Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	27D0652531	06/11/2021
Name of Provider or Supplier	**Street Address, City, State**	
Montana Public Health Laboratory	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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on proficiency testing (PT) records review of the CMS-155 report and the Wisconsin State Laboratory of Hygiene (WLSH) PT results and an interview with the laboratory technical supervisor 1, the laboratory failed to achieve satisfactory performance for the specialty of bacteriology for 2 out of 3 events in 2020. (Refer to D2028)
D2028	BACTERIOLOGY CFR(s): 493.823(e)

	Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on a review of the Wisconsin State Laboratory of Hygiene (WLSH) proficiency testing (PT) scores and an interview with the laboratory technical supervisor 1, the laboratory failed to achieve an overall testing event score of at least 80 percent of acceptable responses for the specialty of bacteriololgy for 2 out of 3 events in 2020 resulting in unsuccessful PT performance. Findings: 1. A review of the 2020 WSLH bacteriology PT program records revealed the overall results for Bacteriology results: Event 2-2020 - 37% and Event 3-2020 - 15%. 2. An interview with the laboratory technical supervisor 1, on June 10, 2021, at 3:30 PM, confirmed the laboratory failed to achieve successful performance in the specialty of bacteriology for events 2 and 3 in 2020.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on a record review and an interview with the technical supervisor 1, the laboratory failed to establish and perform competency assessment for the general supervisors listed on the CLIA CMS-209 Personnel Report form. Findings: 1. A record review of the CMS-209 Personnel Report Form revealed 19 out of 19 personnel listed failed to have competency assessment performed for the general supervisor position for 2019 and 2020. 2. A record review of the laboratory's procedure manual revealed the laboratory failed to have a policy or procedure to assess the general supervisor position. 3. An interview on June 9, 2021 at 3:30 PM, confirmed the laboratory failed to establish a policy or procedure and perform competency for the positions of general supervisor listed on the CMS-209 Personnel Report form.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of testing and proficiency testing records for 2020, and interview with the laboratory technical supervisor 1, the laboratory failed to perform twice annually accuracy verification or proficiency testing for Brucella Total Antibody, Q Fever 1 and 2 IgG, Tularemia Antibody, Rocky Mountain Spotted Fever IgG, West Nile Virus IgM, West Nile Virus IgG, Hantavirus IgM, and Norovirus PCR during 2020. Findings: 1. A review on June 9, 2021, at 10:15 AM of the laboratory test methodology list reveal annual test volumes for Brucella Total Antibody (142), Q

	Fever 1 and 2 IgG (127), Tularemia Antibody (142), Rocky Mountain Spotted Fever IgG (147), West Nile Virus IgM (18), West Nile Virus IgG (18), Hantavirus IgM (49), and Norovirus PCR (29). 2. A review on June 9, 2021, at 10:30 AM of the inter-laboratory proficiency testing binders lacked documentation of twice annually accuracy verification for Brucella Total Antibody, Q Fever 1 and 2 IgG, Tularemia Antibody, Rocky Mountain Spotted Fever IgG, West Nile Virus IgM, West Nile Virus IgG, Hantavirus IgM, and Norovirus PCR during 2020. 3. An interview with the laboratory technical supervisor 1, on June 11, 2021, at 9:00 AM, confirmed the laboratory failed to perform twice annually accuracy verification for these tests during 2020.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record reviews of proficiency testing (PT), and an interview with the laboratory technical supervisor 1, the laboratory failed to document and review corrective actions for failures in the 2020 PT testing events. Findings: 1. A review of the 2020 Wisconsin State Laboratory of Hygiene (WLSH) proficiency testing (PT) records for human immunodeficiency virus (HIV) event 3 (score of 20%), bacteriology event 2 (score of 37%), event 3 (score of 15%), and mycobacteriology event 1 (score 0%), revealed the laboratory failed to document corrective actions for the failed testing events. 2. An interview on June 11, 2021, at 10:45 AM, with the laboratory technical supervisor 1, confirmed the laboratory failed to document corrective actions and have a system in place to review the effectiveness of repeated problems in proficiency testing.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of procedure manuals and interview with the laboratory technical supervisor 1 and laboratory director, the laboratory procedures lacked the current laboratory director's signature and date for approval prior to patient testing. Findings: 1. Review of procedure manuals contained the previous laboratory director's signature and date of approval and lacked the current laboratory director's signature and date of approval. The laboratory currently performs approximately 76 different patients test with a total annual test volume of 294,374. 2. An interview with the laboratory technical supervisor 1 and laboratory director, on June 11, 2021, at 10:00 AM, confirmed that the procedure manuals lacked the current laboratory director signature and date of approval.

D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of maintenance documentation, procedure manual, observation of pipettes, and interview with quality assurance (QA) personnel the laboratory failed to define and perform a function check protocol to verify the accuracy of 10 of 20 Rainin Pipet-Lite pipettes. Findings: 1. No documentation was found to show the laboratory performed a function check protocol to verify the accuracy of 10 Rainin Pipet-Lite pipettes during 2020. 2. Review of the procedure manual revealed: "pipette verification is performed annually but may be done more often if an issue presents". 3. Observation of the 0.5-10 microliter, 5-50 microliter, 20-200 microliter, 20-300 microliter, and 100-1000 microliter Rainin Pipe-Lite pipettes located in the laboratory available for use showed no label of a pipette function check since 2019. 4. An interview with the laboratory QA personnel, on June 10, 2021, at 2:30 PM, confirmed the laboratory failed to perform pipette verifications for these 10 pipettes during 2020.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a record review and an interview with testing personnel 1, the laboratory failed to verify the Ribonuclease P (RNase P) control results for a Bordetella molecular assay met the laboratory's acceptability criteria before reporting out 4 out of 4 patient test results on March 29, 2021. Findings: 1. A Bordetella test record review from March 29, 2021, revealed the laboratory failed to verify that the RNase P control for the polymerase chain reaction (PCR) assay met the acceptability requirements before reporting 4 out of 4 patient test results. 2. An interview on June 10, 2021, at 10: 10 AM, with laboratory testing personnel 1, confirmed the laboratory failed to verify the control for Bordetella PCR assay met acceptability requirements before reporting patient test results.
D6150	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(2) The director or technical supervisor may delegate to the general supervisor the responsibility for ensuring that patient test results are not reported until all corrective actions have been taken and the test system is properly functioning.

	This STANDARD is not met as evidenced by: Based on a record review of molecular testing for Bordetella, and an interview with the general supervior 1, the laboratory failed to ensure that the molecular test system for Bordetella was valid before reporting 4 out of 4 patient test results on March 29, 2021. Findings: 1. A review of the Bordetella molecular test records from March 29, 2021, revealed the laboratory general supervisor 1 failed to ensure the polymerase chain reaction (PCR) Ribonuclease P (RNase P) control was valid before reporting 4 out of 4 patient test results. 2. An interview on June 10, 2021 at 10:10 AM, with the general supervisor 1, confirmed the laboratory failed to ensure the Bordetella molecular test was valid before reporting patient test results.