Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D0644326	01/25/2023
Name of Provider or Supplier	**Street Address, City, State**	
Colorado Dept Of Public Health & Environment	8100 Lowry Blvd, Denver, CO	

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
D5002	BACTERIOLOGY CFR(s): 493.1201 If the laboratory provides services in the subspecialty of Bacteriology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1261, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on observations, record reviews, and interviews, the laboratory failed to ensure the microbioloigy department policies and procedures were reviewed and revised as stated in its policies and procedures (D5401), failed to discard expired media before patient testing (D5417), failed to perform a positive and negative quality control test for Carbapenem-Resistant Enterobacterales test (D5455), failed to perform a positive and negative quality control test for indole (D5471), failed to perform and document quality control testing that demonstrated growth (positive) or inhibition (negative) reactions for Acetate Differential Slant media (D5477), failed to document the lot numbers and expiration dates of reagents, dates of test performance, and identity of testing personnel for bacterial culture specimens (D5787), and failed to follow established quality assessment procedures for the microbiology department (D5791).
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 review of competency documentation and interview with the microbiology

	Technical Supervisor (TS), the laboratory failed to perform competency assessment for 1 of 2 microbiology testing personnel (TP) in 2022. The laboratory performs approximately 1877 MALDI mass spectrometer microbiological identification tests annually. Findings: 1. A review of personnel competency documentation revealed that no competency assessments were performed for TP 1 for the use of the MALDI mass spectrometer for microbiological identification in 2022. 2. On 1-23-2023, at approximately 2:10 PM, the TS 3 confirmed that competency assessment for TP 1 had not been completed.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on reviews of the laboratory procedure manuals, laboratory records, microbiology worksheets, and interviews with the Technical Supervisor (TS 3) and the Quality Assurance Coordinator, the laboratory failed to follow its written procedures for reviewing policies and procedures on an annual basis. The laboratory performed approximately 8,600 microbiology tests per year. Findings: 1. A review of the laboratory's procedure titled "Document Control" states "...Laboratory will review program documents on an annual basis." 2. A review of laboratory records titled "Overdue Micro Procedures and Micro Under Review Procedures" revealed that 29 of 39 microbiology SOPs failed to be reviewed and revised since the last survey conducted on 3-11-2021. 3. An interview on 1-25-2023, at around 10:00 AM, with the Quality Assurance Coordinator confirmed the laboratory failed to review and revise 29 microbiology SOPs since the last survey conducted on 3-11-2021. 4. A review of the laboratory's procedure titled "Data Review, Approval, and Reporting" states "... The data reviewer shall ensure that the data set references the unique identification of all reagents, media, and chemicals used. If data is missing or unacceptable, it shall be returned to the analyst for completion." 5. A review of the laboratory's microbiology worksheets revealed that the laboratory failed to record the unique identification of all reagents, media, and chemicals used. The laboratory failed to collect lot numbers, expiration dates, etc., and does not have a way to correlate patient test results with the specific supplies used for patient testing and quality control. 6. An interview on 1-23-2023, at around 10:15 AM, with TS 3 confirmed the laboratory did not record the unique identification of all reagents, media, and chemicals used on their microbiology worksheets.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on a direct observation and an interview with the microbiology Technical

	Supervisor (TS 3), the laboratory failed to discard laboratory supplies when they had exceeded their expiration date. The laboratory performed approximately 5,058 microbiology cultures annually. Findings: 1. An observation of the microbiology bench on 1-23-2023, at around 9:30 AM, revealed one sleeve of 10 plates of expired microbiology media, MacConkey agar (lot #514595) expired 12-29-2022. 2. An interview on 1-23-2023, at around 9:35 AM., with the TS 3 confirmed the media was expired and unable to confirm if the media was used for patient testing.
D5455	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(v)(g) 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-- At least once a day patient specimens are assayed or examined perform the following for-- Each molecular amplification procedure, include two control materials and, if reaction inhibition is a significant source of false negative results, a control material capable of detecting the inhibition. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a record review of the GeneXpert Cepheid Carbapenem-Resistant Enterobacterales (CRE) quality control test results, and an interview with the Technical Supervisor (TS 3), the laboratory failed to perform a positive and a negative quality control test for CRE prior to patient test results being reported. The laboratory performed approximately 10 CRE tests during November and December 2022. Findings: 1. A record review of the GeneXpert Cepheid Carbapenem-Resistant Enterobacterales (CRE) quality control test results revealed the laboratory failed to document positive and negative quality control test results during November and December 2022, prior to patient test results being reported. 2. An interview with the TS 3, on 1-24-2023, at approximately 1:30 PM, confirmed that the microbiology laboratory failed to perform and document quality control test results for the CRE test.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on an observation of the microbiology laboratory workbench, a record review of the microbiology laboratory quality control forms, and an interview with the Technical Supervisor (TS 3), the laboratory failed to perform a positive and a negative quality control test for Indole at least concurrent with patient testing. The laboratory performed approximately 2500 bacterial culture tests per year. Findings: 1. An observation of the microbiology workbench, on 1-24-2023, at 9:35 AM, revealed two opened boxes of BD BBL Indole droppers, lot numbers B01E206M and B05E111M,

	with no open dates indicated on the boxes or in laboratory records and which both failed to have positive and negative control tests performed and documented prior to patient test results reported. 2. A record review of the laboratory database where microbiology quality control results were recorded failed to show that quality control testing was performed and documented for the two lots of Indole. 3. An interview with the TS 3, on 1-24-2023, at approximately 10:00 AM, confirmed that the microbiology laboratory failed to perform and document quality control test results for Indole.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a record review of quality control logs and an interview with the Technical Supervisor (TS 3), the laboratory failed to perform and document quality control tests that demonstrated growth (positive) or inhibition (negative) reactions for one lot of Hardy Acetate Differential Slant media prior to patient test results being reported. The laboratory performed approximately 1050 bacterial culture tests for Escherichia coli and Shigella per year. Findings: 1. An observation of the microbiology workbench, on 1-24-2023, at 9:35 AM, revealed one lot of Hardy Acetate Differential Slant media, lot number 505121, opened on 1-10-2023, which failed to have positive and negative control tests performed and documented prior to patient test results being reported. 2. A record review of the laboratory database where microbiology quality control results were recorded failed to show that quality control testing for the Acetate media was performed and documented. 3. An interview with the TS 3, on 1-24-2023, at approximately 10:00 AM, confirmed that the microbiology laboratory failed to perform and document quality control test results for the Acetate media.
D5513	MYCOBACTERIOLOGY CFR(s): 493.1262(b)(c) (b) For antimycobacterial susceptibility tests, the laboratory must check each batch of media and each lot number and shipment of antimycobacterial agent(s) before, or concurrent with, initial use, using an appropriate control organism(s). (b)(1) The laboratory must establish limits for acceptable control results. (b)(2) Each week tests are performed, the laboratory must use the appropriate control organism(s) to check the procedure. (b)(3) The results for the control organism(s) must be within established limits before reporting patient results. (c) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a record review of quality control logs and an interview with the Technical Supervisor (TS 3), the laboratory failed to document the lot numbers, date opened,

	and expiration dates for the Flurochrome acid-fast quality control reagents used for mycobacterial smears from the dates reviewed 10-25-2022 through 12-13-2022. Findings: 1. A record review of the Fluorochrome Stain Quality Control results log revealed the laboratory failed to record or document the lot numbers, expiration dates, and the open dates of the acid-fast stain from 10-25-2022 through 12-13-2022. 2. An interview with the TS 3, on 1-24-2023, at approximately 1:30 PM, confirmed that the microbiology laboratory failed to document the acid-fast quality control reagent lot numbers and dates.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on a record review and an interview with the microbiology Technical Supervisor (TS 3), the laboratory failed to document the lot numbers and expiration dates of reagents, dates of test performance, and identity of testing personnel for 6 out of 6 bacterial culture worksheets reviewed from December 2022 through January 2023. Findings: 1. A record review of the Shigella Culture/Confirmation and Tuberculosis Culture Worksheets, revealed the laboratory culture worksheets failed to document testing personnel, dates of each test performed, and lot numbers and dates of reagents used for bacterial identification by culture for patient bacteriology specimens. 2. An interview with the microbiology TS 3, on 1-24-2023, at approximately 1:30 PM, confirmed the laboratory failed to document each step of testing for bacteriology cultures on the worksheets. This is a repeat deficiency from the last survey March 11, 2021.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of laboratory procedure manuals, quality control (QC) records, observations, and interviews with the Technical Supervisor (TS 3), the laboratory failed to follow established policies that monitor, assess, identify, and correct problems in the microbiology department analytic system. The laboratory performed approximately 8,600 microbiology tests per year. Findings: 1. A review of the microbiology laboratory policies revealed the laboratory failed to follow its policies to monitor the analytic testing systems in microbiology. 2. A review of QC records revealed that the laboratory failed to conduct quality control for Indole, Acetate Differential Slant media, and the GeneXpert Cepheid Carbapenem-Resistant

	Enterobacterales. (Cross refer D5455, D5471 and D5477) 3. An observation of expired MacConkey agar. (Cross refer D5417) 4. An observation of the failure to document the open and expiration dates of the acid-fast stain. (Cross refer D5513) 5. An interview on 1-25-2023, at around 10:15 AM, with TS 3, confirmed the laboratory failed to follow its procedures to monitor, identify and correct the analytic system issues in the microbiology department.