Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	17D1052648	10/23/2024
Name of Provider or Supplier	**Street Address, City, State**	
Kansas Medical Center, Llc	1124 W 21st Street, Andover, 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
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 a review of proficiency testing (PT) records from American Proficiency Institute (API) for 2023 and to date of survey 2024, and interview with general supervisor (GS) #3, the laboratory failed to evaluate its unacceptable proficiency testing results for seven analytes in five test events for 2023. Findings: The following samples were scored unacceptable by API. No documentation of the laboratory's evaluation was provided at the time of survey. Listed by event, analyte- sample ID. 1. 2023 Chemistry-Core 2nd Event-Hemoglobin (EG7+)- IB-08. 2. 2023 Chemistry-Core 3rd Event-pO2 (EG7+)- IB-13. 3. 2023 Hematology/Coagulation 2nd Event-Eos %, Lymph %, Mono %, Neutrophil %- XE-08, APPT-COA-08. 4. 2023 Microbiology 2nd Event-RSV A-RSP-07, Human Rhinovirus/Enterovirus-RSP-08. 5. 2023 Microbiology 3rd Event-C. Difficile Toxin- CDF-12. RSV-RSP-12. 6. Interview with the GS #3 on 10/22/24 at 12:45 p.m. confirmed the laboratory failed to evaluate its unacceptable proficiency testing results for seven analytes in five test events for 2023.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

	This STANDARD is not met as evidenced by: Based on a review of PT records from API and interview with GS #3, the laboratory failed to evaluate its proficiency testing results that were not scored by the PT program for four of fifteen events in 2023 and 2024. Findings: Review of PT results from API for 2023 and 2024 revealed the following ungraded results with no evaluation provided at the time of survey. 1. 2023 Hematology/Coagulation 3rd event-ten ungraded results for: a. Fibrinogen: samples COA-06, 07, 08, 09 and 10. b. Blood Cell ID: samples ECI-06, 07, 08, 09, and 10. 2. 2023 Immunology /Immunohematology 3rd Event for Compatibility: sample SER-12. 3. 2023 Microbiology 2nd Event-two ungraded results for: a. Legionella pneumophilia: sample RSP-09 b. Influenza A: sample RSP-10 4. 2023 Microbiology 3rd Event-two ungraded results for: a. Coronavirus: sample RSP-11 b. Parainfluenza Virus: sample RSP-12. 5. Interview with GS #3 on 10/22/24 at 12:45 p.m. confirmed the laboratory failed to evaluate its proficiency testing results that were not scored by the PT program for four of fifteen events in 2023 and 2024.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's 2023, and 2024 to date of survey API PT performance evaluations and interview with GS #3, the laboratory failed to institute corrective action for five of five test events of unacceptable results when clerical error was the documented cause for the failure. Findings: 1. Review of the laboratory's 2023, and 2024 to date of survey API PT Performance Review and Corrective Action forms revealed 11 unacceptable sample results for five separate test events due to clerical error. a. 2023 Chemistry-Core 2nd Event: Total protein, sample CH-06. Cause listed as clerical error. No corrective action documented. b. 2023 Chemistry-Core 3rd Event: Total CK, sample CM-15 and CM-12. Cause listed as clerical error. No corrective action documented. c. 2023 Microbiology 3rd Event: Group A Strep Antigen, samples ST-11 and ST-12. Cause listed as clerical error. No corrective action documented. d. 2024 Chemistry-Core 1st Event: ALT, sample CH-04; Direct Bilirubin, sample CH-05. Cause listed as clerical error. No corrective action documented. e. 2024 Chemistry-Miscellaneous 1st Event: CSF Glucose, samples SCH-02 and SCH-03; CSF Protein, samples SCH-02 and SCH-03. Cause listed as clerical error. No corrective action documented. 2. Interview with GS #3 on 10/22/24 at 12:45 p.m. confirmed the laboratory failed to institute corrective action for five of five test events of unacceptable results when clerical error was the documented cause for the failure.
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 upon a review of the laboratory procedures and interview with GS #3, the laboratory failed to define by written procedure: criteria for specimen acceptability and rejection as described in 493.1242 for histology frozen section samples. Findings: 1. Review of the procedure " Kansas Medical Center Procedure Manual for Frozen Sections" revealed no criteria for specimen acceptability and rejection. No documentation of specimen acceptability and rejection for histology frozen section samples was provided at the time of survey. 4. Interview with the GS #3on 10/22/24 at 11:00 a.m. confirmed, the laboratory failed to define by written procedure: criteria for specimen acceptability and rejection as described in 493.1242 for histology frozen section samples.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of instrument type, manufacturer's instructions, lack of an accepted normal range study, patient testing volumes and interview with GS #3, the laboratory failed to follow manufacturer's instruction on reagent lot changes for SynthASil reagent for partial thromboplastin time (PTT) prior to use for patient testing. Findings: 1. Partial prothrombin time (PTT) testing are performed on the ACL Elite coagulation analyzer from Instrumentation Laboratory/Werfen. 2. ACL Elite instrument setting for PTT testing showed SynthASil reagent lot #N0138474, expiration 2/28/25. 3. Manufacturer's instructions for SynthASil under expected values it is stated: "Due to many variables which may affect clotting times, each laboratory should establish its own normal range." 4. The surveyor asked for the PTT normal range study for SynthASil reagent lot #N0138474 implementation. The laboratory provided a "Verification of Reference Interval" document that showed the study evaluated on 4/13 /23 did not verify the normal range listed as 22-32 seconds. 5. The surveyor asked for the repeated normal range study. No documentation of an acceptable normal range study for SynthASil reagent lot #N0138474 was provided at the time of survey. 6.

	SynthASil reagent lot #N0138474 was placed into use for patient testing on 7/1/23 with 5,518 patient results reported from 7/1/23 to 10/23/24. 7. Interview with GS #3 10 /23/24 at 12:30 p.m. confirmed, the laboratory failed to follow manufacturer's instruction on reagent lot changes for SynthASil reagent for partial thromboplastin time (PTT) prior to use for patient testing.
D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on a tour of the histology testing area, the lack of maintenance and function check documentation, and interview, the laboratory failed to establish a maintenance protocol and perform function checks for accuracy on their AWS Gemini 20 scale. Findings: 1. During the tour of the histology testing area, the surveyor observed a AWS Gemini 20 scale in this space. 2. Request was made to review the scale maintenance protocol and records. No documentation was made available at the time of survey. 3. Request was made for function checks performed to ensure the scale provides accurate results. No documentation was made available at the time of survey. 4. Interview with GS #3 on 10/22/24 at 11 a.m. confirmed, the laboratory failed to establish a maintenance protocol and perform function checks for accuracy on their AWS Gemini 20 scale.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on the review of the individualized quality control plan (IQCP) for Abbott i-STAT for B Natriuretic peptide (BNP), Troponin I, and Chem 8+ tests cartridges, historical quality control (QC) data, patient test volumes, and interview with TC #1, the laboratory failed to perform QC each day of patient testing for BNP, Troponin I, and the Chem 8+ cartridge which consists of sodium (Na), potassium (K), chloride (Cl), total carbon dioxide (TCO2), ionized calcium (iCa), glucose (Glu), Urea Nitrogen (BUN), creatinine (Crea), hematocrit (Hct) on each i-STAT analyzer used each day of patient testing. Findings: 1. The laboratory performs the above listed

	analytes on five i-STAT analyzers. Serial numbers a 359870, 336256, 337603, 334164, and 400142. 2. Review of the IQCP for testing performed on Abbott i-STAT analyzers did not include the analyzer serial numbers. The surveyor asked if the historical data statement to allow QC to be performed monthly included QC for each cartridge type performed on all five analyzers each month. TC #1 stated that QC was not performed on each cartridge type on all five analyzers each month. Failure to have QC on each cartridge type on all five analyzers each month makes the historical date utilized to set the QC interval invalid. 3. Patient test volumes from 12/14/22 to 10/23 /24 was as follows: a. BNP-9,414 results b. Troponin I-325 results c. Chem 8+ -1,503 results 4. Interview with TC #1 on 10/23/24 at 10:20 a.m. confirmed the laboratory failed to perform QC each day of patient testing for BNP, Troponin I, and the Chem 8+ cartridge which consists of Na, K, Cl, TCO2, iCa, Glu, BUN, Crea, and Hct on each i-STAT analyzer used each day of patient testing.
D5537	ROUTINE CHEMISTRY CFR(s): 493.1267(b)(d) For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of IQCP documentation for the Abbott i-STAT test system, lack of acceptable historical QC data for QC interval, patient test results and interview with TC #1, the laboratory failed to perform QC every eight hours of patient testing for the Abbott i-STAT for pH, pCO2 and pO2 patient testing. Findings: 1. Review of the IQCP for the Abbott i-STAT test system revealed the QC interval was based on unacceptable historical data. (refer to D5445) 2. The test cartridge EG7+ consists of the following measured analytes: Na, K, iCA, Hct, pH, pCO2, pO2. Review of QC documents revealed at 36,960 patient results were reported from 12/14/22 to 10/23/24 without QC performed every 8 hours of patient testing. 3. Interview with TC #1 on 10 /23/24 at 10:20 a.m. confirmed the laboratory failed to perform QC every eight hours of patient testing for the Abbott i-STAT for pH, pCO2 and pO2 patient testing.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) The laboratory director must ensure the proficiency testing samples are tested as required under subpart H of this part. This STANDARD is not met as evidenced by: Based on a lack of delegation documents to allow a designee to sign PT attestation statements, review of PT documents from API for attestation statements, and interview with GS #3, the laboratory director (LD) failed to ensure that PT samples are tested as required for participation in PT testing for laboratories performing non-waived testing. Findings: 1. Request was made for delegation documentation to allow a designee to sign attestation statements on behalf of the LD. No documentation to allow a designee to sign attestation statements was provided at the time of survey. 2. Review of PT attestation pages for 2023 and 2024 revealed 12 of 30 test event attestations were not signed by LD or delegated individual as required. Events not

	signed were as follows: a. 2023 Chemistry-Core 2nd Event b. 2023 Chemistry-Core 3rd Event c. 2023 Hematology/Coagulation 1st Event d. 2023 Hematology /Coagulation 2nd Event e. 2023 Microbiology 2nd Event f. 2023 Microbiology 3rd Event g. 2024 Chemistry-Core 1st Event h. 2024 Chemistry-Miscellaneous 1st Event i. 2024 Hematology/Coagulation 1st Event j. 2024 Microbiology 1st Event k. 2024 Chemistry-Core 2nd Event l. 2024 Chemistry-Core 3rd Event 3. Interview with GS#3 on 10/22/24 at 12:45 p.m. confirmed, the LD failed to ensure that PT samples are tested as required for participation in PT testing for laboratories performing non-waived testing.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on the review of the IQCPs for the Hemochron Signature Elite for ACT+, Binax Now Strep pneumo antigen, Quidel Triage Toxicology Drugs of Abuse, Abbott i-STAT for B Natriuretic peptide (BNP), Troponin I, Chem 8+, and EG7+ for arterial blood gas (ABG), Meridian ImmunoCard C. Diff toxin A & B, Biofire Respiratory Panel 2.1, Beckman Coulter Icon 25 Serum HCG, Techlab Leuko EZ Vue Fecal Lactoferrin, lack of documented review for the stated IQCPs effectiveness, and interview with GS #3, the LD failed to assure the quality of laboratory services provided and identify failures in quality as they occur. Findings: 1. The review of the IQCPs revealed the LD signature date of 11/16/22 for Hemochron Signature Elite for ACT+, Binax Now Strep pneumo antigen, Quidel Triage Toxicology Drugs of Abuse, Abbott i-STAT for B Natriuretic peptide (BNP), Troponin I, Chem 8+, and EG7+ for arterial blood gas (ABG), Meridian ImmunoCard C. Diff toxin A & B, and Beckman Coulter Icon 25 Serum HCG. a. No documentation of a review of the effectiveness or need for revision for 2023 and to date of survey 2024 was provided at the time of survey. 2. Review of the remaining IQCPs revealed the LD signature date of 3/9/23 for Biofire Respiratory Panel 2.1, and 11/10/23 for Techlab Leuko EZ Vue Fecal Lactoferrin. a. No documentation of a review of the effectiveness or need for revision to date of survey 2024 was provided at the time of survey for the Biofire Respiratory Panel 2.1. 3. Review of the IQCP for the Abbott i-STAT for B Natriuretic peptide (BNP), Troponin I, Chem 8+, and EG7+ for arterial blood gas revealed that no acceptable stability study had been performed on the five i-STAT analyzers. (refer to D5445 and D5537) 4. Interview with GS#3 on 10/23/24 at 10:20 a.m. confirmed the LD failed to assure the quality of laboratory services provided and identify failures in quality as they occur.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

	This STANDARD is not met as evidenced by: Based on the review of the laboratory's CMS-209 Laboratory Personnel Report, lack of competency assessment documentation and interview with GS #3, the Technical Supervisor (TS) failed to perform competencies for seven of seven high complexity testing personnel (TP) performing histology frozen section testing. Findings: 1. Review of the CMS-209 Laboratory Personnel Report found seven individual listed as high complexity TP that had performed histopathology testing. 2. The surveyor requested competencies for the seven TP that had performed histopathology testing. No competencies for the seven TP was provided at the time of survey. 3. Interview with GS #3 10/22/24 at 10:15 a.m. confirmed the TS failed to perform competencies for seven of seven high complexity TP performing histology frozen section testing.