

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D2222261	(X3) Date Survey Completed 01/11/2023
Name of Provider or Supplier State Hygienic Laboratory	Street Address, City, State Ia Lab Facility - Biomonitoring Program, 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	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure manual, competency documentation, patient results, and interviews with the technical supervisors (TS) #1, #2, the laboratory failed to have a policy and perform competency evaluations for two of two TS for 2021 and 2022. Findings: 1. Review of the procedure manual revealed a lack of written policies and procedures to assess employees in the position of TS. 2. Review of 2021 and 2022 competency documentation revealed the laboratory failed to perform two of two assessments for the position of TS. 3. Interview with the TS #1, #2 on January 11, 2023 at 12:00 PM confirmed the laboratory failed to have written policies and perform annual competencies for 2021 and 2022 for the positions of TS.</p>
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the technical supervisors</p>

(TS) #1, #2, the laboratory failed to establish written criteria for acceptability of quality control (QC) for urine toxicology. Findings: 1. Review of the procedure, "Trace Elements in Urine Using ICP-MS" revealed a lack of written criteria for the acceptability of QC. 2. Interview with the TS #1, #2 on January 11, 2023 at 12:00 PM confirmed the laboratory failed to have a written procedure for acceptability of QC for trace elements in urine. 3. The laboratory reports out approximately 1000 patient results for trace elements in urine annually.