Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0473165	01/27/2023
Name of Provider or Supplier	**Street Address, City, State**	
Cleveland Area Hospital	1401 W Pawnee Street, Cleveland, 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 recertification survey was performed on 01/25,26,27/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the director of diagnostic imaging and laboratory, laboratory manager, and testing person #5 during an exit conference performed at the conclusion of the survey.
D2094	ROUTINE CHEMISTRY CFR(s): 493.841(e) (1) For any unsatisfactory analyte or test performance or testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) For any unacceptable analyte or testing event score, remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager, the laboratory failed to take remedial action for unacceptable proficiency testing scores for one of four Chemistry Core events reviewed in 2021 and 2022. Findings include: (1) On 01/25/2023 at 11:15 am, the laboratory manager stated the laboratory performed Creatinine and Total Protein testing using the Siemens Dimension EXL 200 analyzer; (2) A review of Chemistry Core proficiency testing records for the third 2021, first 2022, second 2022, and third 2022 events identified the following failures for one of four events reviewed: (a) Creatinine - The laboratory received a score of 60%. The results for samples CH-14 and CH-15 had failed. There was no documentation to prove that remedial action had been taken for the failures; (b) Total Protein - The laboratory received a score of 40%. The results for samples CH-11, CH-12, and CH-15 had failed. There was no documentation to prove that remedial action

	had been taken for the failures. (3) The records were reviewed with the laboratory manager who stated on 01/27/2023 at 03:05 pm, there was no evidence that remedial action had been taken for the failures.
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 unacceptable proficiency testing scores for one of four Chemistry Core events reviewed in 2021 and 2022. Findings include: (1) On 01/25/2023 at 11:15 am, the laboratory manager stated the laboratory performed Acetaminophen, Lactic Acid, Salicylate, and Troponin I testing using the Siemens Dimension EXL 200 analyzer; (2) A review of Chemistry Core proficiency testing records for the third 2021, first 2022, second 2022, and third 2022 events identified the following failures for one of four events reviewed: (a) Acetaminophen - The laboratory received a score of 0%. The results for samples CH-11, CH-12, CH-13, CH-14, and CH-15 had failed. There was no documentation to prove that remedial action had been taken for the failures; (b) Lactic Acid - The laboratory received a score of 0%. The results for samples CH-11, CH-12, CH-13, CH-14, and CH-15 had failed. There was no documentation to prove that remedial action had been taken for the failures; (c) Salicylate - The laboratory received a score of 60%. The results for samples CH-14 and CH-15 had failed. There was no documentation to prove that remedial action had been taken for the failures; (d) Troponin I - The laboratory received a score of 0%. The results for samples CM-11, CM-12, CM-13, CM-14, and CM-15 had failed. There was no documentation to prove that remedial action had been taken for the failures. (3) The records were reviewed with the laboratory manager who stated on 01/27/2023 at 03:05 pm, there was no evidence that remedial action had been taken for the failures.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values.

	(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on a review of policies and procedures and interview with the laboratory manager, the laboratory failed to have a step by step procedure for one of five procedures reviewed. Findings include: (1) On 01/25/2023 at 11:00 am, the laboratory manager stated urine microscopic testing was performed in the laboratory; (2) On 01 /26/2023 a review of the urine microscopic procedure titled, "Urinalysis Microscopic Policy and Procedure" did not specify the speed and time to process the specimens in the centrifuge for microscopic examination of the sediment; (3) The procedure was reviewed with the laboratory manager who stated on 01/26/2023 at 10:05 am, the procedure did not include the speed and time the urines were to be processed for microscopic analysis.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager and testing person #2, the laboratory failed to follow the manufacturer's instructions for implementing one of two coagulation reagents. Findings include: (1) On 01/25/2023 at 11:43 am, the laboratory manager stated the laboratory performed PTT (Partial Thromboplastin Time) testing using the ACL Elite analyzer; (2) On 01/26/2023 at 09:15 am, the laboratory manager stated the current PTT reagent, SynthaSIL lot #N1117768, was put into use on 01/28/2022; (3) A review of the manufacturer's instructions contained in the "Hemostasis Performance Manual" under "Establishing A Normal Reference Interval" under the heading "Specimen Collection and Preparation" stated the following for a 20 donor study: (a) "Donors should be healthy and have no known pathological conditions. Don't use samples from inpatients (due to medical conditions and treatment regiments). Donors should not be on medication affecting coagulation, including (but not limited to) oral contraceptives, estrogen therapy (HRT), anticoagulants, high-dose aspirin, etc"; (b) "Donors should span the adult age range"; (c) Donors should be equally divided between male/female". (4) A review of the implementation records for the PTT reagent identified that, although the laboratory had used 20 donors (identified as ten males and ten females), there was no documentation to show the health status and medication history of the donors to ensure they met the requirements for a normal donor; (5) The records were reviewed with the laboratory manager and testing person #2. Both stated on 01/27/2023 at 10:15 am, there was no documentation to prove the the health status and medication history of the donors.
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: Based on a review of records and interview with the laboratory manager, the laboratory failed to verify the reference ranges and failed to ensure the performance specification data had been evaluated prior to implementing the new testing for one of two new analyzers introduced into the laboratory. Findings include: (1) On 01/25/2023 at 11:15 am, the laboratory manager stated the laboratory began performing Albumin, Ammonia, Alkaline Phosphatase, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Amylase, Total Bilirubin, BUN, Calcium,Chloride, CK (Creatine Kinase), CKMB (Creatine Kinase Isoenzyme), CO2, Creatinine, Glucose Magnesium, Potassium, Total Protein, Sodium, Troponin I, Uric Acid, Acetaminophen, CRP (C-Reactive Protein), Direct Bilirubin, Alcohol, Digoxin, Lactic Acid, HCG (Human Chorionic Gonadotropin), Prealbumin, Phenytoin, Phosphorus, Salicylate, TSH (Thyroid Stimulating Hormone), Valproic Acid, and Vancomycin testing using the Siemens Dimension EXL 200 analyzer in late July 2021 (the exact date could not be determined); (2) On 01/27/2023 a review of the performance specification records for the new test system identified the following: (a) There was no evidence the laboratory had verified the reference ranges for each analyte (no documentation to prove where the reference ranges were derived); (b) There was no evidence the performance specification data had been reviewed and evaluated by the laboratory. (3) The records were reviewed with the laboratory manager who stated the following on 01/27/2023 at 03:10 pm: (a) There was no documentation to prove the reference ranges had been verified for each analyte; (c) There was no documentation to prove the data had been reviewed and evaluated by the laboratory prior to beginning patient testing.
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: Based on a review of records, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures for two of three analyzers reviewed from 01/01/2022 through 12/31/2022. Findings include: CELL DYN RUBY (1) On 0125/2023 at 11:05 am, the laboratory manager stated CBC (Complete Blood Count) testing was performed using the Cell Dyn Ruby analyzer; (2) On 01/26/2022, a review of the manufacturer's maintenance log showed the following required weekly maintenance procedure: (a) "Clean Loader Components" (3) A review of maintenance logs from 01/01/2022 through 12/31/2022 identified weekly maintenance had not been documented as performed between: (a) 5/14/22-5/28/22 (4) The records were reviewed with the laboratory manager who stated on 01/26/2023 at 01:30 pm, the weekly maintenance had not been documented as performed as above. DIMENSION

	EXL 200 (1) On 01/25/2023 at 11:15 am, the laboratory manager stated the laboratory performed Albumin, Ammonia, Alkaline Phosphatase, ALT (Alanine Aminotransferase), AST (Aspartate Aminotransferase), Amylase, Total Bilirubin, BUN, Calcium,Chloride, CK (Creatine Kinase), CKMB (Creatine Kinase Isoenzyme), CO2, Creatinine, Glucose Magnesium, Potassium, Total Protein, Sodium, Troponin I, Uric Acid, Acetaminophen, CRP (C-Reactive Protein), Direct Bilirubin, Alcohol, Digoxin, Lactic Acid, HCG (Human Chorionic Gonadotropin), Prealbumin, Phenytoin, Phosphorus, Salicylate, TSH (Thyroid Stimulating Hormone), Valproic Acid, and Vancomycin testing using the Siemens Dimension EXL 200 analyzer; (2) On 01/27/2023 a review of the manufacturer's maintenance log showed the following required weekly maintenance procedures: (a) Clean outside of R2 Probe (b) Clean outside of HM Wash Probe (3) A review of maintenance logs from 01/01/2022 through 12/31/2022 identified weekly maintenance had not been documented as performed between: (a) 09/04/2022 and 09/20/2022 (b) 09/20/2022 and 10/02/2022 (4) The records were reviewed with the laboratory manager who stated on 01/26/2023 at 05:20 pm, the weekly maintenance had not been documented as performed as shown above.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of records and interview with the laboratory manager and testing person #5, the laboratory failed to perform quality control as stated in the IQCP's (Individualized Quality Control Plans) for three of four test systems. Findings include: (1) On 01/25/2023 at 11:15 am, the laboratory manager stated the laboratory performed the following testing and IQCP's had been developed for the test systems: (a) D-dimer testing using the BioSite Triage Meter Pro analyzer; (b) Troponin I testing using the BioSite Triage Meter Pro analyzer; (c) Blood Gas (pH, pCO2, pO2) testing using the iSTAT 1 analyzer and the EG6+ cartridge. (2) On 01/26/2023 a review of the QCP's (Quality Control Plans) for the above IQCP's identified the following: (a) D-dimer - Two levels of QC (quality control) materials were to be tested each 30 days and with new lot numbers of cartridges; (b) Troponin I - Two levels of QC materials were to be tested each 30 days and with new lot numbers of cartridges; (c) Blood Gas - Two levels of QC materials were to be tested each 30 days and with new lot numbers of cartridges. (3) A review of QC records for the test systems from 01/01/2022 through 12/31/2022 identified that QC testing had not been performed as stated in the QCP's as follows: (a) D-dimer - There was no documentation to prove QC had been performed between: (i) 06/30/2022 and 08/09/2022 (b) Troponin I - There was no documentation to prove QC had been performed between: (i) 06/16/2022 and 09/05/2022 (c) Blood Gas - There was no documentation

	to prove QC had been performed between: (i) 02/25/2022 and 04/05/2022. (4) The records were reviewed with testing person #5 who stated on 01/26/2023 at 11:00 am, QC had not been performed as stated above.
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, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results for Routine Chemistry and Troponin I testing performed using two test methods during the review period of June 2021 through the current date. Findings include: (1) On 01/25/2023 at 11:15 am, the laboratory manager stated the laboratory performed the following testing: (a) Troponin I testing using the Siemens Dimension EXL 200 analyzer as the primary method and the BioSite Triage Meter Pro analyzer as the backup method; (b) Sodium, Potassium, Chloride, CO2, Glucose, BUN, and Creatinine testing using the Siemens Dimension EXL 200 analyzer as the primary method and the iSTAT 1 analyzer Chem 8+ cartridge as the backup method. (2) A review of records from June 2021 through the current date identified no records to prove the relationship between the different test methods had been evaluated during the review period; (3) Interview with the laboratory manager on 01/25/2023 at 02:45 pm confirmed the relationship between the above test methods had not been evaluated.
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 and interview with the laboratory manager, the laboratory failed to follow their policy for monitoring the effectiveness of their QCP (Quality Control Plan) for four of four test systems. Findings include: (1) On 01/25 /2023 at 11:15 am, the laboratory manager stated the laboratory performed the following testing and IQCP's (Individualized Quality Control Plans) had been developed for the test systems: (a) D-dimer testing using the BioSite Triage Meter Pro analyzer; (b) Troponin I testing using the BioSite Triage Meter Pro analyzer; (c) Blood Gas (pH, pCO2, pO2) testing using the iSTAT 1 analyzer and the EG6+ cartridge; (d) Sodium, Potassium, Chloride, CO2, Ionized Calcium, Glucose, BUN, and Creatinine testing using the iSTAT 1 analyzer and the Chem 8+ cartridge. (2) On 01/26/2023 a review of the IQCP's for the above test systems identified that QA (Quality Assessment) reviews of the QCP's were to be performed on an annual basis

	for each test system; (3) A review of records for the test systems from June 2021 through the current date identified no documentation that annual QA reviews had been performed during the review period; (4) The records were reviewed with the laboratory manager who stated on 01/26/2023 at 11:45 am, annual QA reviews had not been documented as performed for the above test systems during June 2021 through the current date.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on a review of a patient report, manufacturer's instructions, and interview with the laboratory manager, the laboratory failed to make appropriate reference ranges available when the reference range was updated for one of two coagulation tests. Findings include: (1) On 01/25/2023 at 11:43 am, the laboratory manager stated the laboratory performed PTT (Partial Thromboplastin Time) testing using the ACL Elite analyzer; (2) On 01/26/2023, a review of the manufacturer's instructions contained in the "Hemostasis Performance Manual" under "Establishing A Normal Reference Interval" stated, "Reference Intervals should be established whenever there is a change in...": (a) "Lot number or reagent" (b) "At least once a year" (3) A review of the data for the annual reference interval study for PTT testing using SynthaSIL PTT reagent lot #N1117768, identified the normal reference interval had been verified as 22.5-31.7; (4) A review of a random patient PTT report with testing performed on 01 /26/2023 had a normal reference range of 23.7-35.3; (5) The report was reviewed with the laboratory manager who stated on 01/26/2023 03:40 pm, the laboratory had not updated the normal reference range into the laboratory's computer information system.
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 evaluate personnel performing moderate complexity testing at least annually and failed ensure evaluations included current moderate complexity testing for five of five persons. Findings include: (1) On 01/25/2023 at 10:45, the laboratory manager stated the laboratory had performed CBC (Complete Blood Count) testing using the Cell Dyn Ruby analyzer since the previous recertification survey performed 05/26/2021; (2) A review of personnel records for five persons performing moderate complexity testing during 2021, 2022, and to date in 2023 identified the following for five of five persons: (a) Testing Person #1/Laboratory Manager - An annual competency assessment had not been documented as performed since 12/01/2021. In addition, the 2021 competency did not include an assessment of the Cell Dyn Ruby analyzer, but listed an assessment for the Cell Dyn 1800 analyzer;

	(b) Testing Person #2 - An annual competency assessment had not been documented as performed since 12/01/2021. In addition, the 2021 competency did not include an assessment of the Cell Dyn Ruby analyzer, but listed an assessment for the Cell Dyn 1800 analyzer; (c) Testing Person #3 - An annual competency assessment had not been documented as performed since 12/01/2021. In addition, the 2021 competency did not include an assessment of the Cell Dyn Ruby analyzer, but listed an assessment for the Cell Dyn 1800 analyzer; (d) Testing Person #4 - An annual competency assessment had not been documented as performed since 12/01/2021. In addition, the 2021 competency did not include an assessment of the Cell Dyn Ruby analyzer, but listed an assessment for the Cell Dyn 1800 analyzer; (e) Testing Person #5 - An annual competency assessment had not been documented as performed since 12/01 /2021. In addition, the 2021 competency did not include an assessment of the Cell Dyn Ruby analyzer, but listed an assessment for the Cell Dyn 1800 analyzer; (3) The records were reviewed with the laboratory manager who stated on 01/25/2023 at 03: 00 pm, annual competency assessments had not been performed since 12/01/2021 and the documentation showed the competencies included an assessment of the Cell Dyn 1800 analyzer instead of the Cell Dyn Ruby analyzer.