Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0475262	03/09/2022
Name of Provider or Supplier	**Street Address, City, State**	
Haskell Regional Hospital, Inc	401 Nw H Street, Stigler, OK	

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	The initial survey was performed on 03/07,08,09/2022. Immediate Jeopardy was determined during the survey due to issues identified with the iSTAT 1 analyzer using the PT (Prothrombin Time)/INR (International Normalized Ratio) cartridges. It was routinely being used to perform PT/INR testing for screening and diagnostic purposes (testing outside of the manufacturer's intended use). In addition, issues identified throughout the analytic systems contributed to the determination. The laboratory was found out of compliance with the following CLIA regulations: 493.1250; D5400: Analytic Systems 493.1403; D6000: Laboratory Director 493.1409; D6033: Technical Consultant 493.1421; D6063: Testing Personnel The findings were reviewed with the hospital administrator, directory of nursing, Labnet CEO, technical consultant, and laboratory manager during an exit conference performed at the conclusion of the survey.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory director or designee failed to sign a proficiency testing attestation statement

	for one of five events. Findings include: (1) A review of the 2021 proficiency testing records revealed for one of five events: (a) Second 2021 Chemistry Miscellaneous Event - The attestation statement had not been signed by the laboratory director or designee. (2) The findings were reviewed with the laboratory manager who stated on 03/07/2022 at 04:15 pm, the attestation statement had not been signed by the laboratory director or designee as shown above.
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the director of nursing, the laboratory failed to follow the manufacturer's instructions for Blood Gas and Lactate testing for 11 of 11 test reports. Findings include: (1) On 03/08 /2022 at 03:35 pm the director of nursing stated the nursing staff in the Emergency Department began performing Blood Gas (pH, pCO2, pO2) and Lactate testing using the CG4+ cartridge and iSTAT 1 analyzer on 12/09/2020; (2) A review of the manufacturer's instructions under the section titled, "Mixing and Test Timing (time from collection to cartridge fill) for Chemistry and Blood Gas Cartridge" stated, "Samples for pH, PCO2, PO2, TCO3 and ionized calcium should be tested within 10 minutes."; (3) A review of patient testing records between 07/01/2021 through 11/06 /2021 identified the following for 11 of 11 patient test reports (NOTE: Result time correlates to time sample tested): (a) Patient Report #10003255 - The collection date and time were not documented and the result date and time were 06/30/2021 at 10:16 pm; (b) Patient Report #10003273 - The collection date and time were 07/01/2021 at 07:40 pm and the result date and time were 07/01/2021 at 08:01 pm (21 minutes later); (c) Patient Report #10003289 - The collection date and time were not documented and the result date and time were 07/02/2021 at 04:06 pm; (d) Patient Report #10003307 - The collection date and time were not documented and the result date and time were 07/04/2021 at 06:07 am; (e) Patient Report #10004480 - The collection date and time were not documented and the result date and time were 09/03 /2021 at 11:04 am; (f) Patient Report #10004495 - The collection date and time were not documented and the result date and time were 09/04/2021 at 03:34 pm; (g) Patient Report #10004523 - The collection date and time were not documented and the result date and time were 09/06/2021 at 04:19 pm; (h) Patient Report #10004588 - The colleection date and time were not documented and the result and and time were 09/09 /2021 at 01:20 am; (i) Patient Report #10004586 - The collection date and time were not documented and the result date and time were 09/09/2021 at 08:03 pm; (j) Patient Report #10004626 - The collection date and time were not documented and the result date and time were 09/10/2021 at 06:05 pm; (k) Patient Report #10005675 - The collection date and time were not documented and the result date and time were 11/06 /2021 at 06:50 pm. (4) The findings were reviewed with the director of nursing. On 03 /08/2022 at 03:00 pm, the director of nursing stated the laboratory could not prove the specimen was collected and tested within 10 minutes as required by the manufacturer.
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 records, written policy, and interview with the laboratory manager, the laboratory failed to have a written technical consultant competency policy based on the position responsibilities as listed in Subpart M for one of one technical consultants. Findings include: (1) On 03/07/2022, a review of the competency policy titled, "Employee Yearly Competency" revealed the policy did not include guidance for assessing the competency of the technical consultant; (2) A review of personnel records for competency assessments performed during 2020 and 2021 revealed there was no evidence of a competency performed for the technical consultant based on their job responsibilities; (3) The records were reviewed with laboratory manager. The laboratory manager stated on 03/08/2022 at 04:10 pm a policy had not been written and the above competencies had not been performed.
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 records and interview with the laboratory manager, the laboratory failed to review and evaluate proficiency testing results for three of five events. Findings include: FAILURE (1) On 03/07/2022, a review of 2021 proficiency testing records revealed the following failures: (a) Second 2021 Chemistry Core Event (i) Creatinine - The laboratory failed the results for one of five samples (IB-07); (ii) Glucose - The laboratory failed the results for one of five samples (IB-07); (iii) Hematocrit - The laboratory failed the results for one of five samples (IB-07); (iv) Hemoglobin - The laboratory failed the results for one of five samples (IB-07); (v) TCO2 - The laboratory failed the results for one of five samples (IB-07). (b) Third 2021 Chemistry Core Event (i) ALT (Alanine Aminotransferase) - The laboratory failed the results for one of five samples (CH-13); (ii) TCO2 - The laboratory failed the results for one of five samples (IB-14). (2) There was no evidence in the records proving the failures had been addressed; (3) The records were reviewed with the laboratory manager. The laboratory manager stated on 03/07/2022 at 04:05 pm corrective action had not been taken. BIASES (1) On 03/07/2022, a review of 2021 proficiency testing records and revealed the following biases (biases were identified using the SDI (Standard Deviation Index) values assigned by the proficiency program): (a) 2021 Second Chemistry Core Event (i) Creatinine - four of five results exhibited a positive bias (aa) Sample CH-07 - SDI of 2.1 (bb) Sample CH-08- SDI of 2.7 (cc) Sample CH-09 - SDI of 3.8 (dd) Sample CH-10 - SDI of 2.5 (ii) Magnesium - three of five results exhibited a positive bias (aa) Sample CH-08 - SDI of 4.2 (bb) Sample CH-09 - SDI of 5.2 (cc) Sample CH-10 - SDI of 3.9 (iii) Potassium - three of five results exhibited a negative bias (aa) Sample CH-06 - SDI of -4.2 (bb) Sample CH-07 - SDI of -2.8 (cc) Sample CH-09 - SDI of -2.5 (b) 2021 Third Chemistry Core Event (i) Glucose - three of five results exhibited a positive bias (aa) Sample CH-12 - SDI of 2.0 (bb) Sample CH-13 - SDI of 2.1 (cc) Sample CH-14 - SDI of 2.0 (ii)

	Magnesium - four of five results exhibited a positive bias (aa) Sample CH-07 - SDI of 2.1 (bb) Sample CH-08- SDI of 2.7 (cc) Sample CH-09 - SDI of 3.8 (dd) Sample CH-10 - SDI of 2.5 (iii) Potassium - four of five results exhibited a negative bias (aa) Sample CH-11 - SDI of -3.1 (bb) Sample CH-12 - SDI of -2.4 (cc) Sample CH-13 - SDI of -2.5 (dd) Sample CH-14 - SDI of -2.4 (c) 2021 Second Hematology Event (i) Hematocrit - three of five results exhibited a positive bias (aa) Sample XE-08 - SDI of 3.3 (bb) Sample XE-09 - SDI of 2.2 (cc) Sample XE-10 - SDI of 2.4 (ii) MCV (Mean Corpuscular Volume) - four of five results exhibited a positive bias (aa) Sample XE-06 - SDI of 2.2 (bb) Sample XE -07 - SDI of 2.1 (cc) Sample XE -08 - SDI of 2.2 (dd) Sample XE -09 - SDI of 2.1 (2) There was no evidence in the records proving the biases had been identified and addressed; (3) The records were reviewed with the laboratory manager. The laboratory manager stated on 03/07/2022 at 04:10 pm the biases had not been addressed.
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 a review of records and interview with the laboratory manager, the laboratory failed to evaluate the accuracy of testing when proficiency results had not been graded by the proficiency program for one of five proficiency testing events reviewed. Findings include: (1) On 03/07/2022, a review of 2021 proficiency testing records revealed for one of five testing events revealed the following: (a) Second 2021 Hematology Event for Blood Cell Identification - two of two result had not been graded by the proficiency testing program: (i) For the result (BCI-07), the following was identified: (aa) BCI-07 - Under "Expected Results" it stated, "See Data Summary". There was no evidence the laboratory reviewed the commentary contained in the "Participant Summary Report" to evaluate their result; (ii) For the result (ECI-07), the following was identified: (aa) ECI-07 - Under "Expected Results" it stated, "See Commentary". There was no evidence the laboratory reviewed the commentary contained in the "Participant Summary Report" to evaluate their result. (2) The records were reviewed with the laboratory manager who stated on 03/07/2022 at 04: 20 pm, the laboratory had not evaluated the results that were not graded by the proficiency testing program.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on interview with the laboratory manager, the laboratory failed to provide written instructions to clients collecting and referring routine Hematology, Chemistry,

	and Urinalysis testing for six of six clients. Findings include: (1) On 03/09/2022 at 11: 20 am, the laboratory manager stated the following: (a) The laboratory performed routine chemistry testing using the Olympus AU 640e analyzer; (b) The laboratory performed routine CBC (Complete Blood Count) testing using the Sysmex XS-1000i analyzer; (c) The laboratory performed urine sediment examinations; (d) Specimens were transported to the laboratory from three home health agencies, one long-term care facility, and two physician clinics. (2) A review of the laboratory's written procedure manual revealed no evidence of written instructions (e.g., client service manual) had been provided to the clients to explain the laboratory's specimen handling policies (e.g., collection, preservation, storage, transport, testing schedule times, and how to obtain additional assistance for unusual circumstances). The laboratory manager stated on 03/09/2022 at 11:40 am specimen handling instructions had not been written and provided to the clients.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a review of records, policies and procedures, manufacturer's instructions, observation, and interview with the laboratory manager and director of nursing, the laboratory failed to monitor and evaluate the overall quality of analytic systems and correct identified problems for each specialty and subspecialty of testing performed. Findings include: (1) The laboratory failed to have a written procedure; failed to have written procedures that explained the current practices and procedures being performed in the laboratory; and failed to follow laboratory procedures. Refer to D5401; (2) The laboratory failed to ensure that written procedures no longer in use had been discontinued. Refer to D5409; (3) The laboratory failed to follow the manufacturer's intended use requirements; and failed to follow the manufacturer's instructions for verifying morphology flags. Refer to D5411; (4) The laboratory failed to ensure materials and analyzers were being stored as required by the manufacturer; and failed to ensure the humidity requirements were met for an analyzer. Refer to D5413; (5) The laboratory failed to ensure the performance specifications had been demonstrated for new test methods; and failed to ensure the reportable ranges had been utilized for new test methods. Refer to D5421; (6) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Refer to D5429; (7) The laboratory failed to perform function checks as defined by the manufacturer. Refer to D5431; (8) The laboratory failed to define a written function check protocol to ensure the urine centrifuge was functioning properly. Refer to D5435; (9) The laboratory failed to perform calibration verification procedures at least once every 6 months. Refer to D5439; (10) The laboratory failed to have control procedures that monitored the accuracy and precision of the testing process; and control procedures that would detect immediate error. Refer to D5441; (11) The laboratory failed to perform two levels of quality control materials each day of patient testing. Refer to D5447; (12) The laboratory failed to follow the manufacturer's quality control specifications. Refer to D5479; (13) The laboratory failed to perform

	one sample of control material each 8 hours of patient testing using a combination of control materials that include both low and high values on each day of blood gas testing. Refer to D5537; (14) The laboratory failed to perform two levels of quality control testing each eight hours of PT/INR and D-dimer testing. Refer to D5545; (15) The laboratory failed to have a system that twice a year evaluated and defined the relationship between test results using different methods. Refer to D5775; (16) The laboratory failed to have an ongoing mechanism for performing quality assessment. Refer to D5791.
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: I. Based on a review of written policies and procedures, and interview with the laboratory manager, the laboratory failed to follow written procedures, failed to have a written procedure; and failed to have written procedures that explained the current practices and procedures being performed in the laboratory for two of two procedures reviewed. Findings include: BLOOD BANK ALARM SYSTEM (1) On 03/07/2022 at 12:55 pm, the laboratory manager stated the following: (a) The laboratory routinely maintained 1 unit of O negative and 1 unit of O positive packed red blood cells in the Helmer blood bank refrigerator. The units were available for emergency patient transfusions (packed red blood cells must be stored at 1-6 degrees Centigrade-C); (b) The laboratory was not staffed 24 hours a day, seven days a week, therefore, remote alarms were housed at the nurses station and emergency department, and the departments would be required to respond to an activated alarm when the laboratory was not staffed. (2) On 03/08/2022, a review of the laboratory's written policy, titled, "Blood Storage and Temperature Monitoring" revealed the alarm checks were to be performed on a quarterly basis. In addition, the policy stated the following: (a) "The Blood Bank refrigerator has a continuous temperature monitor chart recorder"; (b) "Quarterly the temperature probe inside the refrigerator will be placed first in ice slurry. This should cause a low alarm"; (c) "There should be a noticeable decrease of temperature on the chart. Note that an alarm test was being conducted"; (d) "Record the time and individual who called from the nurses station or emergency department"; (e) "Next place the probe in warm water. This should activate the high alarm. Record the same information." (f) "Note the alarm test on the temperature chart". (3) A review of the alarm check records from June 2020 through the current date revealed the alarm checks that had been performed were documented on the temperature recorder chart. The following was identified: (a) Alarm checks had not been performed quarterly. There was no documentation alarm checks had been performed: (i) Between 06/29 /2020 and 10/05/2021; (ii) After 10/05/2021. (b) For the alarm checks that had been performed, the following was identified: (i) There was no documentation of the temperatures that the low and high alarms sounded; (ii) There was no documentation that individuals from the nurses station and emergency department responded to the activated alarms. (4) The records were reviewed with the laboratory manager who stated on 03/08/2022 at 11:00 am, the alarm checks had not been performed quarterly, the temperatures the low and high alarms had not been documented, and the responses to the remote alarms had not been documented. BLOOD PRODUCTS STORAGE (1)

	On 03/07/2022 at 01:00 pm, observation of the thermograph temperature recorder for the blood bank refrigerator revealed the refrigerator had a recorder connected to it for continuously recording the temperature on thermograph charts (Note: units of packed cells must be stored at 1-6 degrees Centigrade). Each chart monitored the temperature for a 7 day period; (2) The chart recorder appeared to not be functional as the pen was not recording the temperature. During an interview on 03/07/2022 at 01:05 pm, the laboratory manager stated the following: (a) The recorder chart had not been operational since 02/23/2022; (b) The laboratory was not documenting the temperature more frequent than once daily. (3) It was determined the packed red blood cells had not been stored in a monitored refrigerator with continuous monitoring from 02/23/2022 through the current date. URINE MICROSCOPIC PROCEDURE (1) On 03/07/2022 at 12:45 pm, the laboratory manager stated the laboratory began performing Urine Microscopic testing on 01/15/2021; (2) A review of the manual titled, "Policies and Procedures" revealed there was no written procedure for Urine Microscopic testing; (3) The laboratory manager stated on 03/07/2022 at 03:15 pm, the procedure had not been written. CURRENT PRACTICES (1) A review of the manual titled, "Policies and Procedures" revealed a procedure titled, "Wet Prep", which had not been identified as a test the laboratory was performing during the tour of the laboratory on 03/07/2022 at 12:45 pm; (2) During an interview on 03/07/2022 at 03:15 pm, the laboratory manager stated Wet Prep testing was not performed in the laboratory. 39088 II. Based on a review of records, written procedure, and interview with the laboratory manager, the laboratory failed to follow the laboratory procedures for one of one annual review; and failed to follow procedures for CBC testing for three of 30 quality control lot numbers. Findings include: TRANSFUSION SERVICE MANUAL (1) On 03/09/2022 at 10:30 am, the laboratory manager stated the following: (a) The laboratory maintained one O Positive and O Negative PRBC (Packed Red Blood Cells) for the purpose of emergency release. (2) On 03/09/2022, the laboratory's transfusion service procedure titled, "BLOOD BANK POLICY AND PROCEDURE MANUAL" was reviewed and stated: (a) "It is the policy of this facility that the procedure manual be reviewed annually.". (3) A review of the transfusion service policy and procedures identified the policy and procedure had not been reviewed annually (last reviewed 09/15/2020); (4) During an interview on 03/09 /2022 at 10:45 am, the laboratory manager stated the transfusion service policy and procedure had not been documented as reviewed annually since 09/15/2020. NEW LOTS OF QUALITY CONTROL - HEMATOLOGY (1) On 03/07/2022 at 01:00 pm, the laboratory manager stated the following: (a) CBC (Complete Blood Count) testing using the Sysmex XS-1000i analyzer; (b) Three levels (low, normal, and high) of Sysmex e-check XS quality control materials were peformed each day of patient testing. (2) On 03/09/2022 at 11:10 am, the laboratory manager stated new lots of quality control material were analyzed in parallel with the current lot at least 10 runs before put into use for patient acceptability testing; (3) A review of 30 quality control lot numbers revealed for three of 30 lot numbers there was no indication the laboratory staff followed their verbal procedure as follows: (a) Lot# 11320801 ran 1 time before put into use on 06/29/2021; (b) Lot# 11320802 ran 1 time before put into use on 06/29/2021; (c) Lot# 11320803 ran 1 time before put into use on 06/29/2021. (4) The findings were reviewed with the laboratory manager who stated on 03/09 /2022 at 11:35 am the procedure had not been followed.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).

	This STANDARD is not met as evidenced by: Based on a review of the procedure manual and interview with the laboratory manager, the laboratory failed to ensure that three of three written procedures no longer in use had been discontinued. Findings include: (1) On 03/07/2022 at 12:45 pm, the laboratory manager stated the laboratory began performing Manual Differential testing on 06/06/2020 and discontinued the testing approximately 09/01 /2021; (2) A review of the manual titled, "Policies & Procedures" identified the following procedures: (a) A procedure titled, "Manual Differential and Smear Review Criteria"; (b) A procedure titled, "WBC and Platelet Estimates from smears". (3) The manual was reviewed with the laboratory manager who stated on 03/07/2022 at 03:15 pm, the procedures should have been indicated as discontinued.
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: I. Based on a review of records, manufacturer's instructions, observation, and interview with the director of nursing, the laboratory failed to follow the manufacturer's intended use requirements for 48 of 102 patients. Findings include: (1) On 03/08/2022 at 03:35 pm the director of nursing stated the nursing staff in the Emergency Department began performing PT/INR (Prothrombin Time/International Normalized Ratio) testing using the PT/INR cartridge and iSTAT 1 analyzer on 06/19 /2020; (2) A review of the manufacturer's instructions contained in the iSTAT User's Manual under "Intended Use" stated, "...intended for the monitoring of patients receiving oral anticoagulation therapy such as Coumadin or Warfarin"; (3) An observation in the laboratory on 03/07/2022 at 12:45 pm, during the entrance tour, identified the laboratory did not have another method for performing PT/INR testing and the director of nursing was interviewed to determine: (a) If the analyzer was used for the monitoring of Coumadin or Warfarin therapy; (b) If patients coming into the Emergency Department, not on Coumadin or Warfarin therapy, were tested for screening or diagnostic purposes. (4) The director of nursing stated on 03/08/2022 at 03:38 pm: (a) The analyzer was used for the monitoring of Coumadin or Warfarin therapy; (b) The analyzer was also routinely used for PT/INR testing, for patients presenting to the ER, for screening or diagnostic purposes. (5) A review of the Emergency Department records was performed for patients who had PT/INR testing performed on the analyzer from December 2020 through February 2022. The director of nursing obtained the records for 102 Emergency Department patients that had testing performed on the analyzer and determined if the patients were on Coumadin or Warfarin therapy at the time of testing. It was determined 48 of the 102 patients were not being monitored, and the testing had been performed for screening or diagnostic purposes as follows (Patient number represents order number): (a) Patient #3501506 - Testing performed on 12/04/2020 (b) Patient #3501685 - Testing performed on 12/09 /2020 (c) Patient #3501939 - Testing performed on 12/16/2020 (d) Patient #3502911 - Testing performed on 01/06/2021 (e) Patient #3502685 - Testing performed on 01/08 /2021 (f) Patient #3503437 - Testing performed on 01/15/2021 (g) Patient #3503456 -

Testing performed on 01/19/2021 (h) Patient #3502684 - Testing performed on 01/20 /2021 (i) Patient #3502592 - Testing performed on 01/20/2021 (j) Patient #3504410 - Testing performed on 02/03/2021 (k) Patient #3504583 - Testing performed on 02/06 /2021 (l) Patient #3504616 - Testing performed on 02/07/2021 (m) Patient #3505229 - Testing performed on 03/24/2021 (n) Patient #3507816 - Testing performed on 04/19 /2021 (o) Patient #3508195 - Testing performed on 04/26/2021 (p) Patient #3508214 - Testing performed on 04/26/2021 (q) Patient #3508922 - Testing performed on 05/06 /2021 (r) Patient #3512134 - Testing performed on 07/01/2021 (s) Patient #3512261 - Testing performed on 07/02/2021 (t) Patient #3514165 - Testing performed on 07/29 /2021 (u) Patient #3514282 - Testing performed on 07/31/2021 (v) Patient #3514372 - Testing performed on 08/01/2021 (w) Patient #3515297 - Testing performed on 08/13 /2021 (x) Patient #3515334 - Testing performed on 08/14/2021 (y) Patient #3515465 - Testing performed on 08/14/2021 (z) Patient #3515857 - Testing performed on 08/20 /2021 (aa) Patient #3516281 - Testing performed on 08/26/2021 (bb) Patient #3513633 - Testing performed on 08/26/2021 (cc) Patient 3516446 - Testing performed on 08/27/2021 (dd) Patient #3516974 - Testing performed on 09/05/2021 (ee) Patient #3517130 - Testing performed on 09/07/2021 (ff) Patient #3518596 - Testing performed on 09/30/2021 (gg) Patient #3518610 - Testing performed on 10/01 /2021 (hh) Patient #3518749 - Testing performed on 10/03/2021 (ii) Patient #3518740 - Testing performed on 10/03/2021 (jj) Patient #3518842 - Testing performed on 10/04 /2021 (kk) Patient #3519212 - Testing performed on 10/08/2021 (ll) Patient #3521799 - Testing performed on 11/17/2021 (mm) Patient #3523211 - Testing performed on 12 /10/2021 (nn) Patient #3523253 - Testing performed on 12/11/2021 (oo) Patient #3524388 - Testing performed on 12/24/2021 (pp) Patient #3525320 - Testing performed on 01/08/2022 (qq) Patient #3526280 - Testing performed on 01/20/2022 (rr) Patient #3526888 - Testing performed on 01/25/2022 (ss) Patient #3527600 - Testing performed on 02/01/2022 (tt) Patient #3527744 - Testing performed on 02/03 /2022 (uu) Patient #3527838 - Testing performed on 02/05/2022 (vv) Patient #3528630 - Testing performed on 02/15/2022 NOTE: Not following the manufacturer's intended use for a test system is considered a modification of the test and defaults the test categorization to LDT (Laboratory Developed Test) which is classified as high complexity. 39088 II. Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for verifying morphology flags for 21 of 54 patient reports. Findings include: (1) On 03/07/2022 at 01:00 pm, the laboratory manager stated the laboratory began performing CBC (Complete Blood Count) testing using the Sysmex XS-1000i analyzer on 06/06/2020; (2) On 03/09/2022, a review of the manufacturer's instructions was performed for verifying morphology flags obtained on the analyzer. The following were examples of flags, with the corresponding instructions: (a) Anisocytosis - "Verify RBC morphology on slide" (b) Atypical Lympho? - "Perform manual differential" (c) Blasts? - "Perform manual differential" (d) Hypochromia - "Verify RBC morphology on slide" (e) Immature Gran? - "Perform manual differential" (f) Left Shift? - "Perform manual differential" (g) Leukocytosis - "Review manual smear" (h) Monocytosis - "Review manual smear" (i) Neutrophilia - "Review manual smear" (j) PLT Clumps? - "Verify on slide" (k) Turbidity/HGB Interf? - "Check sample for interfering substances" (l) WBC Abn Scattergram - "Perform manual differential" (3) A review was performed of 54 patient records that contained flags from CBC testing performed between 06/28/2021 through 07/04/2021, 08/04/2021 through 08/25/2021, 09/06/2021 through 09/12/2021, and 11 /01/2021 through 11/07/2021. For 21 of the records, there was no evidence the laboratory followed the manufacturer's instructions for verifying the flags as follows: (a) Patient Sample #12085 - Testing was performed on 07/01/2021 at 08:58 am, with Immature Gran? and Left Shift? flags obtained; (b) Patient Sample #12198 - Testing

	was performed on 07/01/2021 at 04:55 pm, with an Atypical Lympho? flag obtained; (c) Patient Sample #12272 - Testing was performed on 07/02/2021 at 02:35 pm, with a Neutrophilia and Leukocytosis flags obtained; (d) Patient Sample #16250 - Testing was performed on 08/26/2021 at 06:13 am, with a Neutrophilia flag obtained; (e) Patient Sample #16316 - Testing was performed on 08/26/2021 at 01:10 pm, with an Immature Gran? flag obtained; (f) Patient Sample #16357 - Testing was performed on 08/26/2021 at 04:35 pm, Monocytosis flag obtained; (g) Patient Sample #16427 - Testing was performed on 08/27/2021 at 07:31 am, Blasts? and Left Shift? flags obtained; (h) Patient Sample #16432 - Testing was performed on 08/27/2021 at 08:08 am, Immature Gran? and Anisocytosis flags obtained; (i) Patient Sample #16633 - Testing was performed on 08/30/2021 at 05:10 am, Monocytosis and Left Shift? flags obtained; (j) Patient Sample #16653 - Testing was performed on 08/30/2021 at 06:03 am, Hypochromia flag obtained; (k) Patient Sample #16691 - Testing was performed on 08/30/2021 at 01:27 pm, Atypical Lympho? flag obtained; (l) Patient Sample #16859 - Testing was performed on 09/02/2021 at 08:12 am, Anisocytosis flag was obtained; (m) Patient Sample #16929 - Testing was performed on 09/02/201 at 12:13 am, Monocytosis and Immature Gran? flags obtained; (n) Patient Sample #16954 - Testing was performed on 09/03/2021 at 09:19 am, Atypical Lympho? flag obtained; (o) Patient Sample #16965 - Testing was performed on 09/03/2021 at 11:52 am, Hypochromia flag obtained; (p) Patient Sample #17136 - Testing was performed on 09 /07/2021 at 09:55 am, Immature Gran? flag obtained; (q) Patient Sample #4588 - Testing was performed on 09/09/2021 at 12:28 am, Turbidity/HGB Interf? flag obtained; (q) Patient Sample #17356 - Testing was performed on 09/09/2021 at 11:06 am, WBC Abn Scattergram and PLT Clumps flags obtained; (r) Patient Sample #20389 - Testing was performed on 11/01/2021 at 05:54 am, Immature Gran? flag obtained; (s) Patient Sample #20728 - Testing was performed on 11/04/2021 at 07:46 am, Hypochromia flag obtained; (t) Patient Sample #20829 - Testing was performed on 11/05/2021 at 08:09 am, Immature Gran? flag obtained; (4) The records were reviewed with the laboratory manager, who stated on 03/09/2022 at 01:15 pm that the flags obtained for the above 21 patients had not been verified as shown above.
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 a review of records, manufacturer's storage instructions, observation of the laboratory chemistry freezer, and interview with the laboratory manager, the laboratory failed to ensure five of five bottles of quality control materials were being stored as required by the manufacturer; failed to ensure one of one analyzer was being stored as required by the manufacturer; and failed to ensure the chemistry analyzer was being stored according to manufacturer's humidity requirements for six of six months. Findings include: QUALITY CONTROL MATERIAL - FREEZER TEMPERATURES (1) On 03/07/2022 at 12:50 pm, the laboratory manager stated the laboratory performed pediatric bilirubin testing on the Olympus AU 640e analyzer;

	(2) On 03/09/2022 at 10:30 am, the laboratory manager stated the laboratory stored chemistry controls in the laboratory freezer (Summit Professional Freezer) with an acceptable range of -20 to -70 degrees Centigrade (C); (3) An observation on 03/09 /2022 at 10:40 am revealed five bottles of Bio Rad Liquicheck Pediatric Quality Control material (Lot# 44372V) with a manufacturer's storage requirements of -20 to -50 degrees C; (4) On 03/09/2022, the storage requirements were reviewed with the laboratory manager. The laboratory manager stated on 03/09/2022 at 10:55 am, the current temperature range allowed for temperatures colder than the manufacturer's storage requirement. ALERE D-DIMER - ROOM TEMPERATURE (1) On 03/09 /2022 at 12:20 pm the laboratory manager stated the laboratory performed D-Dimer testing using the the Alere Triage analyzer; (2) A review of the manufacturer's storage and handling requirements for the test devices used on the analyzer revealed the room temperature requirement was between 20 to 24 degrees Centigrade (C) or 68 to 75 degrees Fahrenheit (F); (3) On 03/09/2022, a review of the laboratory's room temperature log revealed acceptable range between 65 to 85 degrees F (18.3 to 29.4 degrees C); (4) The manufacturer's instructions were reviewed with the laboratory manager. On 03/09/2022 at 12:55 pm, the laboratory manager stated the laboratory's room temperature range was too wide for the test device used for D-Dimer testing on the Alere Triage analyzer. HUMIDITY (1) On 03/07/2022 at 12:50 pm, the laboratory manager stated the laboratory performed chemistry testing on the Olympus AU 640e analyzer; (2) On 03/09/2022, a review of the manufacturer's humidity requirements for the analyzer revealed the acceptable range was 40% to 80%; (3) A review of six months (January 2021 through June 2021) of laboratory humidity records revealed for six of six months, the humidity readings were documented as less than 40% as follows: (a) January - 20 of 31 days (days 1,2,3,4,5,6,8,9,10,11,12,13,14,18,19,21,22,23,24,25); (b) February - 25 of 28 days (days 1,2,3,4,5,6,7,8,9,10,11,12,16,17,18,19,20,21,22,23, 24,25,26,27,28); (c) March - 29 of 31 days (days 1,2,3,4,5,6,7,8,9,11,12,13,14,15,17,18,19,20,21,22,23,24 25,16,27,28,29,30,31); (d) April - 28 of 30 days (days 1,2,3,4,6,7,8,9,10,11,12,13,14,15,16,17,18,19,20,21,22,23 24,25,26,27,29,30); (e) May - 20 of 31 days (days 1,3,4,5,6,7,9.10,11,12,13,14,15,20,21,22,23,24,25,26,); (f) June - 1 of 30 days (day 10). (4) The records were reviewed with the laboratory manager. The laboratory manager stated on 03/09/2022 at 10:51 the analyzer had been stored at a humidity below the manufacturer's requirement as shown above.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: I. Based on a review of records, policies and procedures, and interview with the laboratory manager and director of nursing, the laboratory failed to ensure the performance specifications had been demonstrated for six of six new test methods; and failed to ensure the reportable ranges had been utilized for two of six new test methods. Findings include: EXCYTE 10 ANALYZER (1) On 03/07/2022 at 12:45

pm, the laboratory manager stated the laboratory began performing automated ESR (Erythrocyte Sedimentation Rate) testing using the Excyte 10 analyzer on 06/16/2021; (2) A review of the performance specification records for the new test system revealed the following: (a) The reportable range had not been demonstrated; (b) The reference range (normal range) had not been verified; (c) The data was signed and dated as approved by the laboratory director on 09/30/2021 (after the laboratory began patient testing). (3) On 03/08/2022 at 12:10 pm, the findings were reviewed with the laboratory manager who stated the laboratory had not demonstrated the reportable range and reference range; and the data had not been signed and dated prior to patient testing; (4) Refer to D5447 and D5479 for examples of patient testing performed. OLYMPUS AU 640e ANALYZER (1) On 03/07/2022 at 12:50 pm, the laboratory manager stated the laboratory began performing Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), Ammonia, Amylase, AST (Aspartate Aminotransferase), BUN (Blood, Urea, Nitrogen), Calcium, CK (Creatine Kinase), Creatinine, Chloride, CO2, Direct Bilirubin, Glucose, Lipase, Magnesium, Phosphorus, Potassium, Sodium, Total Bilirubin, Total Protein, Uric Acid, and Vancomycin testing using the Olympus AU 640e analyzer on 11/16/2020; (2) On 03/08/2022, a review of the performance specification records for the new test system revealed the following: (a) The reference ranges (normal ranges) had not been verified for each analyte; (b) The following reportable ranges had been demonstrated by the laboratory: (i) Albumin - 1.5-5.9 g/dl (ii) Alkaline Phosphatase - 3.6-979.5 U/L (iii) ALT - 6.0-574.5 U/L (iv) Ammonia - 10.6-481.4 umol/L (v) Amylase - 9.9-1956.3 U/L (vi) BUN - 1.8-111.8 mg/dl (vii) Calcium - 3.0-17.1 mg/dl (viii) CK - 9.4-1956.3 U/L (ix) Creatinine - 0.3-22.9 mg/dl (x) CO2 - 7.4-47.2 mEq/L (xi) Direct Bilirubin - 0.02-5.76 mg/dl (xii) Glucose - 11.6-803.2 mg/dl (xiii) Lipase - 5.6-630.6 U/L (xiv) Magnesium - 0.4-6.4 mg/dl (xv) Total Bilirubin - 0.1-27.1 mg/dl (xvi) Uric Acid - 1.6-27.5 mg/dl (3) The laboratory manager then provided the following reportable ranges that were programmed into the analyzer and being used by the laboratory: (a) Albumin - 1.0-8.0 g/dl (b) Alkaline Phosphatase - 7.0-1200.0 U/L (c) ALT - 8.0-670.0 U/L (d) Ammonia - 10.0-600.0 umol/L (e) Amylase - 10.0-2000 U/L (f) BUN - 0.0-100.0 mg/dl (g) Calcium - -999999.99-999999.9 mg/dl (a range had not been programmed in the analyzer) (h) CK - 10.0-2000.0 U/L (i) Creatinine - 0.20-20.0 mg/dl (j) CO2 - 1.0-50.0 mEq/L (k) Direct Bilirubin - 0.0-30.0 mg/dl (l) Glucose - 10.0-600.0 mg/dl (m) Lipase - 3.0-600.0 U/L (n) Magnesium - 0.2-6.0 mg/dl (o) Total Bilirubin - 0.0-30.0 mg/dl (p) Uric Acid - 1.5-30.0 mg/dl (4) The findings were reviewed with the laboratory manager, who stated on 03/08/2022 at 04:45 pm, there was no documentation to prove the laboratory verified the reference ranges and the laboratory was not using the reportable ranges that had been demonstrated by the laboratory as shown above; (5) Refer to D5441 for examples of patient testing performed. CG4+ AND ISTAT 1 ANALYZER (1) On 03/08/2022 at 03:35 pm the director of nursing stated the nursing staff in the Emergency Department began performing Blood Gas (pH, pCO2, pO2) and Lactate testing using the CG4+ cartridge and iSTAT 1 analyzer on 12/09/2020; (2) A review of the performance specification records for the new test system revealed the following: (a) The precision had not been demonstrated for each analyte; (b) The reportable ranges had not been demonstrated for each analyte; (b) The reference ranges (normal ranges) had not been verified for each analyte. (3) The findings were reviewed with the director of nursing who stated on 03/08/2022 at 03:40 pm, the laboratory had not demonstrated the precision, reportable ranges and reference ranges; (4) Refer to D5447 and D5537 for examples of patient testing performed. CHEM 8+ AND ISTAT 1 ANALYZER (1) On 03/08/2022 at 03:35 pm the director of nursing stated the nursing staff in the Emergency Department began performing BUN, Chloride, CO2, Creatinine, Ionized Calcium, Glucose, Hemoglobin, Hematocrit, Potassium, and Sodium testing using the Chem 8+ cartridge and iSTAT 1 analyzer on

	11/21/2020; (2) A review of the performance specification records for the new test system revealed the following: (a) The precision had not been demonstrated for each analyte; (b) The reportable ranges had not been demonstrated for each analyte; (b) The reference ranges (normal ranges) had not been verified for each analyte. (3) The findings were reviewed with the director of nursing who stated on 03/08/2022 at 03: 40 pm, the laboratory had not demonstrated the precision, reportable ranges and reference ranges; (4) Refer to D5447 for examples of patient testing performed. PT /INR AND ISTAT 1 ANALYZER (1) On 03/08/2022 at 03:35 pm the director of nursing stated the nursing staff in the Emergency Department began performing PT /INR (Prothrombin Time/International Normalized Ratio) testing using the PT/INR cartridge and iSTAT 1 analyzer on 06/19/2020; (2) A review of the performance specification records for the new test system revealed the following: (a) The precision had not been demonstrated; (b) The reportable range had not been demonstrated; (b) The reference range (normal range) had not been verified. (3) The findings were reviewed with the director of nursing who stated on 03/08/2022 at 03:40 pm, the laboratory had not demonstrated the precision, reportable range and reference range; (4) Refer to D5545 for examples of patient testing. TROPONIN I AND ISTAT 1 ANALYZER (1) On 03/08/2022 at 03:35 pm the director of nursing stated the nursing staff in the Emergency Department began performing Troponin I testing using the cTnI cartridge and iSTAT 1 analyzer on 06/19/2020; (2) A review of the performance specification records for the new test system revealed the following: (a) The precision had not been demonstrated; (b) The reference range (normal range) had not been verified; (c) The following reportable range had been demonstrated by the laboratory: (i) 0.32-21.08 ng/ml (3) The director of nursing then provided the following reportable range from the iSTAT User's Manual, that was being used by the laboratory: (a) 0-50 ng/ml (4) The findings were reviewed with the director of nursing who stated on 03/08/2022 at 03:40 pm, the laboratory had not demonstrated the precision and reference range; and the laboratory was not using the reportable ranges that had been demonstrated by the laboratory as shown above; (5) Refer to D5447 for examples of patient testing. 39088 II. Based on a review of records and interview with the laboratory manager, the laboratory failed to demonstrate the performance specifications for two of two new test systems. Findings include: SYSMEX XS-1000i (1) On 03/07/2022 at 01:00 pm, the laboratory manager stated the laboratory began performing CBC (Complete Blood Count) testing using the Sysmex XS-1000i analyzer on 06/06/2020; (2) On 03/09/2022 at 11:15 am, a review of the performance specification records revealed there was no documentation to prove accuracy, precision, and reportable range, had been demonstrated and the reference ranges had been verified for the analyzer; (3) The records were reviewed with the laboratory manager. The laboratory manager stated on 03/09/2022 at 11:35 am, performance specifications could not be located. (4) Refer to D5441 for examples of patient testing performed. ALERE TRIAGE D-DIMER (1) On 03/08/2022 at 01:05 pm, the laboratory manager stated the laboratory began performing D-Dimer testing using the Alere Triage on 07/22/2021; (2) On 03/08/2022 a review of the performance specifications for the analyzer revealed no documentation to prove the reportable range had been demonstrated; (3) The laboratory manager reviewed the performance specification records and stated on 03/08/2022 at 04:45 pm, the laboratory had not demonstrated the reportable range for the new analyzer; (4) Refer to D5545 for examples of patient testing performed.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory

must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
I. Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for one of one chemistry analyzer. Findings include: (1) On 03/07/2022 at 12:50 pm, the laboratory manager stated the following: (a) The laboratory began performing Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), Ammonia, Amylase, AST (Aspartate Aminotransferase), BUN (Blood, Urea, Nitrogen), Calcium, CK (Creatine Kinase), Creatinine, Chloride, CO2, Direct Bilirubin, Glucose, Lipase, Magnesium, Phosphorus, Potassium, Sodium, Total Bilirubin, Total Protein, Uric Acid, and Vancomycin testing using the Olympus AU 640e analyzer on 11/16/2020; (b) The hard drive for the analyzer went down on 11/16 /2021 and was not replaced and operational until 02/25/2022. (2) On 03/09/2022, a review of the manufacturer's maintenance requirements, as stated on the manufacturer's maintenance logs located in the AU64e User's Guide, Chapter F-Maintenance revealed the following requirements: (a) Daily Analyzer (i) Inspect Sample and reagent Syringes for leaks (ii) Inspect wash syringes for leaks (iii) Check the wash solution rolling pump for leaks (iv) Inspect the stability of the uppercover (v) Inspect concentrated wash solution level (vi) Inspect & Clean sample & reagent probes & mix bars (vii) Inspect printer and paper (viii) Prepare sample probe wash (b) Daily ISE (i) Inspect the ISE Reagent Syringe for leaks (ii) ISE Cleaning (c) Weekly Analyzer (i) Perform a W2 (ii) Perform a Photocal (iii) Perform a Photometer Check (d) Weekly ISE (i) Perform a selectivity check for the Na/K electrodes (ii) Wash the mix bars, liquid level sensors, sample pot tubing & sample pot (e) Monthly Analyzer (i) Clean Sample and Reagent Probe Wash Wells (ii) Clean Mix Bar Wash Wells (iii) Clean Wash Nozzle, DI Water Tank and Filter, and Sample Probe Filter (f) Every Three Months Analyzer (i) Replace Wash Solution Rolling Tube (ii) Clean Air Filters (g) Every Three Months ISE (i) Replace Mixture & Mid-standard Pump Roller Tubing (ii) Replace Valve Tubing (2) Maintenance logs from December 2020 through February 2022 were requested and the laboratory manager printed the records from the analyzer's memory. The laboratory manager stated the following on 03/09/2022 at 11:15 am: (a) The laboratory did not manually document maintenance procedures and used the maintenance logs contained in the analyzer's memory; (b) Since the hard drive had crashed and did not come back up until 02/25/2022, the laboratory had lost most of the data prior to 02/25/2022. (3) A review of the maintenance records that had been printed from the analyzer, revealed the following: (a) Daily Analyzer (i) Not documented as performed prior to 02/25/2022. (b) Daily ISE (i) Not documented as performed prior to 02/25/2022. (c) Weekly Analyzer (i) Perform W2 - Not documented as performed prior to 01/13/2022; (ii) Perform Photocal - Not documented as performed prior to 01/20/2022; (iii) Perform Photometer Check - Not documented as performed during the review period. (d) Weekly ISE (i) Perform a selectivity check for the Na/K electrodes - Not documented as performed prior to 12 /17/2021; (ii) Wash the mix bars, liquid level sensors, sample pot tubing & sample pot - Not documented as performed prior to 12/06/2021. (e) Monthly Analyzer (i) Not documented as performed prior to 12/06/2021 (f) Every Three Months Analyzer (i) Not documented as performed prior to 12/06/2021 (g) Every Three Months ISE (i) Not documented as performed prior to 12/06/2021 (4) The records were reviewed with the laboratory manager who stated on 03/09/2022 at 11:20 am, there was no documentation to prove the above maintenance procedures had been performed; (5) Refer to D5441 for examples of patient testing. 39088 II. Based on a review of

	records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's instructions for performing maintenance procedures for 9 of 21 months. Findings include: (1) On 03/07/2022 at 01:00 pm, the laboratory manager stated CBC (Complete Blood Count) testing using the Sysmex XS-1000i analyzer was performed beginning on 06/06/2020; (2) On 03/09/2022 a review of the manufacturer's maintenance requirements, as stated on the manufacturer's maintenance logs, revealed the following: (a) Daily Maintenance (i) Perform Shutdown (ii) Verify Background (b) Weekly Maintenance (i) Power Down IPU (c) Monthly Maintenance (i) Perform Monthly Rinse (3) A review of maintenance records for 21 months (June 2020 through February 2022) revealed the following: (a) There was no evidence the daily, weekly, and monthly maintenance had been performed (i) Between 06/06/2020 and 03/01/2021 (b) There was no evidence the monthly maintenance had been performed: (i) Between 04/09/2021 and 06/21/2021 (ii) Between 06/21/2021 and 08/19/2021 (iii) Between 08/19/2021 and 10/27/2021 (iv) Between 10/27/2021 and 01/14/2022 (4) The records were reviewed with the laboratory manager who stated on 03/09/2022 at 10:10 am, the maintenance had been performed but the documentation could not be located; (5) Refer to D5411 for examples of patient testing performed.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager and director of nursing, the laboratory failed to perform function checks as defined by the manufacturer for one of one analyzer. Findings include: (1) On 03/08/2022 at 03:35 pm the director of nursing stated the nursing staff in the Emergency Department began performing the following testing using the iSTAT 1 analyzer (serial number (21)408446): (a) PT/INR (Prothrombin Time/International Normalized Ratio) testing using the PT/INR cartridge on 06/19/2020; (b) Troponin I testing using the cTnI cartridge on 06/19/2020; (c) BUN, Chloride, CO2, Creatinine, Ionized Calcium, Glucose, Hemoglobin, Hematocrit, Potassium, and Sodium testing using the Chem 8+ cartridge on 11/21/2020; (d) Blood Gas (pH, pCO2, pO2) and Lactate testing using the CG4+ cartridge on 12/09/2020. (2) A review of the manufacturer's instructions regarding the performance of the thermal probe check stated, "The Handheld's thermal probes should be checked every six months"; (3) Documentation of thermal probe checks during the review period of December 2020 through February 2022 could not be located; (4) During an interview on 03/09/2022 at 11:09 am, the director of nursing stated that, although the thermal probe checks had been performed with CLEW software updates every six months, they had not been documented.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) 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: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the laboratory manager, the laboratory failed to define a written function check protocol to ensure the urine centrifuge was functioning properly for one of three function checks. Findings include: (1) On 03/07/2022 at 12:50 pm, the laboratory manager stated the following: (a) The laboratory began performing urine microscopic testing on 01/15/2021; (b) The urine specimens were processed at a speed of 1500-2000 rpm (revolutions per minute) for 5 minutes using the Labsco Model 614V centrifuge. (2) A function check protocol that defined the frequency of urine centrifuge speed and timer checks and the acceptable limits for the checks could not be located; (3) During an interview on 03/07/2022 01:20 pm, the laboratory manager stated the laboratory did not have a written function check protocol but the centrifuge was checked by the biomedical department of the hospital annually; (4) A review of the centrifuge maintenance records from January 2021 through the current date in 2022 revealed the following for one of three function checks: (a) 11/12/2020 - There was no documentation the timer had been checked for accuracy. (4) The findings were reviewed with the laboratory manager who stated on 03/08/2022 at 11:05 am that the laboratory did not have a written function check protocol for the urine centrifuge and the laboratory did not ensure the urine centrifuge was functioning properly as shown above.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to perform calibration verification procedures at least once every 6 months for one of one chemistry analyzer. Findings include: (1) On 03/07/2022 at 12: 50 pm, the laboratory manager stated the laboratory began performing Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), Ammonia, Amylase, AST (Aspartate Aminotransferase), BUN (Blood, Urea, Nitrogen), Calcium, CK (Creatine Kinase), Creatinine, Chloride, CO2, Direct Bilirubin, Glucose, Lipase, Magnesium, Phosphorus, Potassium, Sodium, Total Bilirubin, Total Protein, Uric Acid, and Vancomycin testing using the Olympus AU 640e analyzer on 11/16/2020; (2) On 03 /09/2022, a review of 2022 calibration records revealed the calibration procedures for the above analytes had been performed with one or two levels of calibrators therefore, calibration verification procedures, using three or more levels of calibration materials that included a low, mid, and high value, were required every six months; (3) A review of analyzer records from December 2020 through February 2022 revealed that calibration verification had not been performed after 03/04/2021; (4) The records were reviewed with the laboratory manager who stated on 03/09/2022 at 11:32 am, calibration verification procedures had not been performed every six months; (5) Refer to D5441 for examples of patient testing performed.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on a review of records and interview with the laboratory manager, the laboratory failed to have control procedures that monitored the accuracy and precision of the testing process for Chemistry testing for 15 of 15 months. Findings include: (1) On 03/07/2022 at 12:50 pm, the laboratory manager stated the following: (a) The laboratory began performing Albumin, Alkaline Phosphatase, ALT (Alanine Aminotransferase), Ammonia, Amylase, AST (Aspartate Aminotransferase), BUN (Blood, Urea, Nitrogen), Calcium, CK (Creatine Kinase), Creatinine, Chloride, CO2, Direct Bilirubin, Glucose, Lipase, Magnesium, Phosphorus, Potassium, Sodium, Total Bilirubin, Total Protein, Uric Acid, and Vancomycin testing using the Olympus AU 640e analyzer on 11/16/2020; (b) Two levels of QC (quality control) materials were performed each day of patient testing. (2) On 03/09/2022, QC records (i.e., Levey-Jennings data) were requested for the above testing performed from December 2020 through February 2022 to ensure QC had been monitored for variances. The laboratory manager stated on 03/09/2022 at 11:30 am, there were no records (i.e., Levey-Jennings data) proving the control results had been monitored for variances during the review period; (3) The following were examples of patient testing performed when control results had not been monitored for shifts and trends (patient

number represents order number): (a) Patient #3501562 - CMP* testing performed on 12/07/2020 (b) Patient #3501552 - Magnesium testing performed on 12/07/2020 (c) Patient #3502051 - Lipase testing performed on 12/16/2020 (d) Patient #3502456 - CMP testing performed on 12/30/2020 (e) Patient #3502509 - CMP testing performed on 01/20/2021 (f) Patient #3503048 - Magnesium testing performed on 01/20/2021 (g) Patient #3502945 - Lipase testing performed on 01/20/2021 (h) Patient #3503050 - Phosphorus testing performed on 01/20/2021 (i) Patient #3502789 - CK testing performed on 01/20/2021 (j) Patient #3504334 - CK testing performed on 02/02/2021 (k) Patient #3522630 - Amylase testing performed on 02/02/2021 (l) Patient #3504416 - Magnesium testing performed on 02/06/2021 (m) Patient #3504018 - CMP testing performed on 02/10/2021 (n) Patient #3505171 - Phosphorus testing performed on 02/24/2021 (o) Patient #3506515 - CMP testing performed on 03/17 /2021 (p) Patient #3506493 - CK testing performed on 03/17/2021 (q) Patient #3506662 - Lipase testing performed on 03/22/2021 (r) Patient #3505355 - Phosphorus testing performed on 03/23/2021 (s) Patient #3505354 - Magnesium testing performed on 03/23/2021 (t) Patient #3506997 - CMP testing performed on 03 /30/2021 (u) Patient #3503938 - Ammonia testing performed on 04/05/2021 (v) Patient #3507327 - CMP testing performed on 04/07/2021 (w) Patient #3507542 - CMP testing performed on 04/12/2021 (x) Patient #3507775 - Phosphorus testing performed on 04/16/2021 (y) Patient #3507991 - Lipase testing performed on 04/21 /2021 (z) Patient #3508055 - Vancomycin Trough testing performed on 04/22/2021 (aa) Patient #3507934 - Magnesium testing performed on 04/26/2021 (bb) Patient #3509148 - Phosphorus testing performed on 05/10/2021 (cc) Patient #3509330 - Lipase testing performed on 05/14/2021 (dd) Patient #3509336 - CK testing performed on 05/18/2021 (ee) Patient #3509755 - Magnesium testing performed on 05 /26/2021 (ff) Patient #3509921 - CMP testing performed on 05/27/2021 (gg) Patient #3510316 - Lipase testing performed on 06/04/2021 (hh) Patient #3510828 - CMP testing performed on 06/14/2021 (ii) Patient #3511015 - Ammonia testing performed on 06/16/2021 (jj) Patient #3511064 - CK testing performed on 06/17/2021 (kk) Patient #3511323 - Phosphorus testing performed on 06/20/2021 (ll) Patient #3511841 - CMP testing performed on 06/28/2021 (mm) Patient #3512031 - Magnesium testing performed on 06/30/2021 (nn) Patient #3512280 - CMP testing performed on 07/02 /2021 (oo) Patient #07/08/2021 - Uric Acid testing performed on 07/08/2021 (pp) Patient #3512768 -Lipase testing performed on 07/12/2021 (qq) Patient #3512952 - CK testing performed on 07/15/2021 (rr) Patient #3514002 - Phosphorus testing performed on 07/27/2021 (ss) Patient #3514053 - Magnesium testing performed on 07 /28/2021 (tt) Patient #3514458 - Vancomycin Trough testing performed on 08/06 /2021 (uu) Patient #3515083 - CMP testing performed on 08/10/2021 (vv) Patient #3515208 - Uric Acid testing performed on 08/11/2021 (ww) Patient #3515855 - Phosphorus testing performed on 08/20/2021 (xx) Patient #3516024 - CK testing performed on 08/24/2021 (yy) Patient #3516181- CMP testing performed on 08/25 /2021 (zz) Patient #3516429 - Ammonia testing performed on 08/27/2021 (aaa) Patient #3516503 - Lipase testing performed on 08/28/2021 (bbb) Patient #3516501- Magnesium testing performed on 08/28/2021 (ccc) Patient #3517226 - Magnesium testing performed on 09/08/2021 (ddd) Patient #3517455 - Lipase testing performed on 09/10/2021 (eee) Patient #3517510 - CMP testing performed on 09/13/2021 (fff) Patient #3517654 - Uric Acid testing performed on 09/15/2021 (ggg) Patient #3518019 - Phosphorus testing performed on 09/21/2021 (hhh) Patient #3518481 - CMP testing performed on 09/29/2021 (iii) Patient #3519014 - CMP testing performed on 10/07/2021 (jjj) Patient #3519350 - Uric Acid testing performed on 10 /12/2021 (kkk) Patient #3519408 - CK testing performed on 10/13/2021 (lll) Patient #3519456 - Amylase testing performed on 10/14/2021 (mmm) Patient #3519881 - Magnesium testing performed on 10/21/2021 (nnn) Patient #3520077 - Phosphorus

testing performed on 10/27/2021 (ooo) Patient #3520204 - CMP testing performed on 10/28/2021 (ppp) Patient # 3520754 - CMP testing performed on 11/04/2021 (qqq) Patient #3521560 - CMP testing performed on 11/15/2021 (rrr) Patient #3522394 - CMP testing performed on 11/30/2021 (sss) Patient #3523787 - CK testing performed on 12/16/2021 (ttt) Patient #3523863 - CMP testing performed on 12/17/2021 (uuu) Patient #3524001 - Magnesium testing performed on 12/20/2021 (vvv) Patient #3524131 - CMP testing performed on 12/22/2021 (www) Patient #3524704 - Ammonia testing performed on 12/29/2021 (xxx) Patient #3524716 - CMP testing performed on 12/29/2021 (yyy) Patient #3525389 - Phosphorus testing performed on 01/10/2022 (zzz) Patient #3525388 - Magnesium testing performed on 01/10/2022 (aaaa) Patient #3525535 - Lipase testing performed on 01/11/2022 (bbbb) Patient #3525749 - Uric Acid testing performed on 01/13/2022 (cccc) Patient #3526133 - CMP testing performed on 01/18/2022 (dddd) Patient #3526504 - CMP testing performed on 01/22/2022 (eeee) Patient #3527209 - CK testing performed on 01/27 /2022 (ffff) Patient #3527430 - CMP testing performed on 01/31/2022 (gggg) Patient #3527888 - Amylase testing performed on 02/05/2022 (hhhh) Patient #3528166 - CMP testing performed on 02/09/2022 (iiii) Patient #3528935 - Magnesium testing performed on 02/18/2022 (jjjj) Patient #3528905 - Lipase testing performed on 02/18 /2022 (kkkk) Patient #3528832 - CMP testing performed on 02/21/2022 (llll) Patient #3529160 - Uric Acid testing performed on 02/23/2022 (mmmm) Patient #3529299 - CK testing performed on 02/24/2022 (nnnn) Patient #3529564 - CMP testing performed on 02/27/2022 (oooo) Patient #3529610 - Phosphorus testing performed on 02/28/2022 *Comprehensive Metabolic Panel (CMP) - Albumin, Alkaline Phosphatase, ALT, AST, BUN, Calcium, Chloride, CO2, Creatinine, Glucose, Potassium, Sodium, Total Bilirubin and Total Protein 39088 II. Based on a review of records and interview with the laboratory manager, the laboratory failed to have control procedures that monitored the accuracy and precision of the testing process for Hematology testing for 16 of 16 months. Findings include: (1) On 03/07/2022 at 01: 00 pm, the laboratory manager stated the following: (a) The laboratory began performing CBC (Complete Blood Count) testing using the Sysmex XS-1000i analyzer on 06/06/2020; (b) Three levels of QC (quality control) materials were performed each day of patient testing. (2) On 03/09/2022, QC records (i.e., Levey-Jennings data) were requested for the above testing performed from November 2020 through February 2022 to ensure QC had been monitored for variances. The laboratory manager stated on 03/09/2022 at 12:15 pm, there were no records (i.e., Levey-Jennings data) proving the control results had been monitored for variances during the review period; (3) The following were examples of patient testing performed when control results had not been monitored for shifts and trends (patient number represents order number): (a) Patient #3525585 - testing performed on 11/11 /2020 (b) Patient #3526056 - testing performed on 11/17/2020 (c) Patient #3500689 - testing performed on 11/16/2020 (d) Patient #3501202 - testing performed on 11/26 /2020 (e) Patient #3501315 - testing performed on 11/30/2020 (f) Patient #3501788 - testing performed on 12/11/2020 (g) Patient #3502328 - testing performed on 12/24 /2020 (h) Patient #3502377 - testing performed on 12/27/2020 (i) Patient #3503052 - testing performed on 01/07/2021 (j) Patient #3503846 - testing performed on 01/23 /2021 (k) Patient #3504038 - testing performed on 01/27/2021 (l) Patient #3505403 - testing performed on 02/24/2021 (m) Patient #3506126 - testing performed on 03/06 /2021 (n) Patient #3506752 - testing performed on 03/22/2021 (o) Patient #3508160 - testing performed on 04/23/2021 (p) Patient #3507879 - testing performed on 04/20 /2021 (q) Patient #3509095 - testing performed on 05/09/2021 (r) Patient #3509383 - testing performed on 05/16/2021 (s) Patient #3509847 - testing performed on 05/26 /2021 (t) Patient #3510272 - testing performed on 06/04/2021 (u) Patient #3511858 - testing performed on 06/27/2021 (v) Patient #3512680 - testing performed on 07/09

	/2021 (w) Patient #3513991 - testing performed on 07/27/2021 (x) Patient #3514656 - testing performed on 08/05/2021 (y) Patient #3515905 - testing performed on 08/21 /2021 (z) Patient #3516951 - testing performed on 09/03/2021 (aa) Patient #3518547 - testing performed on 09/30/2021 (bb) Patient #3519450 - testing performed on 10/14 /2021 (cc) Patient #3521013 - testing performed on 11/08/2021 (dd) Patient #3521505 - testing performed on 11/15/2021 (ee) Patient #3522038 - testing performed on 11/20 /2021 (ff) Patient #3524073 - testing performed on 12/21/2021 (gg) Patient #3524652 - testing performed on 12/29/2021 (hh) Patient #3524981 - testing performed on 01/03 /2022 (ii) Patient #2535908 - testing performed on 01/14/2022 (jj) Patient #3526036 - testing performed on 01/17/2022 (kk) Patient #3528238 - testing performed on 02/10 /2022 (ll) Patient #3528412 - testing performed on 02/12/2022 (mm) Patient #3528527 - testing performed on 02/14/2022 (nn) Patient #3528605 - testing performed on 02/16/2022 (oo) Patient #3529004 - testing performed on 02/19/2022 (pp) Patient #3529628 - testing performed on 02/28/2022
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and director of nursing, the laboratory failed to perform two levels of quality control materials 11 of 71 days of patient automated erythrocyte sedimentation rate testing reviewed; 47 of 54 days of patient Troponin I testing reviewed; 35 of 49 days of patient Lactate testing reviewed; and 48 of 99 days of patient Chem 8+ testing reviewed. Findings include: ERYTHROCYTE SEDIMENTATION RATE (1) On 03/07/2022 at 12:45 pm, the laboratory manager stated the following: (a) The laboratory began performing automated ESR (Erythrocyte Sedimentation Rate) testing using the Excyte 10 analyzer on 06/16/2021; (b) Two levels (normal and abnormal) of EliTech Group Accu-Sed Plus QC (quality control) materials were performed each day of patient testing. (2) On 03/08/2022, a review of QC and patient testing records from 06/16 /2021 through 03/07/2022 revealed that two levels of QC materials had not been performed 11 of 71 days of patient testing; (3) The records were reviewed with the laboratory manager who stated on 03/08/2022 at 12:30 pm, two levels of QC materials had not been performed each day of patient testing; (4) The following were patients that had been testing on the days that at least two levels of QC materials had not been performed (patient number represents medical record number): (a) Patient #202322 - Testing performed on 06/17/2021 (b) Patient #202589 - Testing performed on 06/18 /2021 (c) Patient #204270 - Testing performed on 06/29/2021 (d) Patient #204400 - Testing performed on 07/06/2021 (e) Patient #204470 - Testing performed on 07/08 /2021 and 07/19/2021 (f) Patient #204599 - Testing performed on 07/14/2021 (g) Patient #204620 - Testing performed on 07/15/2021 (h) Patient #200640 - Testing performed on 07/22/2021 (i) Patient #204935 - Testing performed on 07/29/2021 (j) Patient #201365 - Testing performed on 08/12/2021 TROPONIN I AND ISTAT 1 ANALYZER (1) On 03/08/2022 at 03:35 pm the director of nursing stated the following: (a) The laboratory began performing Troponin I testing using the cTnI cartridge and iSTAT 1 analyzer on 06/19/2020; (b) An IQCP (Individualized Quality

Control Plan) had not been developed for the test system. (2) It was determined that two levels of QC materials must be performed each day of patient testing; (3) A review of QC and patient testing records from 11/03/2020 through 02/28/2022 revealed two levels of QC materials had not been performed 47 of 54 days of testing reviewed; (4) The records were reviewed with the director of nursing who stated on 03/08/2022 at 03:43 pm, two levels of QC materials had not been performed each day of patient Troponin I testing: (5) The following were examples of patient Troponin I testing performed when two levels of QC materials had not been tested (Patient number represents order number): (a) Patient #3500208 - Testing performed on 11/03/2020 (b) Patient #3500540 - Testing performed on 11/11/2020 (c) Patient #3500939 - Testing performed on 11/20/2020 (d) Patient #3501246 - Testing performed on 11/28/2020 (e) Patient #3501554 - Testing performed on 12/04/2020 (f) Patient #3501987 - Testing performed on 12/15/2020 (g) Patient #3502578 - Testing performed on 12/31/2020 (e) Patient #3504180 - Testing performed on 01/26/2021 (f) Patient #3504180 - Testing performed on 01/29/2021 (g) Patient #3504426 - Testing performed on 03/03/2021 (h) Patient #3506153 - Testing performed on 03/07/2021 (i) Patient #3506332 - Testing performed on 03/11/2021 (j) Patient #3507292 - Testing performed on 04/06/2021 (k) Patient #3507498 - Testing performed on 04/11/2021 (l) Patient #3507826 - Testing performed on 04/19/2021 (m) Patient #3508530 - Testing performed on 04/29/2021 (n) Patient #3509231 - Testing performed on 05/12/2021 (o) Patient #3509737 - Testing performed on 05/26/2021 (p) Patient #3510179 - Testing performed on 06/02/2021 (q) Patient #3510885 - Testing performed on 06/14/2021 (r) Patient #3511348 - Testing performed on 06/21/2021 (s) Patient 3512075 - Testing performed on 06/30/2021 (t) Patient #3512555 - Testing performed on 07/08/2021 (u) Patient #3513286 - Testing performed on 07/19/2021 (v) Patient #3514141 - Testing performed on 07/29/2021 (w) Patient #3514320 - Testing performed on 08/06/2021 (x) Patient #3515007 - Testing performed on 08/10/2021 (z) Patient #3512075 - Testing performed on 08/242021 (aa) Patient #3516669 - Testing performed on 08/30/2021 (bb) Patient #3517381 - Testing performed on 09/09/2021 (cc) Patient #3517842 - Testing performed on 09/18/2021 (dd) Patient #3519412 - Testing performed on 10/13/2021 (ee) Patient #3520071 - Testing performed on 10/26/2021 (ff) Patient #3520984 - Testing performed on 11/08/2021 (gg) Patient #3521523 - Testing performed on 11/15/2021 (hh) Patient #3522036 - Testing performed on 11/20/2021 (ii) Patient #3522530 - Testing performed on 11/30/2021 (jj) Patient #3522952 - Testing performed on 12/07/2021 (kk) Patient #3524362 - Testing performed on 12/24/2021 (ll) Patient #3524707 - Testing performed on 12/29/2021 (mm) Patient #3524899 - Testing performed on 01/01/2022 (nn) Patient #3525656 - Testing performed on 01/12/2022 (oo) Patient #3526398 - Testing performed on 01/20/2022 (pp) Patient #3527017 - Testing performed on 01/26/2022 (qq) Patient #3527461 - Testing performed on 01/31/2022 (rr) Patient #3527606 - Testing performed on 02/02/2022 (ss) Patient #3503848 - Testing performed on 02/19/2022 LACTATE (CG4+) AND ISTAT 1 ANALYZER (1) On 03/08/2022 at 03:35 pm the director of nursing stated the following: (a) The laboratory began peforming Lactate testing using the CG4+ cartridge and iSTAT 1 analyzer on 12/09/2020; (b) An IQCP had not been developed for the test system. (2) It was determined that two levels of QC materials must be performed each day of patient testing; (3) A review of QC and patient testing records from 12/09/2020 through 02/28/2022 revealed that two levels of QC materials had not been performed 35 of 49 days of testing reviewed; (4) The records were reviewed with the director of nursing who stated on 03/08/2022 at 03:43 pm, two levels of QC materials had not been performed each day of patient Lactate testing: (5) The following were examples of patient Lactate testing performed when two levels of QC materials had not been tested (Patient number represents order number): (a) Patient #3501673 - Testing performed on 12/09/2020 (b) Patient #3502112 - Testing performed on 12/17/2020 (c)

Patient #3502314 - Testing performed on 12/24/2020 (d) Patient #3502549 - Testing performed on 12/31/2020 (e) Patient #3503220 - Testing performed on 01/11/2021 (f) Patient #3503372 - Testing performed on 01/27/2021 (g) Patient #3504741 - Testing performed on 02/10/2021 (h) Patient #3505175 - Testing performed on 02/19/2021 (i) Patient #3506309 - Testing performed on 03/10/2021 (j) Patient #3506776 - Testing performed on 03/23/2021 (k) Patient #3507359 - Testing performed on 04/08/2021 (l) Patient #3508450 - Testing performed on 04/29/2021 (m) Patient #3509382 - Testing performed on 05/17/2021 (n) Patient #3509811 - Testing performed on 05/26/2021 (o) Patient #3510285 - Testing performed on 06/04/2021 (p) Patient #3511548 - Testing performed on 06/22/2021 (q) Patient #3512318 - Testing performed on 07/05/2021 (r) Patient #3513008 - Testing performed on 07/15/2021 (s) Patient #3514236 - Testing performed on 07/30/2021 (t) Patient #3516006 - Testing performed on 08/10/2021 (u) Patient #3516061 - Testing performed on 08/24/2021 (v) Patient #3518176 - Testing performed on 09/23/2021 (w) Patient #3518914 - Testing performed on 10/05/2021 (x) Patient #3519692 - Testing performed on 10/19/2021 (y) Patient #3521234 - Testing performed on 11/11/2021 (z) Patient #3522327 - Testing performed on 11/26 /2021 (aa) Patient #3523057 - Testing performed on 12/08/2021 (bb) Patient #3523694 - Testing performed on 12/15/2021 (cc) Patient #3524689 - Testing performed on 12/29/2021 (dd) Patient #3525444 - Testing performed on 01/10/2022 (ee) Patient #3526528 - Testing performed on 01/21/2022 (ff) Patient #3527065 - Testing performed on 01/27/2022 (gg) Patient #3528828 - Testing performed on 02/18 /2022 (hh) Patient #3529289 - Testing performed on 02/23/2022 (ii) Patient #3529522 - Testing performed on 02/26/2022 CHEM 8+ AND ISTAT 1 ANALYZER (1) On 03 /08/2022 at 03:35 pm the director of nursing stated the following: (a) The laboratory began performing BUN, Chloride, CO2, Creatinine, Ionized Calcium, Glucose, Hemoglobin, Hematocrit, Potassium, and Sodium testing using the Chem 8+ cartridge and iSTAT 1 analyzer on 11/21/2020; (b) An IQCP had not been developed for the test system. (2) It was determined that two levels of QC materials must be performed each day of patient testing; (3) A review of QC and patient testing records from 11/21 /2020 through 02/28/2022 revealed that two levels of QC materials had not been performed 48 of 99 days of testing reviewed; (4) The records were reviewed with the director of nursing who stated on 03/08/2022 at 03:43 pm, two levels of QC materials had not been performed each day of patient Chem 8+ testing: (5) The following were examples of patient Chem 8+ testing performed when two levels of QC materials had not been tested (Patient number represents order number): (a) Patient #3501114 - Testing performed on 11/24/2020 (b) Patient #3501253 - Testing performed on 11/28 /2020 (c) Patient #3501411 - Testing performed on 12/02/2020 (d) Patient #3502072 - Testing performed on 12/17/2020 (e) Patient #3502421 - Testing performed on 12/28 /2020 (f) Patient #3502631 - Testing performed on 01/20/2021 (g) Patient #3504585 - Testing performed on 02/06/2021 (h) Patient #3505199 - Testing performed on 02/19 /2021 (i) Patient #3505716 - Testing performed on 03/08/2021 (j) Patient #3505253 - Testing performed on 03/24/2021 (k) Patient #3506893 - Testing performed on 03/26 /2021 (l) Patient #3506976 - Testing performed on 03/31/2021 (m) Patient #3507288 - Testing performed on 04/07/2021 (n) Patient #3507493 - Testing performed on 04/12 /2021 (o) Patient #3507880 - Testing performed on 04/20/2021 (p) Patient #3508315 - Testing performed on 04/27/2021 (q) Patient #3508630 - Testing performed on 05/03 /2021 (r) Patient #3509864 - Testing performed on 05/26/2021 (s) Patient #3510011 - Testing performed on 05/31/2021 (t) Patient #3510333 - Testing performed on 06/07 /2021 (u) Patient #3510988 - Testing performed on 06/16/2021 (v) Patient #3511351 - Testing performed on 06/21/2021 (w) Patient #3512005 - Testing performed on 06/30 /2021 (x) Patient #3512385 - Testing performed on 07/06/2021 (y) Patient #3513282 - Testing performed on 07/19/2021 (z) Patient #3513806 - Testing performed on 07/27 /2021 (aa) Patient #3514717 - Testing performed on 08/06/2021 (bb) Patient

	#3515462 - Testing performed on 08/14/2021 (cc) Patient #3516009 - Testing performed on 08/27/2021 (dd) Patient #3517145 - Testing performed on 09/07/2021 (ee) Patient #3517780 - Testing performed on 09/19/2021 (ff) Patient #3518455 - Testing performed on 09/28/2021 (gg) Patient #3518861 - Testing performed on 10/05 /2021 (hh) Patient #3519693 - Testing performed on 10/19/2021 (ii) Patient #3520235 - Testing performed on 10/28/2021 (jj) Patient #3520750 - Testing performed on 11/04 /2021 (kk) Patient #3521906 - Testing performed on 11/18/2021 (ll) Patient #3522208 - Testing performed on 11/24/2021 (mm) Patient #3522845 - Testing performed on 12 /05/2021 (nn) Patient #3523430 - Testing performed on 12/14/2021 (oo) Patient #3524837 - Testing performed on 12/31/2021 (pp) Patient #3525226 - Testing performed on 01/06/2022 (qq) Patient #3526034 - Testing performed on 01/17/2022 (rr) Patient #3526942 - Testing performed on 01/26/2022 (ss) Patient #3527362 - Testing performed on 01/29/2022 (tt) Patient #3527810 - Testing performed on 02/04 /2022 (uu) Patient #3528600 - Testing performed on 02/15/2022 (vv) Patient #3529554 - Testing performed on 02/27/2022
D5479	CONTROL PROCEDURES CFR(s): 493.1256(e)(5)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to follow the manufacturer's quality control specifications for one of one test system. Findings include: (1) On 03/07/2022 at 12: 45 pm, the laboratory manager stated the following: (a) The laboratory began performing automated ESR (Erythrocyte Sedimentation Rate) testing using the Excyte 10 analyzer on 06/16/2021; (b) Two levels (normal and abnormal) of EliTech Group Accu-Sed Plus QC (quality control) materials were performed each day of patient testing. (2) On 03/08/2022, a review of the manufacturer's instructions for the control materials stated "Each laboratory should establish its own intralaboratory mean and standard deviation for each lot of ESR Control according to its own established procedures": (3) A review of QC records for the current lot numbers of control materials (Normal control lot #216010 and Abnormal control lot #217110) used from 06/16/2021 through 03/07/2022 revealed the laboratory had used the package insert means and limits for each level of control instead of establishing their own means and limits as stated in the manufacturer's package insert; (4) The findings were reviewed with the laboratory manager who stated on 03/08/2022 at 12:30 pm, the laboratory had not established their own means and limits of acceptability, but instead used the manufacturer's package insert limits; (5) The following were examples of patient ESR testing performed: (a) Patient #202322 - Testing performed on 06/17/2021 (b) Patient #202589 - Testing performed on 06/18/2021 (c) Patient #204270 - Testing performed on 06/29/2021 (d) Patient #204400 - Testing performed on 07/06/2021 (e) Patient #204470 - Testing performed on 07/08/2021 and 07/19/2021 (f) Patient #204599 - Testing performed on 07/14/2021 (g) Patient #204620 - Testing performed on 07/15 /2021 (h) Patient #200640 - Testing performed on 07/22/2021 (i) Patient #204935 - Testing performed on 07/29/2021 (j) Patient #201365 - Testing performed on 08/12 /2021 (k) Patient #204799 - Testing performed on 08/30/2021 (l) Patient #200611 - Testing performed on 09/09/2021 (m) Patient #204799 - Testing performed on 09/13

	/2021 (n) Patient #200766 - Testing performed on 09/28/2021 (o) Patient #204304 - Testing performed on 10/06/2021 (p) Patient #202826 - Testing performed on 10/29 /2021 (q) Patient #207260 - Testing performed on 11/15/2021 (r) Patient #207634 - Testing performed on 12/08/2021 (s) Patient #204291 - Testing performed on 12/15 /2021 (t) Patient #201295 - Testing performed on 01/13/2022 (u) Patient #208322 - Testing performed on 02/12/2022 (v) Patient #208670 - Testing performed on 02/25 /2022 (w) Patient #206426 - Testing performed on 03/07/2022
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 a review of records and interview with the director of nursing, the laboratory failed to perform one sample of control material each 8 hours of patient testing using a combination of control materials that include both low and high values on each day of blood gas testing for 24 of 25 patients tested. Findings include: (1) On 03/08/2022 at 03:35 pm the director of nursing stated the following: (a) The nursing staff in the Emergency Department began performing arterial and venous blood gas (pH, pCO2, pO2) testing in the Emergency Department using the CG4+ cartridge and iSTAT 1 analyzer on 12/09/2020; (b) An IQCP (Individualized Quality Control Program) had not been developed for the test system. (2) It was determined that two levels of QC materials must be performed each day of patient testing; (3) A review of QC and patient testing records from 12/09/2020 through 02/28/2022 revealed that QC testing had not been performed each eight hours of patient testing for 24 of 25 patients reviewed; (4) The records were reviewed with the director of nursing who stated on 03 /08/2022 at 03:43 pm, QC materials had not been performed each eight hours of patient blood gas testing: (5) The following were examples of patient Blood Gas testing performed when one sample of control material had not been performed each 8 hours of patient testing using a combination of control materials that included both low and high values on each day of patient testing (Patient number represents order number): (a) Patient #3501683 - Venous blood gas testing performed on 12/09/2021 (b) Patient #3501743 - Arterial blood gas testing performed on 12/10/2021 (c) Patient #3503160 - Arterial blood gas testing performed on 01/10/2021 (d) Patient #3503687 - Venous blood gas testing performed on 01/20/2021 (e) Patient #3504466 - Venous blood gas testing performed on 02/04/2021 (f) Patient #3506013 - Arterial blood gas testing performed on 03/04/2021 (g) Patient #3506304 - Arterial blood gas testing performed on 03/10/2021 (h) Patient #3506774 - Arterial blood gas testing performed on 03/23/2021 (i) Patient #3507371 - Venous blood gas testing performed on 04/08 /2021 (j) Patient #3507526 - Arterial blood gas testing performed on 04/12/2021 (k) Patient #3508303 - Venous blood gas testing performed on 04/26/2021 (l) Patient #3509448 - Arterial blood gas testing performed on 05/17/2021 (m) Patient #3505446 - Arterial blood gas testing performed on 08/14/2021 (n) Patient #3515859 - Arterial blood gas testing performed on 08/20/2021 (o) Patient #3517854 - Venous blood gas testing performed on 09/18/2021 (p) Patient #3519100 - Arterial blood gas testing performed on 10/07/2021 (q) Patient #3520903 - Venous blood gas testing performed on 11/07/2021 (r) Patient #3521055 - Arterial blood gas testing performed on 11/09 /2021 (s) Patient #3521845 - Arterial blood gas testing performed on 11/18/2021 (t)

	Patient #3523842 - Arterial blood gas testing performed on 12/17/2021 (u) Patient #3526438 - Arterial blood gas testing performed on 01/21/2022 (v) Patient #3526578 - Arterial blood gas testing performed on 01/22/2022 (w) Patient #3526636 - Arterial blood gas testing performed on 01/23/2022 (x) Patient #3526736 - Arterial blood gas testing performed on 01/24/2022
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: I. Based on a review of records and interview with the director of nursing, the laboratory failed to perform two levels of quality control testing each eight hours of PT /INR testing for 47 of 49 patients tested. Findings include: (1) On 03/08/2022 at 03:35 pm, the director of nursing stated the following: (a) The nursing staff in the Emergency Department began performing PT/INR (Prothrombin Time/International Normalized Ratio) testing using the PT/INR cartridge and iSTAT 1 analyzer on 06/19 /2020; (b) An IQCP (Individualized Quality Control Program) had not been developed for the test system. (2) It was determined two levels of QC (quality control) materials must be performed each eight hours of patient testing; (3) A review of QC and patient testing records from 11/06/2020 through 02/28/2022 revealed that two levels of QC materials had not been performed each eight hours of patient testing for 47 of 49 patients tested; (4) The records were reviewed with the director of nursing who stated on 03/08/2022 at 03:43 pm, two levels of QC materials had not been performed each eight hours of patient PT/INR testing: (5) The following were examples of patient PT /INR testing performed when two levels of QC materials had not been tested each eight hours of patient testing. (Patient number represents order number): (a) Patient #3500396 - Testing performed on 11/03/2020 (b) Patient #3501506 - Testing performed on 12/04/2020 (c) Patient #3501685 - Testing performed on 12/09/2020 (d) Patient #3501939 - Testing performed on 12/16/2020 (e) Patient #3502685 - Testing performed on 01/08/2021 (f) Patient #3503437 - Testing performed on 01/15/2021 (g) Patient #3503456 - Testing performed on 01/19/2021 (h) Patient #3502684 - Testing performed on 01/20/2021 (i) Patient #3504410 - Testing performed on 02/03/2021 (j) Patient #3504583 - Testing performed on 02/06/2021 (k) Patient #3504616 - Testing performed on 02/07/2021 (l) Patient #3506351 - Testing performed on 03/11/2021 (m) Patient #3506627 - Testing performed on 03/18/2021 (n) Patient #3505229 - Testing performed on 03/24/2021 (o) Patient #3507816 - Testing performed on 04/19 /2021 (p) Patient #3508214 - Testing performed on 04/26/2021 (q) Patient #3508922 - Testing performed on 05/06/2021 (r) Patient #3509298 - Testing performed on 05/13 /2021 (s) Patient #3510704 - Testing performed on 06/10/2021 (t) Patient #3511732 - Testing performed on 06/25/2021 (u) Patient #3512134 - Testing performed on 07/01 /2021 (v) Patient #3514165 - Testing performed on 07/29/2021 (w) Patient #3514282 - Testing performed on 07/31/2021 (x) Patient #3514372 - Testing performed on 08/01 /2021 (y) Patient #3515297 - Testing performed on 08/13/2021 (z) Patient #3515334 - Testing performed on 08/14/2021 (aa) Patient #3515857 - Testing performed on 08/20 /2021 (bb) Patient #3516446 - Testing performed on 08/27/2021 (cc) Patient # 3516974 - Testing performed on 09/05/2021 (dd) Patient #3517130 - Testing performed on 09/07/2021 (ee) Patient #3517917 - Testing performed on 09/19/2021

	(ff) Patient #3518610 - Testing performed on 10/01/2021 (gg) Patient #3518749 - Testing performed on 10/03/2021 (hh) Patient #3518842 - Testing performed on 10/04 /2021 (ii) Patient #3519212 - Testing performed on 10/08/2021 (jj) Patient #3519659 - Testing performed on 10/18/2021 (kk) Patient #3521799 - Testing performed on 11/17 /2021 (ll) Patient #3523211 - Testing performed on 12/10/2021 (mm) Patient #3523253 - Testing performed on 12/11/2021 (nn) Patient #3524388 - Testing performed on 12/24/2021 (oo) Patient #3525320 - Testing performed on 01/08/2022 (pp) Patient #3526280 - Testing performed on 01/20/2022 (qq) Patient #3526888 - Testing performed on 01/25/2022 (rr) Patient #3527744 - Testing performed on 02/03 /2022 (ss) Patient #3527838 - Testing performed on 02/05/2022 (tt) Patient #3527838 - Testing performed on 02/15/2022 (uu) Patient #3529162 - Testing performed on 02 /22/2022 39088 II. Based on a review of records and interview with the laboratory manager, the laboratory failed to perform two levels of quality control testing each eight hours of D-Dimer testing for 24 of 24 patients tested. Findings include: (1) On 03 /08/2022 at 01:05 pm, the laboratory manager stated the following: (a) The laboratory performed D-Dimer testing using the the Alere Triage beginning 07/22/2021; (b) An IQCP (Individualized Quality Control Plan) had not been developed for the test system. (2) It was determined that two levels of QC (quality control) materials must be performed each eight hours of patient testing; (3) A review of QC and patient testing records from 09/04/2021 through 03/01/2022 revealed that two levels of QC materials had not been performed each eight hours of patient testing for 24 of 24 patients tested; (4) The records were reviewed with the laboratory manager who stated on 03/09/2022 at 12:15 pm, two levels of QC materials had not been performed each eight hours of patient D-Dimer testing: (5) The following were examples of patient D-Dimer testing performed when two levels of QC materials had not been tested each eight hours of patient testing. (Patient number represents order number): (a) Patient #3517007 - Testing performed on 09/04/2021 (b) Patient #3518267 - Testing performed on 09/24/2021 (c) Patient #3518237 - Testing performed on 09/24/2021 (d) Patient #3518626 - Testing performed on 10/01/2021 (e) Patient #3519097 - Testing performed on 10/07/2021 (f) Patient #3520598 - Testing performed on 11/02/2021 (g) Patient #3521516 - Testing performed on 11/15/2021 (h) Patient #3522120 - Testing performed on 11/22/2021 (i) Patient #3522531 - Testing performed on 11/30/2021 (j) Patient #3523359 - Testing performed on 12/13/2021 (k) Patient #3523407 - Testing performed on 12/13/2021 (l) Patient #3523473 - Testing performed on 12/14/2021 (m) Patient #3523667 - Testing performed on 12/15/2021 (n) Patient #3523796 - Testing performed on 12/16/2021 (o) Patient #3524140 - Testing performed on 12/22 /2021 (p) Patient #3524323 - Testing performed on 12/23/2021 (q) Patient #3524403 - Testing performed on 12/24/2021 (r) Patient # 3524536 - Testing performed on 12/28 /2021 (s) Patient #3526781 - Testing performed on 01/24/2022 (t) Patient #3527000 - Testing performed on 01/26/2022 (u) Patient #3527463 - Testing performed on 01/31 /2022 (v) Patient #3527868 - Testing performed on 02/06/2022 (w) Patient #3529526 - Testing performed on 02/26/2022 (x) Patient #3529668 - Testing performed on 03/01 /2022
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. (c) The laboratory must document all test result comparison activities.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and director of nursing, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results using different methods for three of three test systems. Findings include: (1) On 03/07/2022 at 12:50 pm, the laboratory manager stated the laboratory began performing testing as follows: (a) Hemoglobin and Hematocrit testing using the Sysmex XS-1000i analyzer on 06/06/2020; (b) BUN, Chloride, CO2, Creatinine, Glucose, Potassium, and Sodium testing using the Olympus AU 640e analyzer on 11/16/2020. (2) On 03/08/2022 at 03:35 pm the director of nursing stated the nursing staff in the Emergency Department began performing testing as follows: (a) Hemoglobin, Hematocrit, BUN, Chloride, CO2, Creatinine, Glucose, Potassium, and Sodium testing using the Chem 8+ cartridge and iSTAT 1 analyzer on 11/21/2020. (3) A review of records from 01/01/2021 through 02 /28/2022 revealed no indication the relationship between the testing performed using the different test methods had been evaluated twice annually; (4) The laboratory manager provided documentation to prove the relationship between BUN, Chloride, CO2, Creatinine, Glucose, Potassium, and Sodium performed using the Chem 8+ cartridge and the Olympus AU 640e analyzer had been evaluated on 02/28/2022 and stated the following on 03/08/2022 at 04:30 pm: (a) The relationship between BUN, Chloride, CO2, Creatinine, Glucose, Potassium, and Sodium testing using the Chem 8+ cartridge and the Olympus AU 640e analyzer had not been evaluated prior to 02/28 /2022; (b) The relationship between Hemoglobin and Hematocrit testing using the Chem 8+ analyzer and the Sysmex XS-1000i analyzer had not been evaluated during the review period.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, manufacturer's instructions, observation, and interview with the laboratory manager and director of nursing, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to have a written procedure; failed to have written procedures that explained the current practices and procedures being performed in the laboratory; and failed to follow laboratory procedures. Refer to D5401; (b) The laboratory failed to ensure that written procedures no longer in use had been discontinued. Refer to D5409; (c) The laboratory failed to follow the manufacturer's intended use requirements; and failed to follow the manufacturer's instructions for verifying morphology flags. Refer to D5411; (d) The laboratory failed to ensure materials and analyzers were being stored as required by the manufacturer; and failed to ensure the humidity requirements were met for an analyzer. Refer to D5413; (e) The laboratory failed to ensure the performance specifications had been demonstrated for new test methods; and failed to ensure the reportable ranges had been utilized for new test methods. Refer to D5421;

	(f) The laboratory failed to follow the manufacturer's instructions for performing maintenance procedures. Refer to D5429; (g) The laboratory failed to perform function checks as defined by the manufacturer. Refer to D5431; (h) The laboratory failed to define a written function check protocol to ensure the urine centrifuge was functioning properly. Refer to D5435; (i) The laboratory failed to perform calibration verification procedures at least once every 6 months. Refer to D5439; (j) The laboratory failed to have control procedures that monitored the accuracy and precision of the testing process; and control procedures that would detect immediate error. Refer to D5441; (k) The laboratory failed to perform two levels of quality control materials each day of patient testing. Refer to D5447; (l) The laboratory failed to follow the manufacturer's quality control specifications. Refer to D5479; (m) The laboratory failed to perform one sample of control material each 8 hours of patient testing using a combination of control materials that include both low and high values on each day of blood gas testing. Refer to D5537; (n) The laboratory failed to perform two levels of quality control testing each eight hours of patient PT/INR and D-dimer testing. Refer to 5545; (o) The laboratory failed to have a system that twice a year evaluated and defined the relationship between test results using different methods. Refer to D5775.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, policies and procedures, manufacturer's instructions, observation, and interview with the laboratory manager and director of nursing, the laboratory director failed to provide overall management and direction. Findings include: (1) The laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Refer to D6013; (2) The laboratory director failed to ensure that laboratory personnel were performing the test methods as required for accurate and reliable results. Refer to D6014; (3) The laboratory director failed to ensure enrollment and participation in a proficiency testing program. Refer to D6015; (4) The laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Refer to D6020; (5) The laboratory director failed to ensure a quality assessment program had been established and maintained. Refer to D6021; (6) The laboratory director failed to ensure that persons performing moderate complexity testing had the appropriate training. Refer to D6029; (7) The laboratory director failed to ensure policies and procedures were established for monitoring the training and competency of testing persons. Refer to D6030; (8) The laboratory director failed to ensure that an approved procedure manual was available to all personnel responsible for the testing process. Refer to D6031.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently

	and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the laboratory manager and director of nursing, the laboratory director failed to ensure verification procedures for new test systems were adequate to determine the performance characteristics. Findings include: (1) The laboratory director failed to ensure the performance specifications had been demonstrated for new test methods; and failed to ensure the reportable ranges had been utilized for new test methods. Refer to D5421.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, manufacturer's instructions, observation, and interview with the laboratory manager and director of nursing, the laboratory director failed to ensure test methods were performed as required for accurate and reliable results. Findings include: (1) The laboratory director failed to ensure the manufacturer's instructions had been followed for Blood Gas and Lactate testing. Refer to D5203; (2) The laboratory director failed to ensure the manufacturer's intended use requirement had been followed for PT/INR testing and failed to ensure the manufacturer's instructions had been followed for verifying morphology flags. Refer to D5411; (3) The laboratory director failed to ensure materials and analyzers were being stored as required by the manufacturer. Refer to D5413; (4) The laboratory director failed to ensure the manufacturer's instructions had been followed for performing maintenance procedures. Refer to D5429; (5) The laboratory director failed to ensure function checks had been performed as defined by the manufacturer. Refer to D5431; (6) The laboratory director failed to ensure a written function check protocol had been defined to ensure the urine centrifuge was functioning properly. Refer to D5435.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

	This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory director failed to ensure enrollment and participation in a proficiency testing program for four of four events. Findings include: (1) On 03/07/2022, a review of proficiency testing records revealed no evidence the laboratory was enrolled in proficiency testing for hematology and chemistry testing for four of four events (2020 third chemistry event, 2020 third hematology event, 2021 first hematology event, and 2021 first chemistry event); (2) On 03/07/2022 at 01:00 pm, the laboratory manager stated the following: (a) The laboratory performed hematology testing using the Sysmex XS-1000i beginning 06/06/2020; (b) The laboratory performed chemistry and hematology testing using the iSTAT analyzer and Chem 8+ cartridge (Sodium, Potassium, Chloride, Total Carbon Dioxide, Ionized Calcium, Glucose, Urea Nitrogen, Creatinine, and Hematocrit) beginning 06/06/2020. (3) During an interview on 03/07/2022 at 01:50 pm, the laboratory manager stated the specific enrollment was not available. Phone call to the proficiency testing provider at 02:30 pm confirmed the laboratory had not enrolled for hematology and chemistry testing events until 03/31 /2021.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager and director of nursing, the laboratory director failed to ensure a quality control program was maintained to ensure the quality of laboratory services. Findings include: (1) The laboratory director failed to ensure calibration verification procedures had been performed at least once every 6 months. Refer to D5439; (2) The laboratory director failed to ensure the laboratory had control procedures that monitored the accuracy and precision of the testing process, and detect immediate error. Refer to D5441; (3) The laboratory director failed to ensure two levels of quality control materials had been performed each day of patient testing. Refer to D5447; (4) The laboratory director failed to ensure the manufacturer's quality control specifications had been followed. Refer to D5479; (5) The laboratory director failed to ensure one sample of control material had been performed each 8 hours of patient testing using a combination of control materials that include both low and high values on each day of blood gas testing. Refer to D5537; (6) The laboratory director failed to ensure two levels of quality control materials had been performed each eight hours of PT/INR and D-dimer testing. Refer to D5545; (7) The laboratory director failed to ensure there was a system that twice a year evaluated and defined the relationship between test results using different methods. Refer to D5775.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)

	The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, manufacturer's instructions, observation, and interview with the laboratory manager and director of nursing, the laboratory director failed to ensure a quality assessment program had been established and maintained. Findings include: (1) The laboratory director failed to ensure the laboratory had an ongoing mechanism for performing effective analytic quality assessment. Refer to D5791.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory director failed to ensure that persons performing moderate complexity testing had the appropriate training for 26 of 26 testing persons. Findings include: (1) On 03/07/2022, a review of personnel records revealed the following: (a) Testing Person #1 - This person was hired to perform patient testing on 06/06/2020. There was no documentation this person had been initially trained; (b) Testing Person #2 - This person was hired to perform patient testing on 06/06/2020. There was no documentation this person had been initially trained; (c) Testing Person #3 - This person was hired to perform patient testing on 06/06/2020. There was no documentation this person had been initially trained; (d) Testing Person #4 - This person was hired to perform patient testing on 12/26/2020. There was no documentation this person had been initially trained; (e) Testing Person #5 - This person was hired to perform patient testing on 05/15/2020. There was no documentation this person had been initially trained; (f) Testing Person #6 - This person was hired to perform patient testing on 05/15/2020. There was no documentation this person had been initially trained; (g) Testing Person #7 - This person was hired to perform patient testing on 05/15/2020. There was no documentation this person had been initially trained; (h) Testing Person #8 - This person was hired to perform patient testing on 05/15/2020. There was no documentation this person had been initially trained; (i) Testing Person #9 - This person was hired to perform patient testing on 07/13/2020. There was no documentation this person had been initially trained; (j) Testing Person #10 - This

	person was hired to perform patient testing on 12/29/2020. There was no documentation this person had been initially trained; (k) Testing Person #11 - This person was hired to perform patient testing on 05/15/2020. There was no documentation this person had been initially trained; (l) Testing Person #12 - This person was hired to perform patient testing on 08/27/2020. There was no documentation this person had been initially trained; (m) Testing Person #13 - This person was hired to perform patient testing on 05/15/2020. There was no documentation this person had been initially trained; (n) Testing Person #14 - This person was hired to perform patient testing on 05/15/2020. There was no documentation this person had been initially trained; (o) Testing Person #15 - This person was hired to perform patient testing on 05/15/2020. There was no documentation this person had been initially trained; (p) Testing Person #16 - This person was hired to perform patient testing on 11/19/2020. There was no documentation this person had been initially trained; (q) Testing Person #17 - This person was hired to perform patient testing on 05/15/2020. There was no documentation this person had been initially trained; (r) Testing Person #18 - This person was hired to perform patient testing on 11/02/2020. There was no documentation this person had been initially trained; (s) Testing Person #19 - This person was hired to perform patient testing on 05/06/2021. There was no documentation this person had been initially trained; (t) Testing Person #20 - This person was hired to perform patient testing on 08/27/2021. There was no documentation this person had been initially trained; (u) Testing Person #21 - This person was hired to perform patient testing on 09/24/2020. There was no documentation this person had been initially trained; (v) Testing Person #22 - This person was hired to perform patient testing on 11/02/2020. There was no documentation this person had been initially trained; (w) Testing Person #23 - This person was hired to perform patient testing on 09/09/2021. There was no documentation this person had been initially trained; (x) Testing Person #24 - This person was hired to perform patient testing on 05/15/2020. There was no documentation this person had been initially trained; (y) Testing Person #25 - This person was hired to perform patient testing on 11/01/2020. There was no documentation this person had been initially trained; (z) Testing Person #26 - This person was hired to perform patient testing on 11/01/2020. There was no documentation this person had been initially trained. (2) The findings were reviewed with the laboratory manager who stated on 03/07/2022 at 02:55 pm there was no additional documentation to prove the above persons had been initially trained to perform moderate complexity testing.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;

	This STANDARD is not met as evidenced by: Based on a review of records, written policy, and interview with the laboratory manager, the laboratory director failed to ensure policies and procedures were established for monitoring the training and competency of testing persons. Findings include: (1) On 03/07/2022 at 01:00 pm, the laboratory manager stated the laboratory began performing testing as follows: (a) CBC (Complete Blood Count) testing using the Sysmex XS-1000i analyzer on 06/06/2020; (b) Troponin I testing using the TnI cartridge and the iSTAT 1 analyzer on 06/06/2020; (c) Sodium, Potassium, Chloride, Ionized Calcium, Total CO2, Glucose, BUN, Creatinine, Hemoglobin, and Hematocrit testing using the Chem 8+ cartridge and the iSTAT 1 analyzer on 06/06/2020; (d) Blood Gas (pH, pCO2, pO2) and Lactate testing using the CG4+ cartridge and the iSTAT 1 analyzer on 06/06/2020; (e) PT/INR (Prothrombin Time/International Normalized Ratio) testing using the PT/INR cartridge and the iSTAT 1 analyzer on 06 /06/2020; (f) Chemistry testing using the Olympus AU 640E on 11/16/2020; (g) Urine sediment testing on 01/15/2021; (h) Erythrocyte Sedimentation Rate testing using the Excite analyzer on 06/16/2021; (i) D-Dimer testing using the Alere Triage on 07/22 /2021. (2) A review of the written laboratory procedures titled, "Policies And Procedures" revealed a procedure titled, "Employee Yearly Competency" which explained how the laboratory performed annual competencies, but a written policy that explained how the laboratory monitored and assessed initial training and semi-annual competencies for testing persons performing non-waived testing could not be found; (3) During an interview on 03/08/2022 at 12:48 pm, the laboratory manager stated the laboratory did not have a policy to monitor and assess initial training and semi-annual competencies for testing persons performing nonwaived testing; (4) The laboratory failed to have a written technical consultant competency policy based on the position responsibilities as listed in Subpart M for one of one technical consultants. Refer to D5209; (5) The laboratory failed to ensure that new testing persons had been trained. Refer to D6029.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on a review of written policies and procedures, and interview with the laboratory manager, the laboratory director failed to ensure that an approved procedure manual was available to all personnel responsible for the testing process. Findings include: (1) On 03/07/2022 at 12:45 pm, laboratory manager stated to surveyor #1 the laboratory began performing the following testing: (a) CBC (Complete Blood Count) testing using the Sysmex XS-1000i analyzer on 06/06/2020; (b) Troponin I testing using the TnI cartridge and the iSTAT 1 analyzer on 06/06 /2020; (c) Sodium, Potassium Chloride Ionized Calcium Total CO2, Glucose, BUN, and Creatinine testing using the Chem 8+ cartridge and the iSTAT 1 analyzer on 06/06 /2020; (d) Blood Gas (pH, pCO2, pO2) and Lactate testing using the CG4+ cartridge and the iSTAT 1 analyzer on 06/06/2020; (e) PT/INR (Prothrombin Time /International Normalized Ratio) testing using the PT/INR cartridge and the iSTAT 1

	analyzer on 06/06/2020. (2) A review of the manual titled, "Policies and Procedures" revealed it had not been approved, signed, and dated by the laboratory director until 09 /15/2020 (after the laboratory began patient testing); (3) The laboratory manager reviewed the manual and stated on 03/07/2022 at 03:10 pm, the procedure manual had not been approved, signed, and dated by the laboratory director until 09/15/2020; (4) The laboratory director failed to ensure the laboratory had a written technical consultant competency policy based on the position responsibilities as listed in Subpart M. Refer to D5209; (5) The laboratory director failed to ensure the laboratory had a written procedure; had written procedures that explained the current practices and procedures being performed in the laboratory; and followed current procedures. Refer to D5401; (6) The laboratory director failed to ensure procedures no longer in use had been discontinued. Refer to D5409.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on a review of records, policies and procedures, manufacturer's instructions, observation and interview with the laboratory manager and director of nursing, the technical consultant failed to provide technical oversight in accordance with 493.1413 of this subpart. Findings include: (1) The technical consultant failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications. Refer to D6035; (2) The technical consultant failed to ensure that verification procedures were adequate to determine the performance characteristics. Refer to D6040; (3) The technical consultant failed to ensure enrollment in a proficiency testing program. Refer to D6041; (4) The technical consultant failed to ensure a quality control program had been establised to which ensured the establishment and maintenance of acceptable levels of analytic performance. Refer to D6042; (5) The technical consultant failed to ensure semi-annual evaluations of all moderate complexity testing had been performed for 24 of 24 testing persons. Refer to D6053; (6) The technical consultant failed to ensure annual evaluations of all moderate complexity testing had been performed for 24 of 24 testing persons. Refer to D6054.
D6035	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 (a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required. (b) The technical consultant must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or (b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or

	subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or (b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and (b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or (b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and (b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible. Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure the individual who performed the duties and responsibilities of the technical consultant, met the qualifications for four of five proficiency testing attestation forms. Findings include: (1) On 03/07/2022, a review of 2021 proficiency testing records revealed that four of five attestation statements had been signed by an individual who did not meet the minimal educational qualifications of a technical consultant or designee. The attestation statement had been signed by the laboratory manager (this individual had earned a high school diploma). The following attestation statement had been signed by the laboratory manager: (a) Second 2021 Chemistry Core Event (b) Third 2021 Chemistry Core Event (c) Second 2021 Hematology Event (d) First 2021 Chemistry Miscellaneous Event (2) The records were reviewed with the laboratory manager who stated on 03/07/2022 at 04:00 pm, the attestation statements, as shown above, had been signed and dated by an individual who did not meet the regulatory qualification requirements of a technical consultant or designee.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on a review of records, policies and procedures, and interview with the laboratory manager and director of nursing, the technical consultant failed to ensure that verification procedures were adequate to determine the performance

	characteristics. Findings include: (1) The technical consultant failed to ensure the performance specifications had been demonstrated for new test methods; and failed to ensure the reportable ranges had been utilized for new test methods. Refer to D5421.
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the technical consultant failed to ensure enrollment in a proficiency testing program for four of four events. Findings include: (1) On 03/07/2022, a review of proficiency testing records revealed no evidence the laboratory was enrolled in proficiency testing for hematology and chemistry testing for four of four events (2020 third chemistry event, 2020 third hematology event, 2021 first hematology event, and 2021 first chemistry event); (2) On 03/07/2022 at 01:00 pm, the laboratory manager stated the following: (a) The laboratory performed hematology testing using the Sysmex XS-1000i beginning 06/06/2020; (b) The laboratory performed chemistry and hematology testing using the iSTAT analyzer and Chem 8+ cartridge (Sodium, Potassium, Chloride, Total Carbon Dioxide, Ionized Calcium, Glucose, Urea Nitrogen, Creatinine, and Hematocrit) beginning 06/06/2020. (3) During an interview on 03/07/2022 at 01:50 pm, the laboratory manager stated, the specific enrollment was not available. Phone call to the proficiency testing provider at 02:30 pm confirmed the laboratory had not enrolled for hematology and chemistry testing events until 03/31/2021.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, observation, and interview with the laboratory manager and director of nursing, the technical consultant failed to establish a quality control program which ensured the establishment and maintenance of acceptable levels of analytic performance. Findings include: (1) The technical consultant failed to ensure the laboratory had control procedures that monitored the accuracy and precision of the testing process. Refer to D5441; (2) The technical consultant failed to ensure two levels of quality control materials had been performed each day of patient testing. Refer to D5447; (3) The technical consultant failed to ensure the manufacturer's quality control specifications had been followed. Refer to D5479; (4) The technical consultant failed to ensure one sample of control material had been performed each 8 hours of patient testing using a combination of control materials that include both low and high values on each day of blood gas testing.

	Refer to D5537; (5) The technical consultant failed to ensure two levels of quality control materials had been performed each eight hours of PT/INR testing. Refer to D5545.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the technical consultant failed to ensure semi-annual evaluations of all moderate complexity testing had been performed for 24 of 24 testing persons. Findings include: (1) On 03/07/2022 at 01:00 pm, the laboratory manager stated the laboratory began performing testing as follows: (a) CBC (Complete Blood Count) testing using the Sysmex XS-1000i analyzer on 06/06/2020; (b) Troponin I testing using the TnI cartridge and the iSTAT 1 analyzer on 06/06/2020; (c) Sodium, Potassium, Chloride, Ionized Calcium, Total CO2, Glucose, BUN, Creatinine, Hemoglobin, and Hematocrit testing using the Chem 8+ cartridge and the iSTAT 1 analyzer on 06/06/2020; (d) Blood Gas (pH, pCO2, pO2) and Lactate testing using the CG4+ cartridge and the iSTAT 1 analyzer on 06/06 /2020; (e) PT/INR (Prothrombin Time/International Normalized Ratio) testing using the PT/INR cartridge and the iSTAT 1 analyzer on 06/06/2020; (f) Chemistry testing using the Olympus AU 640E on 11/16/2020; (g) Urine sediment testing on 01/15 /2021; (h) Eythrocyte Sedimentation Rate testing using the Excyte 10 analyzer on 06 /16/2021; (i) D-Dimer testing using the the Alere Triage on 07/22/2021. (2) A review of personnel records for 24 testing persons revealed semi-annual competency had not been performed for the following testing persons: (a) Testing Person #1 - This person was hired to perform patient testing on 06/06/2020. There was no evidence that a semiannual evaluation had been performed; (b) Testing Person #2 - This person was hired to perform patient testing on 06/06/2020. There was no evidence that a semiannual evaluation had been performed; (c) Testing Person #3 - This person was hired to perform patient testing on 06/06/2020. There was no evidence that a semiannual evaluation had been performed; (d) Testing Person #4 - This person was hired to perform patient testing on 12/26/2020. There was no evidence that a semiannual evaluation had been performed; (e) Testing Person #5 - This person was hired to perform patient testing on 05/15/2020. There was no evidence that a semiannual evaluation had been performed; (f) Testing Person #6 - This person was hired to perform patient testing on 05/15/2020. There was no evidence that a semiannual evaluation had been performed; (g) Testing Person #7 - This person was hired to perform patient testing on 05/15/2020. There was no evidence that a semiannual evaluation had been performed; (h) Testing Person #8 - This person was hired to perform patient testing on 05/15/2020. There was no evidence that a semiannual evaluation had been performed; (i) Testing Person #9 - This person was hired to perform patient testing on 07/13/2020. There was no evidence that a semiannual evaluation had been performed; (j) Testing Person #10 - This person was hired to perform patient testing on 12/29/2020. There was no evidence that a semiannual evaluation had been performed; (k) Testing Person #11 - This person was hired to perform patient testing on 05/15/2020. There was no evidence that a semiannual evaluation had been performed; (l) Testing Person #12 - This person was hired to perform patient testing on 08/27/2020. There was no evidence that a

	semiannual evaluation had been performed; (m) Testing Person #13 - This person was hired to perform patient testing on 05/15/2020. There was no evidence that a semiannual evaluation had been performed; (n) Testing Person #14 - This person was hired to perform patient testing on 05/15/2020. There was no evidence that a semiannual evaluation had been performed; (o) Testing Person #15 - This person was hired to perform patient testing on 05/15/2020. There was no evidence that a semiannual evaluation had been performed; (p) Testing Person #16 - This person was hired to perform patient testing on 11/19/2020. There was no evidence that a semiannual evaluation had been performed; (q) Testing Person #17 - This person was hired to perform patient testing on 05/15/2020. There was no evidence that a semiannual evaluation had been performed; (r) Testing Person #18 - This person was hired to perform patient testing on 11/02/2020. There was no evidence that a semiannual evaluation had been performed; (s) Testing Person #19 - This person was hired to perform patient testing on 05/06/2021. There was no evidence that a semiannual evaluation had been performed; (t) Testing Person #21 - This person was hired to perform patient testing on 09/24/2020. There was no evidence that a semiannual evaluation had been performed; (u) Testing Person #22 - This person was hired to perform patient testing on 11/02/2020. There was no evidence that a semiannual evaluation had been performed; (v) Testing Person #24 - This person was hired to perform patient testing on 05/15/2020. There was no evidence that a semiannual evaluation had been performed; (w) Testing Person #25 - This person was hired to perform patient testing on 11/01/2020. There was no evidence that a semiannual evaluation had been performed; (x) Testing Person #26 - This person was hired to perform patient testing on 11/01/2020. There was no evidence that a semiannual evaluation had been performed. (3) The findings were reviewed with the laboratory manager who stated on 03/08/2022 at 04:30 pm that the semi-annual competencies had not been performed as indicated above.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the technical consultant failed to ensure annual evaluations of all moderate complexity testing had been performed for 24 of 24 testing persons. Findings include: (1) On 03/07/2022 at 01:00 pm, the laboratory manager stated the laboratory began performing testing as follows: (a) CBC (Complete Blood Count) testing using the Sysmex XS-1000i analyzer on 06/06/2020; (b) Troponin I testing using the TnI cartridge and the iSTAT 1 analyzer on 06/06/2020; (c) Sodium, Potassium, Chloride, Ionized Calcium, Total CO2, Glucose, BUN, Creatinine, Hemoglobin, and Hematocrit testing using the Chem 8+ cartridge and the iSTAT 1 analyzer on 06/06/2020; (d) Blood Gas (pH, pCO2, pO2) and Lactate testing using the CG4+ cartridge and the iSTAT 1 analyzer on 06/06 /2020; (e) PT/INR (Prothrombin Time/International Normalized Ratio) testing using the PT/INR cartridge and the iSTAT 1 analyzer on 06/06/2020; (f) Chemistry testing using the Olympus AU 640E on 11/16/2020; (g) Urine sediment testing on 01/15 /2021; (h) Erythrocyte Sedimentation Rate testing using the Excyte 10 analyzer on 06 /16/2021; (i) D-dimer testing using the Alere Triage analyzer on 07/22/2021. (2) A review of personnel records for 24 testing persons revealed annual competencies had

	not been performed for the following testing persons: (a) Testing Person #1 - This person was hired to perform patient testing on 06/06/2020. There was no evidence that an annual evaluation had been performed; (b) Testing Person #2 - This person was hired to perform patient testing on 06/06/2020. There was no evidence that an annual evaluation had been performed; (c) Testing Person #3 - This person was hired to perform patient testing on 06/06/2020. There was no evidence that an annual evaluation had been performed; (d) Testing Person #4 - This person was hired to perform patient testing on 12/26/2020. There was no evidence that an annual evaluation had been performed; (e) Testing Person #5 - This person was hired to perform patient testing on 05/15/2020. There was no evidence that an annual evaluation had been performed; (f) Testing Person #6 - This person was hired to perform patient testing on 05/15/2020. There was no evidence that an annual evaluation had been performed; (g) Testing Person #7 - This person was hired to perform patient testing on 05/15/2020. There was no evidence that an annual evaluation had been performed; (h) Testing Person #8 - This person was hired to perform patient testing on 05/15/2020. There was no evidence that an annual evaluation had been performed; (i) Testing Person #9 - This person was hired to perform patient testing on 07/13/2020. There was no evidence that an annual evaluation had been performed; (j) Testing Person #10 - This person was hired to perform patient testing on 12/29/2020. There was no evidence that an annual evaluation had been performed; (k) Testing Person #11 - This person was hired to perform patient testing on 05/15/2020. There was no evidence that an annual evaluation had been performed; (l) Testing Person #12 - This person was hired to perform patient testing on 08/27/2020. There was no evidence that an annual evaluation had been performed; (m) Testing Person #13 - This person was hired to perform patient testing on 05/15/2020. There was no evidence that an annual evaluation had been performed; (n) Testing Person #14 - This person was hired to perform patient testing on 05/15/2020. There was no evidence that an annual evaluation had been performed; (o) Testing Person #15 - This person was hired to perform patient testing on 05/15/2020. There was no evidence that an annual evaluation had been performed; (p) Testing Person #16 - This person was hired to perform patient testing on 11/19/2020. There was no evidence that an annual evaluation had been performed; (q) Testing Person #17 - This person was hired to perform patient testing on 05/15/2020. There was no evidence that an annual evaluation had been performed; (r) Testing Person #18 - This person was hired to perform patient testing on 11/02/2020. There was no evidence that an annual evaluation had been performed; (s) Testing Person #19 - This person was hired to perform patient testing on 05/06/2021. There was no evidence that an annual evaluation had been performed; (t) Testing Person #21 - This person was hired to perform patient testing on 09/24/2020. There was no evidence that an annual evaluation had been performed; (u) Testing Person #22 - This person was hired to perform patient testing on 11/02/2020. There was no evidence that an annual evaluation had been performed; (v) Testing Person #24 - This person was hired to perform patient testing on 05/15/2020. There was no evidence that an annual evaluation had been performed; (w) Testing Person #25 - This person was hired to perform patient testing on 11/01/2020. There was no evidence that an annual evaluation had been performed; (x) Testing Person #26 - This person was hired to perform patient testing on 11/01/2020. There was no evidence that an annual evaluation had been performed. (3) The findings were reviewed with the laboratory manager who stated on 03/08/2022 at 04:35 pm the annual competencies had not been performed as indicated above.
D6063	LABORATORY TESTING PERSONNEL

	CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to ensure individuals who performed moderate complexity testing met the educational qualifications. Findings include: (1) The laboratory failed to ensure testing persons met the educational qualifications. Refer to D6065.
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a review of records and interview with the director of nursing and laboratory manager, the laboratory failed to ensure testing persons met the required educational qualifications to perform moderate complexity testing for 26 of 26 testing persons. Findings include: (1) On 03/07/2022 at 02:30 pm, the director of nursing stated the following testing was performed in the emergency department by 26 testing persons: (a) Blood Gas (pH, pCO2, pO2) and Lactate testing using the CG4+ cartridge and iSTAT 1 analyzer beginning 12/09/2020; (b) BUN, Chloride, CO2, Creatinine, Ionized Calcium, Glucose, Hemoglobin, Hematocrit, Potassium, and Sodium testing using the Chem 8+ cartridge and iSTAT 1 analyzer beginning 11/21/2020; (c) PT/INR (Prothrombin Time/International Normalized Ratio) testing using the PT/INR cartridge and iSTAT 1 analyzer beginning 06/19/2020; (d) Troponin I testing using the cTnI cartridge and iSTAT 1 analyzer beginning 06/19/2020. (2) A review of personnel records for the testing persons revealed education documents (a minimum of a high school diploma/transcript or equivalent (GED)) could not be located in the records for 26 of 26 testing persons; (3) The findings were reviewed with the director of nursing who stated on 03/07/2022 at 03:08 pm, the education documents could not be located.