Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0660877	12/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Utah Public Health Laboratory	4431 South 2700 West, Taylorsville, UT	

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
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 the correct range for reagent storage. Findings include: 1. Review of the 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. Based on a review of the TempTrak logs the laboratory did not maintain reagents at the correct temperature for 90 of the last 90 days. Review of temperatures logs for the storage freezer in room 331D revealed that the following reagents were being stored at a range of -14 to -27. a. CDC Trioplex Primers and Probes b. CDC Influenza Primers and Probes c. Quanta Master Mix 3. In an interview conducted on 12/12/2018 at 9:30 AM, the Diagnostic Immunology technical supervisor confirmed that molecular primers and probes were not being stored at -20C or less.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) 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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on the lack of documentation and staff interview, there were no records of daily maintenance or day of use maintenance being performed in rooms 331D, 331C and 331B. Findings include: 1. Review of maintenance logs for 2018 revealed that daily maintenance was not documented from January through December of 2018 for the following: a. Eppendorf Thermometer b. Cleaning of lab surfaces c. pH Meter AR 81203613 d. Workstation #1 AC632LFUVC41907 e. Workstation #2 AC632LFUVC41906 f. Cleaning of centrifuges 1 (5417) and centrifuge 3(5424) g. QIACubes #1, #2 and #3 h. Eppendorf Thermomixers #1 and #3 i. ABI #1 275010887 j. ABI #2 275010869 k. ABI #3 275011115 2. Review of the maintenance logs also revealed that no monthly maintenance was recorded for March 2018 for all three rooms. 3. In an interview conducted on 12/12/2018 at 8:35 AM, the Diagnostic Immunology technical supervisor confirmed that daily maintenance was not recorded. Additionally, the technical supervisor stated that March 2018 monthly maintenance was not 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/Virology the laboratory failed to include a reference interval or normal value, 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 Reagin Ab b. Syphilis TPPA c. Influenza d. Chlamydia trachomastis e. Neisseria gonorrhea 2. In an interview conducted on 12/11/18 at 10:50 AM, both Serology/Virology technical supervisors 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 the laboratory failed to document the prompt notification to the authorized person ordering the test. Findings include: 1. Review of the amended test reports for Serology /Virology in 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. Call logs could not be found for lab number 1253158 and 1251385. 2. In an interview conducted on 12/11/2018 at 10:55 AM, both technical supervisors confirmed that the only instruction in the Comprehensive Quality Management Plan was to create a corrective action item for amended reports.