

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 16D0709302	(X3) Date Survey Completed 05/29/2025
Name of Provider or Supplier State Hygienic Laboratory	Street Address, City, State 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
D0000	An onsite recertification survey was conducted on May 28, 2025 through May 29, 2025 and standard level deficiencies were identified.
D5311	<p>SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory's client service manual, patient request forms, patient test reports, and interview with general supervisor #5 (GS# 5) and technical supervisor #5 (TS# 5), the laboratory failed to ensure specimen acceptability for five of 19 patient Blood Lead tests. Findings include: 1. On 05/28/25 at 12:30 pm, GS #5 confirmed the laboratory performed blood lead testing using the PerkinElmer NexION 300 ICP-MS (Inductively Coupled Plasma Mass Spectrometry). 2. The laboratory's client service manual stated, "Temperature and Stability: Room Temperature, stable for 3-5 Days". 3. Review of the laboratory's "Blood Lead Test Request Form" revealed the laboratory failed to ensure specimen acceptability beyond the five days of stability for five of 19 patients as follows: a. Patient# 2639507 - specimen collected on 05/06/25, received into the laboratory on 05/19/25 (13 days later), and reported on 05/27/25 b. Patient# 2640944 - specimen collected on 05/15/25, received into the laboratory on 05/21/25 (6 days later), and reported on 05/27/25 c. Patient# 2641905 - specimen collected on 05/16/25, received into the laboratory on 05/22/25 (6 days later), and reported on 05/27/25 d. Patient# 2641906 - specimen collected on 05/16/25, received into the</p>

laboratory on 05/22/25 (6 days later), and reported on 05/27/25 e. Patient# 2641907 - specimen collected on 05/16/25, received into the laboratory on 05/22/25 (6 days later), and reported on 05/27/25 4. Interview on 05/28/25 at 02:00 pm with TS #5 confirmed the findings above. 5. Laboratory performs 3,700 lead tests annually.

D5401

PROCEDURE MANUAL

CFR(s): 493.1251(a)

(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 written policy and procedure, observation, and interview with general supervisor #5 (GS# 5) and technical supervisor #5 (TS # 5), the laboratory failed to follow written laboratory procedure for an expiration date for one of one bottle of Blood Metals Intermediate Standards. Findings include: 1. On 05/28/29 at 12:30 pm, GS #5 confirmed the following: a. The laboratory performed blood lead testing using the PerkinElmer NexION 300 ICP-MS (Inductively Coupled Plasma Mass Spectrometry). b. Blood Metals Intermediate Standards HPS (High Purity Standard) lot# CTA 001401 was used for patient testing to ensure accurate analysis of metals in blood samples. 2. Review of the laboratory's written policy and procedure titled, "Trace Elements in Whole Blood Using ICPMS" section, "8.3.1" stated, the Blood Metals Intermediate Standards HPS "...expires six months from date of preparation". 3. Observation on 05/28/25 at 12:15 pm of one bottle of Blood Metals Intermediate Standards HPS lot# CTA 001401 revealed a preparation date of 03/27/25 and expiration date of 03/27/26, 12 months later (not the required 6 months). 4. Interview on 05/28/25 at 02:13 pm with TS #5 confirmed the findings above. 5. Laboratory performs 3,700 lead tests annually.

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, review of manufacturer's instructions, temperature and humidity records, and interviews with the Technical Supervisor (TS) and Quality Assurance (QA) Manager, the laboratory failed to monitor and document humidity levels for Room D129 and failed to establish acceptable temperature ranges for Rooms D129 and D121, where newborn screening and mass spectrometry testing were performed. Findings: 1. During a facility tour of the newborn screening main room (Room D129) on May 28, 2025, at approximately 10:30 AM, the following

instruments were observed: -Four Revvity Genetic Screening Processor (GSP) analyzers -Two Revvity Victor2 D instruments -Four Revvity Migele Gel Electrophoresis units -One Bio-Rad Variant NBS analyzer During a facility tour of the mass spectrometry room (Room D121) on May 28, 2025, at approximately 11:00 AM, the following instruments were observed: -Three Waters Xevo TQ-S Micro Triple Quadrupole Mass Spectrometers -One Tecan Fluent Liquid Handler 2. Review of the manufacturer's instructions indicated the following temperature and relative humidity requirements: Revvity Migele Electrophoresis Unit: temperature 18 - 30 C, humidity (non-condensing) 20-80% Bio-Rad Variant NBS analyzer: temperature 18 - 30 C, humidity (non-condensing) 10-90% Revvity GSP analyzer: temperature 18 - 30C, relative humidity 10-80% Revvity Victor2 D instrument: temperature 15 - 30 C, relative humidity 10-85% Waters Xevo TQ-S Micro Mass Spectrometer: temperature 15 - 28 C, relative humidity 20-80% Tecan Fluent Liquid Handler: temperature 15 - 32C, relative humidity 30-80% 3. Review of the humidity log for room D129 on May 29, 2025, at approximately 11:00 AM, for the months of January, February, and March 2025, revealed that humidity levels were not documented on 29 of the 92 days reviewed. 4. Review of temperature records for rooms D129 and D121 on May 29, 2025, at approximately 12:00 PM, for the year 2025, revealed that the laboratory had not established acceptable temperature ranges for either room, both of which were used for newborn testing. 5. During an interview conducted on May 29, 2025, at approximately 1:40 PM, TS #2 and the QA Manager confirmed that the laboratory had not documented humidity levels for room D129 on multiple days between January and March 2025, and had not established temperature ranges for rooms D129 and D121. 6. The laboratory performed approximately 70,000 newborn screening tests and approximately 50,000 neonatal mass spectrometry test per year. 47272 II. Based on review of written policy and procedure, observation, environmental records, and interview with general supervisor #5 (GS# 5) and technical supervisor #5 (TS# 5), the laboratory failed to ensure quality control (QC) materials were being stored as required for one of one QC lot for 18 of 18 days. Findings include: 1. On 05/28/25 at 12:30 pm, GS #5 confirmed the following: a. The laboratory performed blood lead testing using the PerkinElmer NexION 300 ICP-MS (Inductively Coupled Plasma Mass Spectrometry) b. Three levels (low, medium, high) of CDC (Centers for Disease Control and Prevention) lot#013 QC (Quality Control) were analyzed each day of patient testing. 2. Review of the laboratory's written policy and procedure titled, "Trace Elements in Whole Blood Using ICPMS" section, "11. Quality Control/Quality Checks" stated, "QC Material storage" bulk aliquots are stored at -80C and the working aliquot is stored at 2-6C." 3. Observation on 05/28/25 at 02:10 pm, revealed three levels (low, medium, high) of CDC lot#013 QC bulk aliquots stored in "REES 15" freezer. 4. Record review of May 2025 "REES 15" freezer documented temperatures revealed temperatures warmer than -80C for 18 of 18 days: a. 05/01/25 documented temperature -75.0C b. 05/02/25 documented temperature -75.4C c. 05/05/25 documented temperature -75.1C d. 05/06/25 documented temperature -74.7C e. 05/07/25 documented temperature -75.4C f. 05/08/25 documented temperature -75.3C g. 05/09/25 documented temperature -74.8C h. 05/12/25 documented temperature -75.3 C i. 05/13/25 documented temperature -74.8C j. 05/14/25 documented temperature -75.3C k. 05/15/25 documented temperature -75.1C l. 05/16/25 documented temperature -75.0C m. 05/19/25 documented temperature -74.7C n. 05/20/25 documented temperature -75.2C o. 05/21/25 documented temperature -74.8C p. 05/22/25 documented temperature -75.1C q. 05/23/25 documented temperature -75.1C r. 05/27/25 documented temperature -75.3C 5. Interview on 05/28/25 at 02:00 pm with TS #5 confirmed the findings above. 6. Laboratory performs 3,700 lead tests annually

D5415

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(c)

(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.

This STANDARD is not met as evidenced by:

I. Based on direct observation and interview with the Technical Supervisor (TS), the laboratory failed to assign an expiration date to two of two boxes of Revvity Lysophosphatidylcholine Internal Standard (LysoPC IS) used in X-linked Adrenoleukodystrophy (X-ALD) testing. Findings: 1. During a facility tour of the mass spectrometry room (Room D121) on May 28, 2025, at approximately 11:00 AM, a freezer was observed containing two boxes, each holding five vials of LysoPC IS (Lot #754141), used in X-ALD testing. Neither box was labeled with an expiration date assigned by the manufacturer or the laboratory. 2. During an interview conducted on May 29, 2025, at approximately 1:40 PM, TS #2 confirmed that the laboratory had not assigned an expiration date to the LysoPC IS used for X-ALD testing. 3. The laboratory performed approximately 50,000 X-ALD tests per year. 47272 II. Based on observation and interview with general supervisor #10 (GS #10) and technical supervisor #5 (TS #5), the laboratory failed to document the expiration date for one of one quality control vials. Findings include: 1. On 05/28/29 at 12:30 pm, GS #5 confirmed the following: a. The laboratory performed blood lead testing using the PerkinElmer NexION 300 ICP-MS (Inductively Coupled Plasma Mass Spectrometry) b. Three levels of CDC (Centers for Disease Control and Prevention) QC (Quality Control) were analyzed each day of patient testing. 2. Observation on 05/28/25 at 02:10 pm, revealed no expiration date for the CDC QC material in use for the following: a. Low control lot# 013 put into use on 08/22/22 b. Medium control lot# 013 put into use on 08/22/22 c. High control lot# 013 put into use on 08/22/22 3. Interview with TS #5 on 05/28/25 at 02:16 pm confirmed the findings above. 4. Laboratory performs 3,700 lead tests annually.

D5775

COMPARISON OF TEST RESULTS

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

This STANDARD is not met as evidenced by:

Based on direct observation, review of instrument comparison records, and interview with the Technical Supervisor (TS), the laboratory failed to perform biannual evaluations to establish and document the relationship between four out of four Revvity Migele Gel Electrophoresis units. These instruments have been in use since July 2024. Findings: 1. During a facility tour of room D129 on May 28, 2025, at approximately 11:00 AM, four Revvity Migele Gel Electrophoresis units were observed in use. The serial numbers of the instruments were: 21180311, 21180315, 21180316, and 21180318. 2. Review of instrument comparison records on May 29, 2025, at approximately 9:00 AM, revealed no documentation of instrument

comparisons for the four Revvity Migele Gel Electrophoresis units. 3. During an interview conducted on May 29, 2025, at approximately 9:40 AM, TS #2 confirmed that instrument comparisons had not been performed for the four Revvity Migele Gel Electrophoresis units since they were first placed into service in July 2024. 4. The laboratory reports performing approximately 70,000 hemoglobing by isoelectric focusing (IEF) tests per year.

D5807

TEST REPORT
CFR(s): 493.1291(d)

(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.

This STANDARD is not met as evidenced by:
Based on review of a written policy and procedure, patient reports, and interview with general supervisor #5 (GS #5) and technical supervisor #6 (TS #6), the laboratory failed to provide an a reference interval according to their own policy for six of six patient test reports. Findings include: 1. On 05/28/29 at 12:30 pm, GS #5 confirmed the laboratory performed blood lead testing using the PerkinElmer NexION 300 ICP-MS (Inductively Coupled Plasma Mass Spectrometry). 2. Review of the laboratory's written policy and procedure titled, "Trace Elements in Whole Blood Using ICPMS" included a normal reference range of "0-3.5 g/dL". 3. On 05/28/25, a review of six patient reports analyzed on 05/22/2025 and reported on 05/27/25 revealed, "The current blood lead test reference range is 0-4 g/dL" a. Patient #2639504 b. Patient #2639507 c. Patient #2641907 d. Patient #2641905 e. Patient #2641906 f. Patient #2640944 4. Interview on 05/28/25 at 03:30 pm with TS #6 confirmed the findings above. 5. Laboratory performs 3,700 lead tests annually.