectious Diseases? | | | | |
| 26 | Has policies and procedures for direct referral of suspicious specimens or isolates to the nearest LRN reference laboratory in its jurisdiction, using ASM Sentinel Level Clinical Microbiology Laboratory Guidelines. https://www.asm.org/Guideline/Packing-and-Shipping-Infectious-Substances | | | | |
| 27 | Does the laboratory participate in an external competency assessment (CAP/LPX, WSLH Proficiency Testing, State Issued Microbiology Challenge Sets, Other). Please list or if no, simply enter N/A. | | | | |
| 28 | Personnel have been trained and certified in Packing and Shipping of Infectious Substances Guidelines, as required by the US Department of Transportation. Online guidance in their brochure: https://www.phmsa.dot.gov/sites/phmsa.dot.gov/files/2024-04/Transporting-Infectious-Substances-Safely-PHH50-0186-0622.pdf | | | | |
| 29 | How many personnel are currently competent to collect, refer, ship, and package infectious substances? | | | | |
| SELECT AGENT PROGRAM | | | | | |
| 30 | Have procedures to track and account for decontamination of laboratory biological waste (specimens, cultures). This should include the destruction of isolates confirmed by MT PHL as select agents before they leave the facility, to comply with select agent regulations. | | | | |
| 31 | The laboratory complies with the rules and regulations of the Select Agent Program, which can be reviewed online at https://www.selectagents.gov/ | | | | |