

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 11D0021848	(X3) Date Survey Completed 02/20/2024
Name of Provider or Supplier Dodge County Hospital Laboratory	Street Address, City, State 901 Griffin Avenue, Eastman, GA	
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	A recertification survey was performed on February 20 and 21, 2024. The facility was found to be NOT in compliance with all applicable CLIA requirements for specialties /subspecialties for 42 CFR.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Quality Control (QC) documents for the GEM Premier 3000 Blood Gas analyzer (GEM3000), and staff interview, the Blood Gas Lab (BGL) failed to retain the package inserts from the QC lot numbers for 2022 and 2023. Findings: 1. A review of the monthly QC documents for the GEM3000, for 2022 and 2023 revealed the laboratory failed to retain copies of the package inserts that contained the manufacturers QC ranges, for each lot number. 2. Interview with the Respiratory Department Manager and the Laboratory Manager, on 2/21/2024, in the Laboratory Manager's office, at approximately 1 pm, confirmed the aforementioned statement.</p>
D5403	<p>PROCEDURE MANUAL CFR(s): 493.1251(b)</p> <p>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.</p>

(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 standard operating procedure manual (SOP) review and interview with the lab manager, the laboratory failed to include a policy and procedure (P&P) for the actions to take if a test system becomes inoperable (downtime policy). Findings include: 1. SOP review revealed the laboratory did not have a written P&P for actions to take if a test system becomes inoperable for the specialties/subspecialties of: Coagulation, Hematology, Chemistry, and Bacteriology. 2. An interview with the lab manager, on 2/21/2024, at 11:53 a.m., in the office, confirmed the lack of the aforementioned procedures.

D5537

ROUTINE CHEMISTRY
CFR(s): 493.1267(b)(d)

For blood gas analyses, the laboratory must perform the following: (b) Test one sample of control material each 8 hours of testing using a combination of control materials that include both low and high values on each day of testing. (d) Document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of the Quality Control (QC) documents for the GEM Premier 3000 Blood Gas Analyzer (GEM3000) for 2022 and 2023 and staff interview, the Laboratory failed to perform QC every 8 hours as required under 493.1267(b)(d). Findings: 1. A review of the QC documents for GEM3000 for 2022 and 2023 confirmed the laboratory was performing QC once per shift of each 12 hour shift. 2. Interview with the Laboratory Manager and the Respiratory Manager, on 02/20, 2024 at approximately 4 pm and again on 02/21/2024 at approximately 3 pm, in the Laboratory Manager's office, the aforementioned statement was confirmed. This citation was also discussed with the Laboratory Director and Administration staff on 2/21/2024, at approximately 3 pm in the closing meeting.

D5553

IMMUNOHEMATOLOGY
CFR(s): 493.1271(b)(f)

(b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
Based on review of the Blood Bank(BB) Policy and Procedure Manual (SOP) and staff interview, the laboratory failed to provide a procedure for the processing of units received from Walter Shepherd Community Blood Center (WSCBB) Blood Product Provider. Findings: 1. A review of the BB SOP confirmed a procedure for the processing of units and blood products received from WSCBB, was not available. 2. Staff interview with the Laboratory Manager (LM) on 2/21/2024, at approximately 2 pm, in the LM's office, confirmed the above aforementioned statement.

D5783

CORRECTIVE ACTIONS
CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:
Based on Urinalysis Quality Control (QC) document review and interview with the lab manager, the laboratory failed to document corrective actions when QC was out of limits for Specific Gravity (SG) and pH. Findings: 1. A review of SG QC results for Abnormal control lot # 163234 revealed the control was out of range (1.010 - 1.025) 3 of 59 days reviewed for February - March 2023 without corrective actions noted. 2. A review of pH QC results for abnormal control lot # 163234 revealed the control was out of range (7 to \geq 9) 27 of 181 days reviewed for February - July 2023 without corrective actions noted. 3. Interview with the lab manager on 2/20/24 at 3:45 PM in her office, confirmed the aforementioned findings.

D6004

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(a)(b)

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on findings during the Recertification Survey on February 20 and 21, 2024, the Laboratory Director failed to ensure that all duties were properly being performed. REFERENCE: D-3032 Retention Requirements D-5403 Procedure Manual D-5537 Routine Chemistry D-5553 Immunohematology D-5783 Corrective Action