Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 17D0648254	(X3) Date Survey Completed 07/03/2025
Name of Provider or Supplier Kansas Health And Environmental Lab	**Street Address, City, State** 6810 Se Dwight Street, Topeka, KS	
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	A recertification survey was conducted 07/01/2025 through 07/03/2025. Standard level deficiencies were cited.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) (b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's CLIA Quality Assurance Plan, Proficiency Test (PT) records review and interview with the Bacteriology Technical Supervisor (TS1) #1 on page 2, of the Form CMS-209, the Laboratory Director (LD) failed to attest PT samples were integrated into routine patient workload using routine laboratory methods for four of four PT records. Findings included: 1. A review of the laboratory's CLIA Quality Assurance Plan, page 7, section 12.2 revealed the following statement: "Sign the attestation statement that proficiency testing samples were tested in the same manner as patient specimens with a signature block to be completed by the individual performing the test as well as the laboratory director." 2. A review of the following PT records revealed there were no attestations by the LD: a. CDC LRN Poxvirus 2023 (Poxviruses-Laboratory Testing) b. 2024 EDLB Reference Laboratories Quality Assurance Panel i. Campylobacter Panel ii. Escherichia/Shigella Panel iii. Salmonella Panel iv. Vibrionaceae and Enterobacterales panel c. CDC LRN 2024 BP1-A (Multiple Agent) d. CDC 2024 WN IgM ELISA and WN/SLE IgM MIA, Kit Lot: 2024 3. An interview with the TS1 on 07/02/2025 at 11:07 AM confirmed four of four PT records reviewed did not have LD attestations.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)

	The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on Proficiency Test (PT) records review and interview with the Bacteriology Technical Supervisor (TS1) #1 on page 2, of the Form CMS-209, the laboratory failed to evaluate one of one PT results. Findings included: 1. A review of the College of American Pathologist (CAP) PT, D-C 2024 Bacteriology Survey revealed no documentation (signature) of evaluating the PT results. 2. An interview with the TS1 on 07/02/2025 at 3:07 PM confirmed the laboratory failed to evaluate one of one PT results from CAP.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by: Based on review of the laboratory's enrolled Proficiency Testing (PT) Program instructions, PT records review and interview with the Bacteriology Technical Supervisor (TS1) #1 on page 2, of the Form CMS-209, the laboratory failed to verify the accuracy of PT scores that did not reflect the laboratory's test performance for four of four PT events. Findings included: 1. A review of the following PT program evaluations revealed the exception reason code [26] = Educational Challenge: a. D-C 2023 Bacteriology Survey Test method, MIC Educational b. D-B 2024 Bacteriology Survey Test method, MIC Educational c. D-C 2024 Bacteriology Survey Test method, MIC Educational d. LPX-A 2024 Laboratory Preparedness Exercise Test Method, LRN Reference Lab 2. A review of the laboratory's College of American Pathologist (CAP) PT program instructions revealed the following statement: "The CAP uses exception reason codes that signify the PT for an analyte has not been graded ... Your laboratory must identify all analytes with an exception reason code, review, and document the acceptability of performance as outlined below and retain documentation for review for at least 2 years." "Code [26], Educational Challenge, Review participant summary for comparative results and document performance accordingly. Evaluation criteria are not established for educational challenges. Laboratories should determine their own evaluation criteria approved by their laboratory director for self-evaluation." 3. An interview with the TS1 on 07/02/2025 at 3:10 PM confirmed the laboratory failed to evaluate, compare, and document the acceptability of performance for analytes with an educational challenge [26] exception reason codes for four of four PT events.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (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. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, the laboratory's online client service manual, laboratory specimen submission forms, patient test reports, and interview with technical supervisor #1 (TS #1), the laboratory failed to define specimen shipment temperature criteria for Shigella testing for two of two patient specimens. Findings included: 1. Review of the laboratory's microbiology procedures revealed the laboratory performed Shigella testing on stool specimens received in Cary Blair transport media. 2. The laboratory's online client service manual titled, "Microbiology Specimen Submission Guidelines", section, "Specimen Shipping Guidelines", stated, "Stool ... Bacteriology Confirmation (E. coli 0157, STEC, Salmonella, Shigella, Other) ... Ship cold (ideal) or at room temperature in an Enteric with Cary Blair mailer with a Biological Substance, Category B - Enteric/Misc Bacterial shipping label." The instructions failed to provide specific temperature criteria for "cold" and for "room temperature". 3. Review of laboratory specimen submission forms for Shigella testing and final patient test reports revealed the laboratory received, tested and reported results for two specimens for Shigella testing and failed to document shipment disposition (or temperature) for the specimens: a. Patient 2740849 - specimen collected on 06/25/24, received into the laboratory on 06/28/24, and reported on 07/09/24 b. Patient 2799174 - specimen collected on 07/03/24, received into the laboratory on 07/05/24, and reported on 07/09/24 4. In an interview on 07/02/25 at 02:30 pm, TS #1 confirmed the above findings.
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 in the Toxicology Rooms 241 and 241B, a review of Gas Chromatography Mass Spec (GCMS) operators manuals, a review of the room temperature/humidity records, and an interview with the Toxicology General Supervisor (GS1) #1 on page 1, of the Form CMS-209, the laboratory failed to ensure operating temperature and humidity ranges were within the instrument manufacturer's specifications for 12 out of 57 test days (room temperature) and 13 out of 57 test days (room humidity). Findings included: 1. During a tour of the Toxicology rooms 241 and 241B on 07/02/2025 at 1:30 PM, the following four instruments were observed: a. Shimadzu GCMS, System ID: GCMS-4 b. Agilent GCMS, 5977B, System ID: GCMS-5 c. Agilent GCMS, 5977C, System ID: GCMS-6 d. Beckman Coulter Biomek Automated Workstation 2. Review of the manufactures operating manual for

	the four instruments mentioned above stated the following temperature and humidity specifications: Room 241 (Instrument room) a. Shimadzu GCMS, temperature range = 18C to 28C, humidity range = 40% to 70% b. Agilent GCMS, temperature range = 15C to 35C, humidity range = 20% to 80% Room 241B (Prep lab) c. Beckman Coulter Biomek Automated Workstation, temperature range = 10C to 30C, humidity range = 20% to 85% 3. Review of the room temperature/humidity records revealed there were no normal room temperature and % humidity ranges set for both rooms 241 and 241B. a. Records for room 241 showed: i. 2 out of 57 test days, room temperature was out of the Shimadzu manufacturer's required temperature range of 18C to 28C. 04/15/2025: Temperature = 17.6C 04/21/2025: Temperature = 17.9C ii. 5 out of 57 test days, the room temperature was not recorded (missed). Missed temperature dates: 04/14/2025 04/24/2025 04/25/2025 05/07/2025 05/22/2025 iii. 3 out of 57 test days, room % humidity was out of the Shimadzu manufacturer's required room humidity range of 40% to 70%. 04/11/2025: Humidity = 34% 05/05 /2025: Humidity = 36% 05/21/2025: Humidity = 37% iv. 5 out of 57 test days, room % humidity was not recorded (missed). Missed humidity dates: 04/14/2025 04/24 /2025 04/25/2025 05/07/2025 05/22/2025 b. Records for room 241B showed: i. 5 out of 57 test days, room temperature and % humidity was not recorded (missed). Missed temperature and humidity dates: 04/14/2025 04/24/2025 04/25/2025 05/07/2025 05/22 /2025 4. An interview with the GS1 on 07/02/2025 at 2:20 pm confirmed the laboratory failed to ensure operating temperature and humidity ranges were within the instrument manufacturer's specifications for 12 out of 57 test days (room temperature) and 13 out of 57 test days (room humidity). 47272 II. Based on manufacturer's instructions, freezer temperature records, and interview with technical supervisor #1 (TS #1), the laboratory failed to store Oxoid Meropenem Antimicrobial Susceptibility Test Discs as required by the manufacturer for five or five days. Findings include: 1. On 07/02/25 at 01:00 pm, TS #1 confirmed the laboratory used Oxoid Meropenem Antimicrobial Susceptibility Test (AST) Discs as part of Carbapenem Resistant Organisms (CRO) testing. 2. On 07/02/25 at 01:10 pm, TS #1 confirmed the laboratory stored the Oxoid Meropenem AST Discs in the laboratory's CM freezer (sensor# 5600000E22BBE328-1). 3. Review of the manufacturer's instructions under section, "Shelf-life and Storage Conditions", stated, "Unopened cartridges of Oxoid Meropenem AST discs have a shelf-life of 12 months if stored under the recommended conditions. Unopened cartridges must be stored at -20 to 8C, until required." 4. Review of CM freezer temperature records from 06/01/25 through 06/05 /25 revealed the laboratory failed to store the Oxoid Meropenem Antimicrobial Susceptibility Test Discs as required by the manufacturer for five or five days. a. 06/01 /25 documented temperature -20.17C b. 06/02/25 documented temperature-20.30C c. 06/03/25 documented temperature -20.23C d. 06/04/25 documented temperature -20.23C e. 06/05/25 documented temperature -20.17C 5. Interview on 07/02/25 at 01: 45 pm with TS #1 confirmed the findings above. 6. The laboratory performs approximately 36 CRO tests annually.
D5471	CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (1) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's written policy and procedures, oxidase quality control (QC) records, and interview with technical supervisor #1 (TS #1), the laboratory failed to perform quality control for six of six days of patient testing. Findings include: 1. On 07/02/25 at 01:30 pm, TS #1 confirmed the laboratory performed the biochemical oxidase testing to determine if a microorganism produces the enzyme cytochrome c oxidase. 2. Review of the laboratory's written policy and procedure titled, "Routine Organism Identification", section, "11. QA/QC Requirements:" stated, "11.3 Oxidase ....11.3.1 QC performed each day testing is performed". 3. Review of quality control and patient records from 12/04/24 through 12/21/24 revealed no evidence of oxidase QC performed with patient testing for six of six days. a. Patient 2851993 - Oxidase test on 12/4/24 b. Patient 2853760 - Oxidase test on 12/12/24 c. Patient 2852521 - Oxidase test on 12/17/24 d. Patient 2854637 - Oxidase test on 12/18/24 e. Patient 2853761 - Oxidase test on 12/20/24 f. Patient 2854089 - Oxidase test on 12/21/24 4. In an interview on 07/02/25 at 02:00 pm, TS #1 confirmed the above findings. 5. The laboratory performed approximately 30 Oxidase tests annually.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: I. Based on the laboratory's written policy and procedure, GALT (Galactose-1-Phosphate Uridyl Transferase) reagent preparation worksheets, and interview with technical supervisor #4 (TS #4), the laboratory failed to follow its own policy and procedure for six of seven GALT reagent preparations. Findings include: 1. On 07/01/25 at 09:00 am, TS #4 confirmed the laboratory performed GALT testing in the newborn screening laboratory. 2. Review of the laboratory's written policy and procedure, "Qualitative Method for Determination GALACTOSE-1-PHOSPHATE URIDYL TRANSFERASE in Neonatal Bloodspots by Fluorescence Detection" section, "6.01 Preparation of a Mixture" stated, "6.01.4 Adjust pH to 8.0 with glacial acetic acid ....6.01.4.1 Note the amount of acetic acid on the worksheet." 3. Record review of the "NEONATAL CHEMISTRY LABORATORY GALT REAGENT PREPARATION WORKSHEET" revealed the laboratory failed to follow its own written policy and procedure for six of seven GALT reagent preparations: a. Mixture lot number - 020324 documented pH of 7.97 on 02/03/24 b. Mixture lot number - 040524 documented pH 8.06 on 04/06/24 c. Mixture lot number - GL 278 documented pH 7.99 on 06/07/24 d. Mixture lot number - 281 documented pH 7.98 on 10-04-24 e. Mixture lot number - GL 283A documented pH 8.06 on 02/05/25 f. Mixture lot number - GL 284A documented pH 8.03 on 04/04/25 4. Interview on 07/01/25 at 09:30 am with TS #4 confirmed the findings above. 5. The laboratory performs approximately 5,500 GALT tests annually. II. Based on the laboratory's

	written policy and procedure, patient test reports, and interview with technical supervisor #4 (TS #4), the laboratory failed to follow its own policy and procedure for Hemoglobinopathy reporting for one of three patient reports. Findings include: 1. On 07/01/25 at 01:30 pm, TS #4 confirmed the laboratory performed Hemoglobinopathy testing in the newborn screening laboratory. 2. Review of the laboratory's written policy and procedure, "VARIANTnbs Hemoglobinopathy" section, "9.1.3.2 Reportable comment:" stated, "Hemoglobin phenotype FAS is consistent with sickle cell trait; a small percent of infants will have hemoglobin Lepore. An evaluation is recommended." 3. Review of patient reports revealed the laboratory failed to follow its own policy and procedure for one of three patients: a. Patient 3260472 - specimen collected on 02/17/25, received into the laboratory on 02/20/25, and reported on 02/21 /25 with the following comment: "Hemoglobin phenotype FAS is consistent with sickle cell trait. An evaluation is recommended." 4. Interview on 07/01/25 at 02:10 pm with TS #4 confirmed the findings above. 5. The laboratory performs approximately 5,500 Hemoglobinopathy tests annually.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individuals performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by: Based on written competency assessment policy, record review, and interview with technical supervisor #4 (TS #4), the laboratory failed to perform an annual (2024) competency for one of six testing person performing high complexity testing in the newborn screening laboratory. Findings include: 1. On 07/01/25 at 07:30 am, TS #4 confirmed testing person #8 (TP #8) performed high complexity testing in the newborn screening laboratory. 2. Review of the laboratory's written competency assessment policy, "Health Section 427: CLIA Quality Assurance Plan (version 1.2)" stated, "3.2.1.7 Personnel competency assessment - Completed six months after date of hire and yearly thereafter." 3. Record review of six testing persons performing high complexity testing in the newborn screening laboratory revealed no evidence of an annual (2024) competency for TP #8. a. TP #8 - annual competency performed on 11 /21/23 and 02/10/25. 4. Interview on 07/01/25 at 07:45 am with TS #4 confirmed the findings above. 5. The laboratory performs approximately 82,439 newborn screening tests annually.