Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	16D0709302	01/11/2023
Name of Provider or Supplier	**Street Address, City, State**	
State Hygienic Laboratory	2220 South Ankeny Blvd, Iowa Lab Facility, Ankeny, IA	

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 the procedure manual, competency documentation, and interview with the laboratory director (LD), the laboratory failed to have a policy and perform competency evaluations for 12 of 12 technical supervisor (TS) and 4 of 4 general supervisor (GS) positions for 2021 and 2022. Findings: 1. Review of the procedure manual revealed a lack of written policies and procedures to assess employees in the positions of TS and GS. 2. Review of 2021 and 2022 competency documentation revealed the laboratory failed to perform 12 of 12 assessments for the position of TS and 4 of 4 assessments for the position of GS. 3. Interview with the LD on January 10, 2023, at 3:00 PM confirmed the laboratory failed to have written policies and perform annual competencies for 2021 and 2022 for the positions of TS and GS.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

	This STANDARD is not met as evidenced by: Based on a review of the blood lead procedure, patient volumes, and interview with the laboratory director (LD), the laboratory failed to establish written criteria for the acceptability of blood lead quality control (QC). Findings: 1. Review of the procedure, "Trace Elements in Whole Blood Using ICPMS" revealed a lack of written criteria for the acceptability of control materials. 2. Interview with the LD on January 11, 2023, at 12:00 PM confirmed the laboratory failed to have a written procedure for acceptability of blood lead QC. 3. The laboratory reported approximately 6000 blood lead results annually.
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 procedure manual and interview with the laboratory director (LD), the laboratory failed to have a step-by-step procedure for instrument comparisons. Findings: 1. Review of the procedure manual showed no procedure for instument comparisons to include instrument acceptable variation. 2. Interview on January 10, 2023 at 3:00 pm with the LD, confirmed that the laboratory failed to have a step-by-step procedure for instument comparisons.
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 the Wisconsin State Laboratory of Hygiene manufacturer's insert for blood metals quality control (QC), observation of one of one freezer, review of patient results, and interview with the laboratory director (LD), the laboratory failed to monitor and document the freezer for proper storage of QC. Findings: 1. Review of the Wisconsin State Laboratory of Hygiene manufacturer's inserts for blood lead QC showed to store the controls at less than or equal to minus 20 degrees Celsius. 2. Observation of the freezer located in the blood lead laboratory showed no temperature monitoring for proper storage of blood lead QC. 3. Interview with the LD on January 11, 2023, at 12:00 PM confirmed the laboratory failed to monitor and document the freezer temperature for proper storage of blood lead QC. 4. The laboratory reports approximately 6000 blood lead patient results annually. 47517 Based on review of Applied Biosystems ViiA7, QuantStudio 5 and 7, MiniAmp Thermal Cycler manufacturer's inserts, room temperature and humidity logs, and interview with laboratory staff, the laboratory failed to monitor and document the humidity of the laboratory. Findings: 1. Review of the Applied Biosystems ViiA7 manufacturer's insert for performance specifications revealed to operate the analyzer in 20-80% relative humidity, noncondensing. 2. Review of the QuantStudio 5 and 7 manufacturer's insert for performance specifications revealed to operate the analyzer in 15-80% relative humidity, noncondensing. 3. Review of the MiniAmp Thermal Cycler mMiniAmp Thermal Cycler manufacture's insert for performance specifications revealed to operate the analyzer in 15-80% relative humidity, noncondensing. 4. Review of the room temperature and humidity documentation logs showed the laboratory failed to document humidity in 3 of 3 rooms in the molecular department. 5. Interview with the technical supervisor #1 on January 10, 2023 at 1:30 PM confirmed the laboratory failed to document the room humidity in the laboratory where the Applied Biosystems ViiA7, QuantStudio 5 and 7, and MiniAmp Thermal Cycler were in operation.