

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 27D0652531	(X3) Date Survey Completed 09/19/2025
Name of Provider or Supplier Montana Public Health Laboratory	Street Address, City, State 1400 Broadway, Room B206, Helena, MT	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	Federal surveyors from the Centers for Medicare & Medicaid Services (CMS) Survey Branch conducted an announced CLIA recertification survey from September 16, 2025, to September 18, 2025. The laboratory was surveyed under 42 CFR part 493 CLIA regulations and was found to be in compliance with condition-level CLIA requirements and the following standard-level deficiencies were found during the CLIA recertification survey.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: I. Based on the review of manufacturers' instructions for use (IFU), review of temperature records, observation of microbiology laboratory (C115), and an interview with the microbiology supervisor, the laboratory failed to store microbiology media by the manufacturers storage requirements for a sampling of 15 out of 15 media slants observed. Findings included: 1. The Hardy Diagnostics Lysine Iron Agar (LIA) IFU storage and shelf life stated, "Upon receipt store at 2-8 C. away from direct light. Media should not be used if there are any signs of deterioration (shrinking, cracking, or discoloration), contamination, or if the expiration date has passed. Product is light and temperature sensitive; protect from light, excessive heat, moisture, and freezing. The expiration date on the product label applies to the product in its intact packaging</p>

when stored as directed. The product may be used and tested up to the expiration date on the product label and incubated for the recommended incubation times as stated below. Refer to the document "Storage" for more information". 2. The Hardy Diagnostics storage document stated, "Media should never be exposed to sunlight or UV light, since many ingredients, especially dyes and indicators, are not stable upon light or heat exposure. Media should be stored in a dark environment. Excessive exposure to light can result in the formation of peroxides that are toxic to bacteria". 3. Observation of the room C115 on September 17, 2025 at 9:00 am revealed, 15 Hardy Diagnostics LIA slants (Lot#6664938, Expiration Date:2026-05-11) with the storage temperature of 2C to 8C, were kept at room temperature (20C - 25C) and were exposed on continuous light. 4. By interview, the microbiology supervisor on September 17, 2025 at 9:20 am, confirmed the LIA slants were kept at room temperature. 38798 II. Based on review of the laboratory's temperature record system, review of the test kit package insert, a review of a Newborn Screening (NBS) procedure, and interview with the Technical Supervisor #3 (TS#3), the laboratory failed to define an acceptable room temperature range consistent with the manufacturer's requirements for one of one newborn screening assay. Findings included: 1. A review of the laboratory's temperature record system revealed a normal room temperature range from 15C to 25C for the Newborn Screening section (room C-108). 2. A review of the Neonatal Galactose-1-Phosphate Uridyl Transferase (GALT) test kit package insert revealed the following assay procedure statement, "All reagents and samples must be brought to room temperature (+20-+25C) before use." 3. A review of the Neonatal GALT Assay by FA procedure, v2.1 revealed the test procedure did not include instructions for bring all reagents and samples to room temperature (20C to 25C) before use, as required by the test manufacturer. 4. In an interview conducted on 09/17/2025 at approximately 1:50 PM, the TS#3 confirmed the findings stated above for one of one NBS assay. III. Based on direct observation during a tour of the Serology and Newborn Screening sections (room C-108), a review of the laboratory's humidity record system, a review of instrument operators manuals, and an interview with the Technical Supervisor #3 (TS#3), the laboratory failed to define an acceptable room humidity range consistent with instrument manufacturer's instructions for two of two test instruments. Findings included: 1. During a tour of laboratory room C-108 on 09/18/2025 at approximately 10:00 AM, the following two instruments were observed used for testing: BioRad Geenius Reader Serial Number: DP9B201512 PerkinElmer Panther Puncher 9 Serial Number: 20810591 2. A review of the laboratory's humidity record system revealed a normal room humidity range set at 15% to 60% for room C-108. 3. A review of the operator's manuals for the two observed test instruments in room C-108 revealed the following manufacturer's required environmental conditions for operation of the instruments: BioRad Geenius Reader Required Humidity Range = 20% to 80%, non-condensing PerkinElmer Panther Puncher 9 Required Humidity Range = 20% to 80% for punches of 3.2 mm or greater, 40% to 80% (not condensed) for 1.5 mm punches. When operating at less than 20% relative humidity, static electricity increases the probability of disks jumping out of the wells. 4. In an interview conducted on 09/18/2025 at approximately 10:15 AM, the TS#3 confirmed the room humidity range set for room C-108 was not consistent with the instrument manufacturer's operating conditions. IV. Based on direct observation during a tour of the Laboratory's Amplification Room (Room C-120), a review of the laboratory's room temperature record system, a review of the instrument operators manual, and an interview with the Technical Supervisor #3 (TS#3), the laboratory failed to define an acceptable room temperature range consistent with the instrument manufacturer's instructions for one of one test instrument. Findings included: 1. During a tour of room C-120, on 09/17/2025 at approximately 2:40 pm, the following instrument was observed, used for specimen

testing: QuantStudio Dx Real Time PCR Serial Number: 287881389 2. A review of the laboratory's temperature record system revealed a normal room temperature range was set at 59F to 77F for room C-120. 3. A review of the operator's manual for the QuantStudio Dx instrument in room C-120 revealed the following manufacturer's environmental condition requirement for operating the instrument: "Ensure that the installation room is maintained under correct environmental conditions. Temperature, acceptable range: 15C to 30C (60F to 85F)". 4. In an interview conducted on 09/17 /2025 at approximately 2:45 PM, the TS#3 confirmed the room temperature range set for room C-120 was not consistent with the instrument manufacturer's environmental condition requirements.

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(c)

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

I. Based on observation of the media preparation laboratory (C103) and interview with the microbiology manager, the laboratory failed to label a sampling of Sigma Aldrich chemicals (four out of ten) stored in laboratory with expiration dates. Findings included: 1. Observation of room C103 on September 16, 2025 at 10:45 pm revealed the following chemicals stored in the laboratory which are used for the preparation of in-house media for the microbiology laboratories that did not include expiration dates: a. One bottle of Sigma Aldrich Potassium Iodine Pcode - 1003748760 Received: 03-07-2025 Opened: 03-07-2025 b. One bottle of Sigma Aldrich Potassium Phosphate Pcode - 1003647193 Received: 01-08-2024 Opened: 03-27-2024 c. One bottle of Sigma Aldrich Sodium Hydroxide Pcode - 1003685311 Received: 08-16-2024 Opened: 09-03-2024 d. One bottle of Sigma Aldrich Trichloroacetic acid Pcode - 1003785272 Received: 06-04-2025 Opened: 06/04/2025 2. By Interview with the microbiology manager on September 16, 202 at 11:00 am confirmed the above chemicals did not include expiration dates. II. Based on observation of the tuberculosis (TB) laboratory - (C112) and interview with the microbiology manager, the laboratory failed to label two of two bottles of immersion oil reagent in use with an open and expiration date. Findings included: 1. Observation of room C112 on September 18, 2025 at 9:60 am revealed one small bottle labeled with only "immersion oil" next to the LEICA DM100 Microscope. 2. The laboratory manager collected and provided the stock bottle of immersion oil - Cargille Laboratories Type A immersion oil - Lot#: 083198, which also did not include an expiration date. 3. By Interview with the microbiology manager on September 18, 202 at 9:40 am confirmed the stock and the aliquot of immersion oil did not include open and expirations dates. 38798 III. Based on direct observation during a tour of the laboratory's Newborn Screening (NBS) section (room C-108), a review of a test kit package insert, and interview with the Technical Supervisor #3 (TS#3), the laboratory failed to label a reagent with the preparation and expiration dates for one of one NBS assay. Findings included: 1. During a laboratory tour of the NBS section on 09/17 /2025 at approximately 2:00 PM, a large plastic container of reconstituted wash solution (DELFIA, Lot # 757877) was observed sitting on the countertop in room C108 with no labeling of preparation date and expiration date. 2. A review of the

AutoDELFLIA Neonatal Immunoreactive Trypsinogen (IRT) test kit package insert revealed the following reagent preparation instructions, "Reagent, Wash Solution for plate processor ... Reconstituted stability, 2 weeks at +2-+25C in a sealed container." 3. In an interview conducted on 09/17/2025 at approximately 2:10 PM, the TS#3 confirmed the findings stated above for the one of one NBS assay. IV. Based on direct observation during a tour of the laboratory's Newborn Screening (NBS) section (room C-108), a review of a quality control package insert, and interview with the Technical Supervisor #3 (TS#3), the laboratory failed to label a quality control with an expiration date for one of one NBS assay. Findings included: 1. During a tour of laboratory room C-108 on 09/17/2025 at approximately 2:15 PM, an open bottle of reconstituted Hemoglobin AFSC Control (Lot # 1-96-3) was observed with no stability expiration date. 2. A review of the Hemoglobin AFSC Controls, Lot # 1-96-3, package insert revealed the following storage and stability statement, "Reconstituted controls are stable for 12 days when refrigerated at 2-8C. 3. In an interview conducted on 09/17/2025 at approximately 2:20 PM, the TS#3 confirmed the findings stated above for one of one NBS assay control.

D5445

CONTROL PROCEDURES
CFR(s): 493.1256(d)(1)(2)(g)

(d) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (d)(3) At least once each day patient specimens are assayed or examined perform the following for:

This STANDARD is not met as evidenced by:
Based on observation of the laboratory, review of microbiology quality control (QC) records, and interview with the microbiology supervisor, the laboratory failed to establish an individualized quality control plan (IQCP) for one out of two Cepheid GeneXpert systems performing patient testing in from September 2023 to September 2025. Findings included: 1. Based on the tour of the public health laboratory on September 16, 2025, the laboratory had the following two Cepheid GeneXpert systems in use for patient testing: a. Four module Cepheid GeneXpert system - Room C112. b. Four module Cepheid GeneXpert system - Room C115. 2. Review of QC records revealed external QC for the following Cepheid GeneXpert system test kits were performed with each new lot and shipments: a. Xpert Norovirus. b. Xpert MTB /RIF. c. Xpert Carba-R. 3. Per the test performed (CY2024) document provided by the laboratory, the following annual tests were performed for each of the Cepheid GeneXpert system test kit: a. Xpert Norovirus - 154. b. Xpert MTB/RIF - 164. c. Xpert Carba-R - 280. 4. Interview with the microbiology supervisor on September 17, 2025 at 2:35 pm confirmed the laboratory did not establish IQCPs for each Cepheid GeneXpert system in use or for the test kits performed. Key: MTB/RIF - Mycobacterium tuberculosis and Rifampin Resistance. Carba-R - carbapenem-resistance in bacteria.

D5781

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(1)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:

Based on the review of calibration log reports, lack of corrective action documents and interview with the microbiology supervisor, the laboratory failed to document corrective actions (CA) for failed calibrations on the Applied Biosystems QuantStuido DX system for two out of seven months (September 2024 to March 2025). Findings included: 1. Review of the calibration records for the Applied Biosystems QuantStuido DX - S/N# 287880227 analyzer on September 17, 2025 at 12:45 pm, revealed the following three calibration failures from September 2024 to March 2025: a. Calibration Type: Dye - 09/18/2024 at 10:23:59. b. Calibration Type: Normalization - 09/18/2025 at 15:06:01. c. Calibration Type: Background - 03/31/2025 at 11:13:05. 2. The laboratory was unable to provide CA documented for the above calibration failures. 3. Review of the molecular Quantstudio procedures revealed, corrective actions to take when calibrations fail to meet the laboratory's criteria for acceptability where not established. 4. By interview, the microbiology laboratory manager confirmed the above findings on September 17, 2025 at 1:00 pm.

D5801

TEST REPORT

CFR(s): 493.1291(a)

(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on direct observation during a tour of the laboratory specimen receiving and accessioning room, review of a final test report, and an interview with the laboratory's Information Systems staff, the laboratory failed to ensure accurate patient-specific data was transmitted from the point of data entry to the final report for one of one patient final report. Findings included: 1. During a tour of the laboratory specimen receiving and accessioning room on 09/17/2025 at approximately 7:20 am, the following specimen was observed being received: Order ID: 20252590130 Test Name: QuantiFERON-TB Gold PLUS Corrected collection date & time: 09/15/2025 at 11:55 AM 2. A review of the final test report for Order ID 20252590130 revealed the following discrepancy: Received date: 09/16/2025 at 11:31 AM 3. In an interview conducted on 09/18/2025 at approximately 11:30 AM, the Information Systems staff

confirmed the discrepancy is a known issue reported for correction to the LIMS programmers on 02/21/2025. Ticket ID: Case-0005338.