Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 37D0473165	(X3) Date Survey Completed 09/26/2024
Name of Provider or Supplier Cleveland Area Hospital	**Street Address, City, State** 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 09/23,24,25,26/2024. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the chief executive officer and laboratory manager 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 failed to ensure proficiency testing attestation statement had been signed by the laboratory director or designee for one of six Microbiology events reviewed in 2023 and 2024. Findings include: (1) A review of the first, second, third of 2023; and first, second, and third of 2024 Microbiology proficiency testing records identified the attestation statement for the third event of 2024 had not been signed by the laboratory director or designee (s); (2) Interview with the laboratory manager on 09/25/2024 at 10:06 am confirmed the attestation statement had not been signed as stated above.
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 one of five hematology Proficiency testing events reviewed in 2023 and 2024. Findings include: (1) A review of Hematology Proficiency testing records for five events (First 2023, Second 2023, Third 2023, First 2024, and second of 2024) identified the following failure with no evidence that corrective action had been documented as performed: (a) First 2023 Event - The laboratory attained a score of 80% for Blood Cell Identification (Sample BCI-04). (2) Interview with the laboratory manager on 09/25 /2024 at 09:30 am confirmed corrective action had not been taken and documented for the failure.
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 testing program for five of five Hematology events reviewed from January 2023 through the current date. Findings include: (1) A review of Hematology proficiency testing records for the period of 2023 through 2024 identified the following for five of five events: (a) First 2023 Event - two of 11 results had not been graded by the proficiency testing program for Educational Blood Cell Identification (sample DIF-01): (i) DIF-01 Immature Cell (DIF) (%) - The laboratory's reported result of 0 did not agree with the "Expected Result" of 57-100. There was no documentation to indicate corrective action had been taken for the unacceptable response; (ii) DIF-01 Lymphocyte, reactive (DIF) (%) - The laboratory's reported result of 85 did not agree with the "Expected Result" of 0-7. There was no documentation to indicate corrective action had been taken for the unacceptable response. (b) Second 2023 Event - Two of seven results had not been graded by the proficiency testing program for Educational Blood Cell Identification (sample DIF-02): (i) DIF-02 Basophils (DIF) (%) - The laboratory's reported result of 4 did not agree with the "Expected Result" of 0-1. There was no documentation to indicate corrective action had been taken for the unacceptable response; (ii) DIF-02 Platelet estimate (DIF) - The laboratory's reported "Decreased" did not agree with the Expected Result "Adequate/Normal." There was no documentation to indicate corrective action had been taken for the unacceptable response. (c) Third 2023 Event - One of five results had not been graded by the proficiency testing program and stated, "See Commentary" under "Expected Result" for Educational Blood Cell Identification (sample ECI-15): (i) ECI-15 The laboratory's reported Lymphocyte normal. There

	was no evidence the laboratory reviewed the "Participant Summary Report" to evaluate their result. (d) First 2024 Event - Three of eight results had not been graded by the proficiency testing program for Educational Blood Cell Identification (sample DIF-01): (i) DIF-01 Immature Cell (DIF) (%) - The laboratory's reported result had not been graded by the proficiency testing program and stated, "See Data Summary" under "Expected Result". There was no evidence the laboratory reviewed the "Participant Summary Report" to evaluate their result; (ii) DIF-01 Neutrophil, seg or band (DIF) (%) - The laboratory's reported result of 1 did not agree with the "Expected Result" of 53-80. There was no documentation to indicate corrective action had been taken for the unacceptable response; (iii) DIF-01 RBC Morphology (DIF) - The laboratory's reported result had not been graded by the proficiency testing program and stated, "See Data Summary" under "Expected Result". There was no evidence the laboratory reviewed the "Participant Summary Report" to evaluate their result. (e) Second 2024 Event - One of nine results had not been graded by the proficiency testing program for Educational Blood Cell Identification (sample DIF-02): (i) DIF-02 RBC Morphology (DIF) - The laboratory's reported result had not been graded by the proficiency testing program and stated, "See Data Summary" under "Expected Result". There was no evidence the laboratory reviewed the "Participant Summary Report" to evaluate their result. (2) Interview with the laboratory manager on 09/24/2024 at 10:05 am confirmed the laboratory had not performed a self-evaluation to evaluate the non-graded results and corrective actions had not been taken as stated above.
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 specimens for testing performed in the laboratory. Findings include: (1) On 09/23/2024 at 12:12 pm, the laboratory manager stated the following testing were performed and specimens were transported to the laboratory from nursing homes and home health care agencies: (a) CBC (complete blood count) testing using the Abbott Cell-Dyn Ruby analyzer; (b) Routine Chemistry testing using the Siemens Dimension EXL 200 analyzer; (2) Interview with the laboratory manager on 09/23/2024 at 12:15 pm confirmed the laboratory did not provide written instructions (i.e., client service manual) to the clients to explain the laboratory's specimen collection and transportation policies.
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:

	Based on a review of written policies and procedures and interview with the laboratory manager, the laboratory failed to follow written procedures for blood bank alarm checks during the review period of 2023 through 2024. Findings include: (1) On 09/23/2024 at 11:00 am, the laboratory manager stated the laboratory routinely maintained four units of O negative 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 Celsius); (2) On 09/25/2024, a review of the laboratory's written procedure, titled, "Helmer Scientific Horizon Series TM Refrigerator - Undercounter Alarm Checks" stated, "Alarm checks should be performed on a quarterly basis for refrigerators that contain blood products"; (3) A review of the alarm check records from January 2023 through the current date identified the alarm checks had not been performed quarterly. There was no documentation alarm checks had been documented as performed between 12/27/2023 and 05/03/2024; (4) Interview with the laboratory manager on 09/25/2024 at 11:00 am confirmed the alarm checks had not been performed quarterly.
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 manger, the laboratory failed to utilize the demonstrated reportable ranges for two of four analytes reviewed on the Siemens Dimension EXL 200 analyzer. Findings include: (1) On 09/25/2024 at 01:00 pm, the laboratory manger stated the laboratory began performing Cholesterol and HDL (High Density Lipoprotein) testing using the Siemens Dimension EXL 200 analyzer on 12/21/2023; (2) A review of the performance specification records identified the laboratory had demonstrated the following reportable ranges: (a) Cholesterol - 71-431 mg/dl (b) HDL - 8-180 mg/dl (3) Interview with the laboratory manager on 09/25/2024 at 03:30 pm confirmed the laboratory was using the following manufacturer's reportable ranges instead of the reportable ranges that had been demonstrated by the laboratory: (a) Cholesterol - 50-600 mg/dl (b) HDL - 3-150 mg/dl
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 and interview with the laboratory manager, the laboratory failed to ensure the manufacturer's instructions were followed for

	performing maintenance procedures on the Abbott Cell-Dyn Ruby analyzer during the review period of October 2023 through the current date. Findings include: (1) On 09 /23/2024 at 12:12 pm, the laboratory manager stated the laboratory performed CBC (Complete Blood Count) testing using the Abbott Cell-Dyn Ruby analyzer; (2) A review of the manufacturer's instruction manual titled, "Cell-Dyn Ruby System Operator's Manual", Table 9.1- Scheduled Services and Maintenance Procedures required the following maintenance procedure: (a) Weekly - Cleaned loader components (3) A review of maintenance logs from October 2023 through the current date identified weekly maintenance had not been documented as performed as follows: (a) Between 12/20/2023 and 01/03/2024 (b) Between 02/13/2024 and 03/01 /2024 (c) Between 03/19/2024 and 04/04/2024 (4) Interview with the laboratory manager on 09/25/2024 at 04:16 pm confirmed the maintenance procedures had not been documented as performed as stated 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, the laboratory failed to perform QC (quality control) as stated in the IQCP (Individualized Quality Control Plan) for two of two i-STAT 1 test systems reviewed between January 2024 through the current date. Findings include: CHEM8+ CARTRIDGE (1) On 09/23/2024 at 12:12 pm, the laboratory manager stated the following: (a) The laboratory performed Sodium, Potassium, Chloride, Ionized Calcium, Glucose, BUN (Blood Urea Nitrogen), Creatinine, Anion Gap, and Total Carbon Dioxide testing using two iSTAT 1 analyzers serial number 421291 (primary) and serial number 327060 (backup) and the Chem 8+ cartridge; (b) Two levels of QC materials, Level 1 and Level 3 were tested monthly as stated in the QCP (Quality Control Plan). (2) A review of QC records from January 2024 through the current date identified no documentation to prove QC had been performed as stated in the QCP as follows: (a) Serial Number 421291: (i) Prior to 02/01/2024 (ii) Between 02/29/2024 and 07/12 /2024 (b) Serial Number 327060: (i) After 06/12/2024 (3) Interview with the laboratory manager on 09/24/2024 at 02:58 pm confirmed QC had not been performed as stated above. EG6+ CARTRIDGE (1) On 09/23/2024 at 12:13 pm, the laboratory manager stated the following: (a) The laboratory performed Blood Gas pH, pO2, and pCO2 testing using the iSTAT 1 analyzers serial number 421291 (primary) and serial number 327060 (backup) and the EG6+ cartridge; (b) Two levels of QC materials, Level 1 and Level 3 were tested monthly according to the QCP. (2) A review of QC records from January 2024 through the current date identified no documentation to prove QC had been performed as stated in the QCP as follows: (a) Serial Number 421291: (i) After 07/31/2024 (b) Serial Number 327060: (i) Between 02/23/2024 and 07/12/2024 (3) Interview with the laboratory manager on 09/24/2024 at 02:58 pm confirmed QC had not been performed as shown above.

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) during the review period of January 2023 through the current date. Findings include: (1) On 09/23/2024 at 12:12 pm, the laboratory manager stated the following: (a) The laboratory performed Sodium, Potassium, Chloride, Ionized Calcium, Glucose, BUN (Blood Urea Nitrogen), Creatinine, Anion Gap, and Total Carbon Dioxide testing using two iSTAT 1 analyzers serial number 421291 (primary) and serial number 327060 (backup) and the Chem 8+ cartridge; (b) The laboratory performed Blood Gas pH, pO2, and pCO2 testing using the iSTAT 1 analyzers serial number 421291 (primary) and serial number 327060 (backup) and the EG6+ cartridge; (c) An IQCP (Individualized Quality Control Plans) had been developed for the test systems. (2) A review of the IQCP identified that QA (Quality Assessment) reviews were to be performed on an annual basis; (3) A review of records from January 2023 through the current date identified no documentation that annual QA reviews had been performed prior to 09/16/2024; (4) Interview with the laboratory manager on 09/24/2024 at 03:04 pm confirmed annual QA reviews had not been documented as performed as stated above.
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 and interview with the laboratory manager, the laboratory failed to provide therapeutic reference intervals for INR (International Normalized Ratio) test results for one of one patient report reviewed. Findings include: (1) On 09/26/2024 at 09:30 am, the laboratory manager stated INR testing was performed using the Werfen IL ACL TOP 350 analyzer; (2) A review of one patient report with INR results for testing performed on 09/07/2024 identified the report did not include a therapeutic range (range for treatment of venous thrombosis, treatment of pulmonary embolism, prevention of systemic embolism, etc); (3) Interview with the laboratory manager on 09/26/2024 at 09:50 am confirmed the patient report did not include a therapeutic range for INR.