Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0660877	05/08/2025
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
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 review of personnel competency records, the laboratory's Quality Assurance policy, and interviews with the Technical Supervisor (TS) and Laboratory Director (LD), the laboratory failed to establish policies and procedures to assess the competency of General Supervisors (GS) and Clinical Consultants (CC) and failed to conduct required competency assessments for 1 of 6 General Supervisors for 2023, and for 4 of 4 Clinical Consultants for 2023 and 2024. Findings: 1. On 05/06/2025, review of competency records revealed the following: a. No documented competency assessment for GS#2 for calendar year 2023. b. No documented competency assessments for CC#1, CC#2, CC#3, or CC#4 for calendar years 2023 and 2024. 2. On 05/06/2025, review of the laboratory ' s 2024 Quality Assurance Comprehensive Policy, Section 2.4, Employee Training and Competency Assessment, indicated: a. "Every employee will be evaluated for competency by the TS or GS two times per year during the first year the employee is testing patient samples (semi-annual and one-year competency), and annually thereafter." b. "The LD will evaluate the competency of each TS annually by reviewing QA activities and documentation." The policy does not address competency assessment procedures for individuals serving as General Supervisors or Clinical Consultants. 3. On 05/06/2025, at approximately 2:50 pm, interviews with TS#4 and the LD (listed on the form CMS 209) confirmed the following: a. Competency assessments were not performed for GS#2 in 2023. b. Competency assessments were not performed for CC#1 through CC#4 in both 2023 and 2024. c. The laboratory ' s current Quality Assurance policy does not include procedures for assessing the competency of individuals serving as GS or CC.

D5305	TEST REQUEST CFR(s): 493.1241(c) (c) The laboratory must ensure the test requisition solicits the following information: (c)(1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (c)(2) The patient's name or unique patient identifier. (c)(3) The sex and age or date of birth of the patient. (c)(4) The test(s) to be performed. (c)(5) The source of the specimen, when appropriate. (c)(6) The date and, if appropriate, time of specimen collection. (c)(7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (c)(8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on a review of final patient test reports for HSV-1, HSV-2, and VZV multiplex PCR testing; the RealStar Alpha Herpes PCR laboratory policy; and an interview with the Technical Supervisor (TS), the laboratory failed to include required interpretive comments in patient reports for 256 of 256 HSV-1, HSV-2, and VZV multiplex PCR tests performed since 01/22/2025. Findings Included: 1. During a random review of final patient test reports on 05/08/2025, at approximately 12:00 pm from January, February, and May 2025, it was identified that reports for HSV-1, HSV-2, and VZV multiplex PCR testing lacked interpretive comments. 2. A review of the laboratory ' s RealStar Alpha Herpes PCR policy on 05/08/2025, at approximately 1:00 pm., Section E: Reportable Comments, revealed that the following interpretive statements are required for inclusion in test reports: For inconclusive results: a. "An inconclusive result may occur if a specimen is improperly collected, transported, stored, or handled. An inconclusive result may also occur if amplification inhibitors are present in the specimen; if inadequate numbers of organisms are present in the specimen; or if the infecting organism has genomic mutations, insertions, deletions, or rearrangements in the target region. Please resubmit." For all results: a. "A false negative result may occur if a specimen is improperly collected, transported, stored, or handled. A false negative result may occur if amplification inhibitors are present in the specimen; if inadequate numbers of organisms are present in the specimen; or if the infecting organism has genomic mutations, insertions, deletions, or rearrangements in the target region." b. "Utah Public Health Lab, which is authorized under the Clinical Laboratory Improvement Amendments (CLIA) to perform high-complexity testing, determined the performance characteristics of this test. It has not been approved by the U.S. Food and Drug Administration. The results of this test are not intended to be used as the sole means for clinical diagnosis or patient management." c. "This assay has only been evaluated for the diagnosis of HSV in cutaneous, genital, and rectal specimens. Diagnosis of HSV in other sites or tissues should not be based solely on assay results but should be considered in the context of patient symptoms and clinical presentation." 3. During an interview with TS#4 (listed on the form CMS 209), on 05 /08/2025, at approximately 2:50 pm, it was confirmed that the laboratory did not include the above required reporting comments in the HSV-1, HSV-2, and VZV multiplex PCR patient reports.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL

	CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on review of laboratory records, manufacturer instructions, the laboratory's online test menu for clients and interview with laboratory staff, the laboratory failed to have a system in place to ensure specimen integrity was maintained (transport conditions) for 2 of 2 specimens for virology testing. Findings included: 1. Review of patient test requisitions and test reports found the following specimens were received, tested and test results reported for Influenza virus PCR that failed to meet the manufacturer's transport temperature requirements, the laboratory's temperature requirements per their procedure and the temperature requirements specified in their online client services manual. a. NP (nasopharyngeal swab in VTM), accession #4005339, collected on 02/16/2025 and received on 02/19/2025. The temperature on receipt in laboratory was 12.2C. The test result was reported on 03/05/2025. b. NP (nasopharyngeal swab in VTM), accession #4006339, collected on 02/18/2025 and received on 02/25/2025. The temperature on receipt in laboratory was 13.1C. The test result was reported on 03/05/2025. c. Review of the Xpert Xpress CoV-2/Flu/RSV 302-8057, Rev. A, September 2023 instructions for use found the following: "12 Specimen Collection, Transport, and Storage Proper specimen collection, storage, and transport are critical to the performance of this test. Inadequate specimen collection, improper specimen handling and/or transport may yield a false result. Nasopharyngeal and anterior nasal swab specimens can be stored at room temperature (15-30 C) for up to 48 hours in VTM/UTM or eNAT until testing is performed on the GeneXpert Instrument Systems. Alternatively, nasopharyngeal and anterior nasal swab specimens can be stored refrigerated (2-8 C) up to seven days in viral transport medium ..." d. Review of the laboratory's procedure VIRO-1143 COVID Xpert Xpress COV-2 Flu RSV Assay, Version 1.4, approved 01/14/2025 found the following: "Specimen ... Storage ... "Nasopharyngeal and anterior nasal swab specimens can be stored at room temperature (15-30C) for up to 48 hours in VTM/UTM or eNAT ... "Nasopharyngeal and anterior nasal swab specimens in VTM/UTM can be stored at (2-8C) for up to 7 days until testing." e. Review of the laboratory's online test menu found the following: "Virology Influenza virus PCR Surveillance ....Processing ... Keep at 2-8C for up to 72 hours ...Transport ...Transport at 2-8C or if frozen, transport frozen (do not thaw)" 3. During interview on 05/07/2025 at approximately 12:20 pm., the Technical Supervisor for Virology (TS#7 listed on the form CMS 209) confirmed the two viral specimens received and tested were outside of the transport temperature. The laboratory failed to ensure specimens submitted for virology testing maintained transport temperatures specified by the manufacturer and required in their own policy. Word Key: VTM - Viral Transport Media UTM - Universal Transport Media eNAT - enhanced Nucleic Acid Transport PCR - polymerase chain reaction C - degree Celsius
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) (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 preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on observation, record review and staff interview, the laboratory's quality assessment policy failed to determine the laboratory used a frost free freezer to store patient specimens in the sample receiving area and failed to monitor the temperature of the frost free freezer for 3 of 3 years. Findings Included: 1. During a tour of the sample receiving area on 05/07/2025 at approximately 11:00 am, a freezer (Summit Commercial accucold, Model #AFS49ML, Serial #21100010) was observed. The Lead for Infectious Disease Sample Receiving stated the freezer stored frozen serums, specimens for SARS-CoV-2 sequencing, Influenza PCR and Influenza sequencing until the specimens were taken to the laboratory sections. The freezer had a laminated note taped to the door that stated the alarm will sound every 12 hours when the freezer enters a defrost cycle. 2. The freezer had a TempTrak sensor (#029141220) installed on 04/04/2022 to record the temperature measurements. The temperature range was set at -15C to -25C. 3. Review of the TempTrak temperature measurements for 4/30 /2025 thru 05/07/2025 revealed the temperature was out of range for the following date /times: 05/02/2025 at 3:45 am -13.3C 05/02/2025 at 3:30 am -13.7C 4. TempTrak temperature measurements were requested for October and November of 2024 but were not provided by the laboratory. During interview on 05/07/2025 at approximately 3:00 pm, the Technical Supervisor of Immunology (TS #5 listed on the form CMS 209) stated the TempTrak sensor on the sample receiving area freezer did not record temperature measurements from the time the sensor was installed on 04/04 /2022 until 04/30/2025. 5. Review of the instruction manual for the freezer found on page 10 the following: "6) How to Set Defrost Frequency ..." 6. Review of the laboratory's Quality Assurance policy, UPHL-QA-1 quality Assurance 2024 Comprehensive, Version 4.0 approved 09/05/2024 found the following on page 11: "3. PRE-ANALYTIC SYSTEMS a. Specimen Identification and Integrity" This section of the policy did not address monitoring temperatures in the sample receiving area. Word Key: C = degree Celsius PCR = Polymerase Chain Reaction
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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. This STANDARD is not met as evidenced by: I. Based on direct observation, interview with staff, review of temperature logs and review of the instrument operator's manual, the laboratory failed to ensure room temperature was within manufacturer's specifications for the Bruker MALDI Biotyper sample preparation area. Findings included: 1. One MALDI Bruker Biotyper Sirius CA analyzer was observed in enterics area during a tour of the Bacteriology laboratory (Room #339) at approximately 10:15 am on 05/07/2025. 2. During

	interview on 05/07/2025 at approximately 10:15 am, the Technical Supervisor of Bacteriology (TS #6 listed on form CMS 209) stated the sample preparation area for the MALDI plates took place on the enteric bench near the analyzer. 3. The operator manual for the Bruker MALDI Biotyper sirius CA analyzer stated the following: "2.4 Environmental Requirements - Sample Preparation ...Test organism samples intended to be analyzed in the MALDI Biotyper Sirius CA System must be prepared under the following conditions. +20C/+68F to +25C/+77F ...For best results, preparation of all solutions, Standard Solvent, and the entire sample preparation process including drying steps must be performed under controlled room temperature." 4. Review of the TempTrak room temperature logs for the enteric area indicated an acceptable room temperature of 16C - 26C. 5. Further review of the TempTrak room temperature logs for the enteric area found the room temperature out of range for 7 of 7 days reviewed. 04/05/ 2025 19.9C 04/12/2025 19.4C 04/13/2025 19.7C 04/26/2025 19.6C 04/27 /2025 19.4C 04/29/2025 19.8C 04/30/2025 19.8C II. Based on direct observation, record review and review of temperature logs, the laboratory failed to ensure temperatures in the laboratory met manufacturers' temperature requirements. 1. During the tour of the enterics area of Bacteriology laboratory (Room #339) on 05/07 /2025 at approximately 3:30 pm, the following was observed stored: a. On the counter, one open box of Remel RapID Inoculation Fluid, Lot #106479, Expiration 04 /02/2026, store at 20C - 25C. b. In a cabinet, one open box of Remel BactiDrop Oxidase reagent, Lot number 220098, Expiration 07/09/2026, store at 20C - 25C. 2. Review of the manufacturers' instructions for use found the following: a. Remel RapID Inoculation Fluid "Storage ...RapID Inoculation Fluid should be stored in the original container at room temperature (20-25C) until used." b. Remel BactiDrop Oxidase "Storage ...Store product in original container at 20-25C until used. Do not freeze or overheat. Protect from light." 3. Review of the TempTrak room temperature logs for the enteric area of the Bacteriology laboratory (Room #339) indicated an acceptable room temperature of 16C - 26C. 4. Further review of the TempTrak room temperature logs for the enteric area found the room temperature out of the manufacturers' temperature range for 7 of 7 days reviewed. 04/05/ 2025 19.9C 04/12 /2025 19.4C 04/13/2025 19.7C 04/26/2025 19.6C 04/27/2025 19.4C 04/29/2025 19.8 C 04/30/2025 19.8C III. Based on direct observation and review of temperature logs, the laboratory failed to ensure temperatures in the laboratory met manufacturer's temperature requirements for storage of antimicrobial susceptibility testing plates. 1. During the tour of the laboratory on 05/08/2025 at approximately 1 pm the following was observed: a. Stored in a hallway outside of Room #353D were approximately 15 boxes of Sensititre GN7F AST (antimicrobial susceptibility testing) plates, Lot #B5141, Expiration 03/31/2027, store at 15C - 25C. 2. The closest TempTrak sensor in was in the Virology area of the laboratory (Room #343), located several benches away from the hallway outside of Room #353D. 3. Review of the TempTrak room temperature logs for the Virology area indicated an acceptable room temperature of 16C - 26C.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) (b)(2)(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. (b)(2)(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 review of laboratory records, manufacturer's specifications, and interview with Technical Supervisor #3, the laboratory failed to have documentation of function checks for one Beckman coulter centrifuge located in the mycobacteriology Biosafety level (BSL-3) laboratory for one of one year reviewed. Findings Included: 1. In an interview with Technical Supervisor #3 on 05/08/205 at 02:31 pm stated that it was the laboratory's policy to have the centrifuged checked (by tachometer) by an outside company annually. 2. In review of the manufacturer's instructions for the Beckman Coulter Model J6-MI serial # CJE09803 states, "The following dynamic temperature calibration procedure will verify the accuracy of the temperature sensing and refrigeration systems. Perform this procedure when temperature control within +/- 1 degree C is required." 3.In review of the manufacturer's instructions for the Beckman Coulter Model J6-MI serial # CJE09803 states, " The speed control actual rotor speed will be with 20 RPM of set speed." 4. In review of the laboratory record #19250 Lab - inspection Workflow non-refrigeration (4) it did not have any documentation of 2024 temperature and rotational speed checks. The laboratory could not provide documentation of the Beckman Coulter CJE09803 centrifuge rotations (Tachometer) or temperature checks perform by the outside company in 2024. 5. In an interview with Technical Supervisor #3 (listed on the form CMS 209) on 05/08/2025 at 2:32 pm confirmed the laboratory did not have documentation for calibration of the centrifuge for thermometer or rotational speed used in the mycobacteriology BSL3 laboratory.
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. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory's quality assessment policy failed to determine the laboratory did not monitor or review TempTrack temperature measurements to ensure the room temperature was in range for clinical testing for 2 of 2 months. Findings Included: 1. Review of TempTrak temperature measurements for the room temperature of the virology and enteric laboratory areas for 2 of 2 months (4 /2025 and 5/2025) found the lower and upper limits were set at 16C and 26C, respectively. The limits do not meet the manufacturer's requirements for reagents stored in these areas nor the testing performed in these areas. See D5413. 2. On 05/08 /2025 at approximately 1:30 pm, the Technical Supervisor of Bacteriology (TS#6 listed on the form CMS 209) stated she did not review TempTrak temperature measurements. 3. On 05/08/2025 at approximately 2:05 pm, the Technical Supervisor of Bacteriology (TS#2 listed on form CMS 209) stated she did not review the TempTrak temperature measurements. 4. On 05/08/2025 at approximately 1:50 pm, the Technical Supervisor of Immunology (TS #4 listed on form CMS 209) stated the alarm on TempTrak sensor#198-156-092 for Refrigerator #1 was inactive on 1/28 /2025. The temperature measurements from 11:30 am - 2 pm ranged from -0.8C to 1.9 C. The temperature range for the refrigerator was set to 2C to 8C. 5. Review of the laboratory's Quality Assurance policy, UPHL-QA-1 quality Assurance 2024 Comprehensive, Version 4.0 approved 09/05/2024 found the following on page 15:

	"4.8 Test Systems, equipment, instruments Temperature, humidity, and water quality will be monitored where necessary, for storage of reagents, testing requirements, etc. according to SOPs."