Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	26D0667822	11/19/2020
Name of Provider or Supplier	**Street Address, City, State**	
Missouri State Public Health Lab	101 North Chestnut Street, Jefferson City, MO	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on review of four of ten proficiency testing (PT) records, review of the "Quality Systems Procedure" and interview with the laboratory director (LD), the LD failed to sign attestation statements for the specialties of virology and bacteriology performed from March 12, 2020 to December 1, 2020. Findings: 1. Review of PT attestation sheet records showed: The 1st Virology event of 2020 (VR1-A 2020), signed by TP #24. The 3rd Virology event of 2020 (VR1-C 2020), signed by TP #27. The 3rd Virology event of 2020 (VR4-C 2020); signed by TP #27 and the 3rd Bacteriology event of 2020 (HC6-C 2020); signed by laboratory staff not listed on form CMS-209. 2. Review of the "Quality Systems Procedure" stated "All proficiency tests are reviewed and signed by the Laboratory Director and CLIA Director." 3. In an interview conducted on November 19, 2020 at approximately 2:15 P.M. the LD confirmed she failed to sign the attestation statements.
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 personnel competency records, procedure manual, and staff interview, the laboratory failed to ensure 17 of 17 general supervisory (GS) and six of six technical supervisor (TS) competency assessments included specific position responsibilities listed in Subpart M. Findings: 1. Personnel competency records failed to include documentation of evaluations of specific GS and TS responsibilities besides duties related to patient testing and/or report patient test results. 2. Review of the procedure manual revealed a lack of written policies and procedures to assess employees in the position of technical and general supervisor positions. 3. In an interview conducted on 11/18/2020 at approximately 2:30 P.M. the LD confirmed that competency assessments for GS and TS failed to include specific position responsibilities.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the procedure manual for COVID-19 PCR testing and interview with the laboratory director, the laboratory failed to include a specimen acceptability and rejection procedure. Findings: 1. No procedure was available for review for specimen acceptability and rejection for COVID-19 testing. 2. Interview with the laboratory director on November 19, 2020 at 10:00 AM confirmed the laboratory failed to include a specimen acceptability and rejection procedure for COVID-19 PCR testing.
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 observation of the molecular and chemistry rooms, review of manufacturer inserts and the Quality Assurance Manual, and interview with technical supervisors (TS) #1, #2, the laboratory failed to monitor the temperature and humidity to ensure proper operation of instrumentation. Findings: 1. Observation of the molecular areas used for PCR testing showed the laboratory failed to monitor and document the room temperature and humidity. 2. Review of the Applied Biosystems 7500 Fast DX used for PCR testing revealed a "temperature range of 15-30 degrees Celsius with 20-80 percent relative humidity noncondensing." 3. Review of the Quality Assurance Manual stated "environmental conditions are established and monitored." 4. Observation of the chemistry room showed the laboratory failed to monitor and document the humidity. 5. Review of the Perkin Elmer 600 manufacturer insert revealed "an ambient relative humidity of 20-80 percent, without condensation." 6. Interview with the TS #1, #2 confirmed the laboratory failed to monitor the room temperature and humidity in the molecular laboratory rooms and failed to monitor the humidity in the chemistry laboratory room.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the microbiology staining areas and interview with the laboratory director, the laboratory failed to document the preparation and expiration dates of the reagents used in staining procedures. Findings: 1. Observation of the microbiology staining areas showed containers of stain with no preparation or expiration dates. 2. Interview with the laboratory director on November 19, 2020 at 10: 00 AM confirmed the laboratory failed to identify staining material with preparation and expiration dates.