Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2086447	05/23/2024
Name of Provider or Supplier	**Street Address, City, State**	
Physician Laboratory Services	2051 E Red Hills Parkway, Suite 7, St George, 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 record review of personnel competency documentation and interview with the general supervisor (GS), the laboratory failed to establish and follow written policies and procedures to assess competency testing for one of one technical supervisors (TS) and one of one general supervisors (GS), since the last survey was conducted on 02/10/2021. Findings: 1. Review of personnel competency documentation revealed the laboratory failed establish and follow written policies and procedures to assess competency for the positions of TS and GS since the last survey was conducted on 20/10/2021. 2. Interview with the GS on May 23, 2024, at 11:10 AM confirmed the laboratory failed to document competency for one of one TS and one of one GS for 2021, 2022, 2023, and 2024.
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 a review of the laboratory procedure manual and an interview with the technical supervisor (TS), the laboratory failed to include imminently life-threatening test results, or panic or alert values in their procedure manual. The laboratory performs approximately 230,000 tests a year. Findings include: 1. Review of the laboratory procedure manual revealed a lack of imminently life-threatening test results, or panic or alert values. 2. Interview with the TS on 05/23/2024 at 2:35 PM confirmed the laboratory failed to include imminently life-threatening test results, or panic or alert values their laboratory procedure manual.
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 document review, direct observation, and interview with the technical supervisor (TS), room temperature and humidity of the laboratory was not monitored and documented since the last survey conducted on 02/10/2021. The laboratory performed approximately 230,000 tests annually. Findings include: 1. Document review of the Pentra 400 Users Manual revealed the chemistry analyzer required an operating environment between 15C to 32C and relative humidity between 20 and 85%. 2. Document review of the MICROS ES60/ESV60 Technical Manual revealed the hematology analyzer required an operating environment between 16C to 30C and maximum relative humidity of 85% without condensation. 3. Direct observation of the laboratory on 05/23/2024 at 12:50 PM failed to locate a thermometer, hygrometer, and a laboratory conditions log. 3. In an interview on 05/23/2024 at 12:55 PM, TS confirmed room temperature and humidity were not monitored and documented for Pentra 400 and Micros ES 60 analyzers.