Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	37D0472805	03/13/2025
Name of Provider or Supplier	**Street Address, City, State**	
Cimarron Memorial Hospital	100 South Ellis, Boise City, 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 03/10,11,12,13/2025. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the chief executive officer and technical consultant #2 during an exit conference performed at the conclusion of the survey.
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on a review of records, written procedures, and interview with technical consultant #2, the laboratory failed to ensure the effectiveness of corrective actions and documentation of communication with staff for two of three proficiency testing failures for Unexpected Antibody Detection reviewed in 2024. Findings include: (1) On 03/10/2025 at 3:00 pm, the technical consultant stated Unexpected Antibody Detection was performed using the tube method; (2) On 03/11/2025, a review of the first, second, and third Immunohematology proficiency testing events identified the laboratory attained 80% scores for Unexpected Antibody Detection for two of three events as follows: (a) First 2024 Event - The laboratory reported "No Unexpected Antibodies" for sample SER-01 and the expected result was "Unexpected Antibody Detected"; (b) Third 2024 Event - The laboratory reported "No Unexpected Antibodies" for sample SER-12 and the expected result was "Unexpected Antibody Detected". (3) A review of the Quality Assessment policy titled, "Quality Assurance Plan" identified the following: (a) Under the heading "Proficiency Testing Assessment" it stated, "To ensure that PT resports are evaluated and unacceptable

	results analyzed to determine the cause of the failure"; (b) Under the heading "Quality Assurance Review with the Staff" it stated, "A laboratory staff meeting will be conducted by the laboratory manager to discuss the results of the laboratory's quality assurance assessment. The staff will be informed of any problems identified and their solutions". (4) A review of the "PT Failure Corrective Action Form" that had been completed by the laboratory to investigate the cause of the failed results identified a question on the form that stated "Could patient results have been affected? If so, explain course of action". The following was identified: (a) First 2024 Event failure - Although the documentation addressed that patient results could have been affected by the failure it did not explain the course of action taken to prevent a recurrence such as documentation of review or revision of procedures and/or communication /retraining of staff as stated in the Quality Assessment policy; (b) Third 2024 Event failure - Although the documentation addressed that the test had been repeated and identified a weak reaction, it did not address if patient results could have been affected by the failure and did not explain the course of action taken to prevent a recurrence such as documentation of review or revision of procedures and/or communication /retraining of staff as stated in the Quality Assessment policy. (5) The findings were reviewed with technical consultant #2 who stated on 03/11/2025 at 10:05 am that although the failures had been reviewed with the staff, the communication and training had not been documented.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(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 records, policies and procedures and interview with technical consultant #2, the laboratory failed to have complete written quality control procedures for one of one procedure reviewed. Findings include: (1) On 03/12/2025 at 04:00 pm, technical consultant #2 stated the following: (a) CBC (Complete Blood Count) testing was performed using the Horiba ABX Micros 60 analyzer; (b) Three levels of QC (quality control) materials were tested each day of patient testing; (c) When new lot numbers of QC material were put into use, the laboratory established a mean for each level and analyte, and used historic standard deviations to set the limits

	of acceptability. (2) A review of the manual titled, "General Procedures, Volume 1 Manual" under the tab "Hematology" identified no evidence of procedures describing the method for establishing QC limits and setting historic standard deviations; (3) The findings were reviewed with technical consultant #2 who stated on 03/13/2025 at 09: 20 am, the CBC procedures did not include the laboratory's method for putting new lot numbers of QC materials into use.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (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 technical consultant #2, the laboratory failed to follow the manufacturer's testing instructions for Blood Gas testing for two of five patients reviewed in 2024. Findings include: (1) On 03/12/2025 at 11:00 am, technical consultant #2 stated Arterial Blood Gas (pH, pCO2, pO2) testing was performed using the CG4+ cartridge and the iSTAT1 analyzer; (2) A review of the manufacturer's "User's Guide" under the section titled, "Blood Collection" stated, "Samples for blood gases should be tested within 10 minutes"; (3) A review of five patient reports for blood gas testing performed from 08 /01/2024 through 02/02/2025 identified no evidence the samples had been tested within ten minutes for two of the five patients as follows: (a) Patient tested on 08/01 /2024 - The sample had been collected at 05:15 am and the result reported at 05:42 am; (b) Patient tested on 12/04/2024 - The sample had been collected at 06:10 am and the result reported at 06:30 am. (4) The records were reviewed with technical consultant #2 who stated on 03/12/2025 at 01:30 pm there was no evidence the samples had been tested within ten minutes.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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, manufacturer's package insert, and interview with technical consultant #2, the laboratory failed to ensure calibration verification for D-dimer testing was performed following the manufacturer's instructions for one of two calibration verification procedures performed in 2024. Findings include: (1) On 03/11 /2025 at 02:50 pm, technical consultant #2 stated the following: (a) D-dimer testing was performed using the Biosite Triage Meter Pro analyzer; (b) Calibration verification procedures were performed at least once every six months using the Quidel Triage Total 5 Calibration Verification materials. (2) A review of records from January 2024 through December 2024 identified calibration verification had been performed on 4/13/2024 and 10/12/2024 with the following identified for one of the two procedures performed: (a) 4/13/2024 - The results attained for level E material (2880) was not within the acceptable limits as defined in the package insert (3020->5000) and there was no documentation that the unacceptable result had been addressed. (3) A review of the manufacturer's package insert for the calibration verification materials under the section titled, "Calibration Verification and Acceptability of Results" stated, "If one or more of the materials fall outside the acceptable range, test another tube of the same material. If the material does not fall into the acceptable range after re-testing, contact Quidel"; (4) The findings were reviewed with technical consultant #2 who stated on 03/11/2025 at 3:30 pm, the laboratory had not followed the manufacturer's instructions for addressing the unacceptable result.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2, the laboratory failed to verify the stated value of control materials before they were put into use for four of four lot numbers reviewed. Findings include: (1) On 03/13/2025 at 09:15 am, technical consultant #2 stated the following: (a) Glucose, BUN, Sodium, Potassium, Chloride, Creatinine, AST (Aspartate Aminotransferase), ALT (Alanine Aminotransferase), Alkaline Phosphatase, Total Bilirubin, Total Protein, Albumin, Calcium, Amylase, Dirct Bilirubin, Total Iron, Lipase, Magnesium, Phosphorus, and Uric Acid testing were performed using the Horiba Pentra C400 analyzer; (b) Two levels of QC (Quality Control) materials were tested each day of patient testing: (c) The manufacturer's provided ranges were used to determine acceptability of QC results. (2) A review of records identified no evidence the provided ranges were verified before the lot numbers were put into use for four of four lot numbers as follows: (a) ABX Pentra N MultiControl lot #N22055 - In use from 01/01/2024 through 06/08/2024; (b) ABX Pentra P MultiControl lot #P22069 - In use from 01/01

	/2024 through 08/19/2024; (c) ABX Pentra N MultiControl lot #N23034 - Put into use on 06/09/2024 and currently in use; (d) ABX Pentra P MultiControl lot #P23049 - Put into use on 08/20/2024 and currently in use. (3) The findings were reviewed with technical consultant #2 who stated on 03/13/2025 at 11:50 am, the manufacturer's stated ranges had not been verified prior to putting the above lot numbers of QC materials into use.
D5789	TEST RECORDS CFR(s): 493.1283(b) (b) Records of patient testing including, if applicable, instrument printouts, must be retained. This STANDARD is not met as evidenced by: Based on a review of records and interview with technical consultant #2, the laboratory failed to maintain patient Blood Gas instrument printouts that reflected accurate dates and times of testing for five of five patient records reviewed. Findings include: (1) On 03/12/2025 at 11:00 am, technical consultant #2 stated the following: (a) Patient Blood Gas (pH, pCO2, pO2) testing was performed using the CG4+ cartridge and the iSTAT 1 analyzer; (b) The analyzer was not directly interfaced with the LIS (Laboratory Information System) and patient results were manually entered into the LIS, with the instrument printouts maintained for at least two years. (2) A review of five patient Blood Gas reports, generated from the LIS, compared to the corresponding instrument printouts identified the dates and times of testing did not correlate as follows: (a) Patient Account 10044165 - The report showed testing was performed on 08/01/2024 at 05:42 am; the instrument printout showed testing was performed on 06/17/2024 at 09:23 pm; (b) Patient Account #10045174 - The report showed testing was performed on 10/16/2024 at 02:53 pm; the instrument printout showed testing was performed on 08/24/2024 at 08:11 am; (c) Patient Account #10045685 - The report showed the testing was performed on 12/04/2024 at 06:30 am; the instrument printout showed testing was performed on 11/28/2024 at 03:12 pm; (d) Patient Account #10045880 - The report showed testing was performed on 12 /20/2024 at 08:19 pm; the instrument printout showed testing was performed on 11/28 /2024 at 06:18 pm; (e) Patient Account #10046346 - The report showed testing was performed on 02/02/2025 at 06:58 pm; the instrument printout showed testing was performed on 11/29/2024 at 12:32 am. (3) The records were reviewed with technical consultant #2 who stated on 03/12/2025 at 01:30 pm, the dates and times reflected on the iSTAT instrument printouts were not accurate.