Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D0644326	11/29/2018
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
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, review of the quality assurance manual, and interview with the Scientific Director, the laboratory failed to follow written procedures for competency assessment in newborn screening (NBS) for seven of 10 employees in 2017 and 2018. Findings include: 1. Section 5.2 of the Quality Assurance manual states staff will be assessed annually for competency. 2. Review of personnel competency documentation revealed no competency was performed for Biotinidase in 2017, and for GSP, no assessment was performed from 6/30/17 and 9/30 /18 for the NBS technical supervisor. 3. Review of personnel competency documentation revealed no competency was performed for CF DNA in 2017, and for PKU and MS/MS, no assessment was performed from 7/31/17 and 10/31/18 for the general supervisor. 4. Review of personnel competency documentation revealed no competency was performed for Biotinidase and PKU in 2017, and for HPLC in 2018 for testing personnel 9. 5. Review of personnel competency documentation revealed no competency was performed for CF DNA in 2017, Biotinidase no assessment was performed from 6/22/17 and 10/31/18, and Hemaglobin IEF no assessment was performed from 8/14/17 and 11/16/18 for testing personnel 2. 6. Review of personnel competency documentation revealed no competency was performed for Biotinidase and GALT in 2017 for testing personnel 8. 7. Review of personnel competency documentation revealed no competency was performed from 3/17/17 and 9/19/18 for CF DNA and 2/23/17 and 5/11/18 for GSP for testing personnel 3. 8. Review of personnel competency documentation revealed no competency was performed for MS /MS in 2017, and for GALT, no assessment was performed from 7/11/17 and 10/2/18

	for testing personnel 4. 9. In an interview conducted on 11/27/2018 at approximately 2:00 PM, the Scientific Director confirmed the competency assessments mention above were not performed according to established policy.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of proficiency testing documentation (PT) and staff interview, the laboratory failed to evaluate CDC Newborn Screening Quality Assurance Program (NSQAP) proficiency testing results in a timely manner for four of four quarters in 2017, and two of four quarters in 2018 in newborn screening. Findings include: 1. 2017 NSQAP Quarter 1 PT specimens were tested on 1/25/17, results were received on 2/15/17, discrepancy report was initiated on 4/17/17, signed as reviewed by the program manager on 6/7/17, and signed by the laboratory director on 6/9/17. 2. 2017 NSQAP Quarter 2 PT specimens were tested on 4/3/17, results were received in June 2017, discrepancy report was initiated on 12/11/17, signed as reviewed by the program manager on 1/26/18, and signed by the scientific director on 5/21/18. 3. 2017 NSQAP Quarter 3 PT specimens were tested on 7/10/17, results were received on 9/30 /17, discrepancy report was initiated in January 2018, signed as reviewed by the quality manager on 4/27/18, and signed by the laboratory director on 5/22/18. 4. 2017 NSQAP Quarter 3 PT specimens were tested on 10/2/17, results were received on 11 /30/17, discrepancy report was initiated in November 2017, signed as reviewed by the program manager on 4/5/18, and signed by the laboratory director on 5/22/18. 5. 2018 NSQAP Quarter 1 PT specimens were tested on 1/10/18, results were received on 3/16 /11, signed as reviewed by the testing supervisor on 8/7/18, and signed by the laboratory director on 9/12/18. 6. 2018 NSQAP Quarter 2 PT specimens were tested on 4/30/18, results were received in July 2018, discrepancy report was initiated on 10 /15/18, and signed by the laboratory director on 10/23/18. 7. In an interview conducted on 11/28/2018 at approximately 11:00 AM, the Scientific Director confirmed the laboratory failed to evaluate the NBS proficiency testing results mentioned above in a timely manner.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of manufacture's storage requirements for reagents used in the Molecular testing laboratory, as well as staff interview, the laboratory failed to define an appropriate range for reagent storage. Findings include: 1. Review of manufacture's

	product insert for primers and probes used in molecular testing revealed the storage requirements to be less than or equal to -20C. 2. Review of temperatures logs for the following storage freezers revealed that reagents were only being stored at -15 or less but not achieving the required -20C. a. Instrument # MOLRFG02 - Refrigerator /Freezer Rm 137A b. Instrument # MOLRFG07- Fisher ISOTemp c. Instrument # MOLFRZ05 - Fisher ISO Temp 137A 3. In an interview conducted on 11/28/2018 at approximately 10:50 AM, the Molecular Testing Supervisor confirmed that this was an oversight by the laboratory and that Molecular primers and probes were not being stored at -20C or less.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: A. Based on the lack of documentation and staff interview, the maintenance on the EVOLIS test system in Serology was not performed as required by the manufacturer. Findings include: 1. Review of maintenance logs for 2018 revealed that weekly maintenance was not documented for 12 of approximately 43 weeks. 2. Review of the Evolis instrument manual indicated that weekly maintenance activities are required. 3. In an interview conducted on 11/27/2018 at approximately 3:00 PM, the Serology Testing Supervisor confirmed that weekly maintenance was sometimes missed on this testing platform. B. Based on lack of documentation, review of quality assurance manual and staff interview, the laboratory failed to define an instrument maintenance protocol for 1 of 2 microscopes used in Serology. Findings include: 1. Observation of the Zeiss D2 microscope revealed no maintenance documentation was available for 2017 or 2018 and no preventive maintenance service documentation was available for 2017. 2. Section 9.2 of the quality assurance manual states "Each program will have procedures for preventative maintenance to be performed on each piece of equipment and each instrument in use in the program." 3. In an interview conducted on 11/27 /2018 at approximately 11:10 AM, the Serology Testing Supervisor confirmed that there were no maintenance records for this microscope, as well as no documentation for the bulb replacement.
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 observation, record review, and personnel interview the laboratory failed to document corrective action each day the MSMS Instrument Room was out of acceptable range for humidity. Findings: 1. Observation of the MSMS Instrument Room on 11/28/2018 at 1:10 PM revealed that the room contained two Perkin Elmer Acquity Ultra Performance LC TQ Detector MSMS instruments. 2. A review of environmental documentation for the MSMS Instrument Room revealed that the laboratory had established an acceptable humidity range for the room of 20-80%. 3. A review of humidity documentation for the MSMS Instrument Room from January 1 through November 28, 2018 revealed 115 days when the humidity was recorded as below 20% with no documented corrective action. 4. An interview with the NBS Operations Manager on 11/28/2018 at 1:20 PM confirmed the above findings. 5. The laboratory runs approximately 70,000 patient samples per year on the MSMS instruments. 41087 Based on review of the room and equipment temperature logs in the Serology and Molecular testing laboratories and staff interview, temperatures were either not recorded or were out of range and no corrective action was documented. Findings include: 1. Review of the refrigerator temperature logs for the VWR refrigerator /freezer in Serology and used for storage of CT/GC testing reagents, revealed that the temperatures were documented as "NTP (No Testing Performed)" on 28 days in 2018 when testing reagents were being stored 2. In an interview conducted on 11/27/2018 at approximately 2:05 PM, the Serology testing supervisor confirmed that temperatures are not recorded on days when the testing person is not in the laboratory. 3. Review of the ambient temperature logs in the Molecular testing laboratory/Rm 135, revealed that the temperatures were out of the acceptable range for 37 of the last 90 days and no corrective action was documented. 4. In an interview conducted on 11/28/2018 at approximately 10:15 AM, the Molecular testing supervisor confirmed that temperatures and humidity are often out of range in this room and that no corrective action has been documented.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on review of the final test reports in Serology and staff interview, the laboratory failed to include a reference interval or normal values, which must be made available to the individuals responsible for using the test results. Findings include: 1. Review of final test reports for the following tests revealed that no normal values were available on the final test reports for the following tests. a. Rapid Plasma Ragin Ab b. Syphilis TPPA c. Fluorescent Treponemal Ab, FTA 2. In an interview conducted on 11/29/2018 at approximately 9:45 AM, the Scientific Director confirmed that these reports do not include the normal values.
D5821	TEST REPORT CFR(s): 493.1291(k) When errors in the reported patient test results are detected, the laboratory must do the following: (k)(1) Promptly notify the authorized person ordering the test and, if applicable, the individual using the test results of reporting errors. (k)(2) Issue corrected reports promptly to the authorized person ordering the test and, if

	applicable, the individual using the test results. (k)(3) Maintain duplicates of the original report, as well as the corrected report. This STANDARD is not met as evidenced by: Based on review of the amended test reports and staff interview, the laboratory failed to document the prompt notification to the authorized person ordering the test. Findings include: 1. Review off the amended test reports for 2018 revealed that there was no documentation of when or how the authorized person was notified, nor was there documentation of who performed the notification. 2. In an interview conducted on 11/29/2018 at approximately 10:35 AM, the Scientific Director confirmed that the laboratory does not document on the reports or on a separate log when or to whom the notification was given.