

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D0027451	(X3) Date Survey Completed 10/08/2025
Name of Provider or Supplier Grove Hill Memorial Hospital	Street Address, City, State 295 S Jackson St, Grove Hill, AL	
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
D2009	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the 2024-2025 American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the General Supervisor (GS), the laboratory failed to ensure the Laboratory Director (or designee) signed the attestation statements for seven of the 24 PT events reviewed. The findings include: 1. A review of the 2024-2025 API PT records revealed the Laboratory Director (or designee) failed to sign the attestation statements for the following PT events: a) 2024 Chemistry Core - 1st and 3rd Events b) 2024 Chemistry Miscellaneous - 2nd Event c) 2024 Hematology/Coagulation - 3rd Event d) 2024 Microbiology - 2nd Event e) 2025 Hematology/Coagulation - 2nd Event f) 2025 Microbiology - 1st Event 2. The Chief Operating Officer and the GS confirmed the above findings during Day 2 exit conference on 10-08-2025 at 4:28 PM.</p>
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(a)</p> <p>(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT)</p>

	<p>records and an interview with the Chief Operating Officer and the General Supervisor (GS), the laboratory received failing scores for the regulated analytes Sodium (Na) and Creatine Kinase (CK) on two out of six 2024 Chemistry PT events. The findings include: 1. A review of the API PT records revealed the laboratory received unsatisfactory scores for the following analytes. a) 2024 Chemistry Core 1st Event, Sodium was 20% b) 2024 Chemistry Miscellaneous 3rd Event, Creatine Kinase was 20% 2. The Chief Operating Officer and the GS confirmed the above findings during Day 2 exit conference on 10-08-2025 at 4:28 PM</p>
<p>D2121</p>	<p>HEMATOLOGY CFR(s): 493.851(a)</p> <p>(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the Chief Operating Officer and the General Supervisor, the laboratory received failing scores for Activated Partial Thromboplastin Time (APTT) testing on one of the six 2023-2025 PT events. The findings include: 1. A review of the API PT records revealed the laboratory received an unsatisfactory score (40%) for APTT testing on 2023 Hematology/Coagulation 3rd Event. 2. The Chief Operating Officer and the GS confirmed the above findings during the Day 2 exit conference on 10-08-2025 at 4:28 PM.</p>
<p>D3031</p>	<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. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Alere Triage Quality Control records for D-Dimer testing and an interview with the Chief Operating Officer and the General Supervisor (GS), the laboratory failed to provide the surveyor Quality Control records for 16 of the 25 months reviewed from September 2023 through September 2025. The findings include: 1. A review of the Alere Triage records revealed the laboratory performed and documented D-Dimer QC from January-September 2025. However, there was no D-Dimer QC documentation provided for review from September 2023 through December 2024. 2. The Chief Operating Officer and the GS confirmed the above findings during Day 2 exit conference on 10-08-2025 at 4:28 PM.</p>
<p>D5211</p>	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p>

This STANDARD is not met as evidenced by:
Based on a review of the 2024-2025 American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the Chief Operating Officer and the General Supervisor (GS), the laboratory failed to document review and evaluation of PT performance. This was noted for six of the 24 PT events reviewed. The findings include: 1. A review of the API PT records revealed no documentation of review of the returned evaluations by the Laboratory Director, or designee, for the following events: a) 2024 Hematology, 2nd Event. b) 2024 Microbiology, 2nd Event. c) 2024 Immunology and Immunochemistry, 1st and 2nd Events. d) 2024 Chemistry Core, 1st and 3rd Events. 2. The Chief Operating Officer and the GS confirmed the above findings during the exit conference on 10-08-2025 at 4:28 PM.

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 review of the Coagulation ACL Top analyzer's Policy and Procedures (P&P) for the Normal Prothrombin Time (PT)/International Normalized Ratio (INR) and an interview with the Chief Operating Officer and the General Supervisor (GS), the laboratory failed to follow the specimen requirements in the collection of patient samples used for the calculation of the normal patient PT mean. The surveyor noted an incorrect mean was utilized in the calculation of the INR in use for patient testing for approximately five of the ten months reviewed in 2025. The findings include: 1. A review of the P&P for the PT/INR calculation revealed specimens utilized in the calculation of the normal patient PT mean should be from individuals meeting the following criteria: a) No anticoagulant use b) No birth control or hormone replacement therapy c) The Citrate Blue Top collection tube must be filled to the correct level 2. A review of the normal patient PT mean study results revealed three of the twenty specimens had PT results outside the laboratory's normal range and were not excluded when calculating the normal mean. 3. The Chief Operating Officer and the GS confirmed the above findings during the Day 2 exit conference on 10-08-2025 at 4:28 PM.

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 reviews of the Beckman Coulter (BC) AU 700 Chemistry analyzer calibration and Quality Control (QC) records, and an interview with the General Supervisor (GS), the laboratory failed to fulfill CLIA Calibration-Verification (C-V) regulatory requirements by performing three levels of QC twice a day or implementing C-V procedures at least every six months. The surveyor noted no documentation of five of the five C-Vs due during the August 2023 through August 2025 review period. The findings include: 1. A review of the calibration records for the BC AU 700 analyzer revealed analytes included in the Complete Metabolic Panel, Lipid Panel, Renal Panel, Hepatic Panel and other Chemistry regulated analytes including Amylase, Lactate Dehydrogenase, Cholesterol LDL, Iron, Magnesium, Phosphorus, and Uric Acid were calibrated with less than three calibrators. 2. A review of the procedures in use during the previous survey period revealed the laboratory had opted to perform three levels of QC twice a day in lieu of performing calibration verification on analytes utilizing less than three calibrators. 3. However, a review of the 2023-2025 QC records revealed days when QC on the BC AU 700 for the above listed analytes was only performed once each day of testing, with no implementation of calibration verification procedures utilizing three or more C-V samples. 4. During the Day 2 exit conference on 10-08-2025 at approximately 4:28 PM, the GS confirmed the above findings, and stated there were days when the laboratory could only perform one QC run due to a limited supply of QC materials from the manufacturer.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(9)

(b)(9) Thereafter, evaluations must be performed at least annually

This STANDARD is not met as evidenced by:

Based on a review of 2023-2025 personnel evaluation records and an interview with General Supervisor, the Technical Consultant (TC) failed to assess and document the 2023 annual competency for one of the six Testing Personnel (TP) responsible for the blood gases testing. The findings include: 1. A review of personnel evaluation records for TP listed on the CMS-209 Form (Laboratory Personnel Report) from 2023-2025 revealed the TC failed to perform and document the annual 2023 competency assessment for TP6. 2. The Chief Operating Officer and the GS confirmed the above findings during the exit conference on 10-08-2025 at 4:28 PM.

D6086

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(3)(ii)

(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and

This STANDARD is not met as evidenced by:
Based on a review of the implementation records for the Beckman Coulter (BC) DxH 690T Hematology analyzer, the BC Operation Qualification Checklist and an interview with General Supervisor (GS), the Laboratory Director (LD) failed to document review and approval (as indicated by a signature and date) of installation procedures verifying the manufacturer's performance specifications before patient testing began on 06-11-2024. This affected one of one new instruments installed in 2024. The findings include: 1. A review of the implementation records for the BC DxH 690T Hematology analyzer revealed the validation studies were not signed by the LD to indicate his review and approval of the following verification studies: A) Precision B) Carryover C) Accuracy and Calibration D) Calibration E) Linearity F) Mixing Studies 2. A further review of the validation records revealed only the Method Comparison was signed by the LD on 06-11-2024. 3. The Chief Operating Officer and the GS confirmed the above findings during the exit conference on 10-08-2025 at 4:28 PM.

D6107

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(15)

(e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on reviews of personnel records, the American Proficiency Institute (API) Proficiency Testing (PT) records and an interview with the General Supervisor (GS), the Laboratory Director (LD) failed to specify in writing which of the LD's duties and responsibilities were assigned to a designee. The surveyor noted there was no written documentation for the designation of authority from the date of the last survey, 08-24-2023 to the date of the current survey, 10-08-2025. The findings include: 1. A review of personnel records revealed the LD had no documentation authorizing a qualified designee to perform certain duties and responsibilities in all phases of the laboratory testing process. 2. A review of the API PT records revealed Testing Personnel #1 had signed the following PT attestation events. a) 2023 Chemistry Core, Chemistry Miscellaneous, Hematology, Microbiology, Immunology and Immunochemistry 3rd events. b) 2024 Hematology 1st event c) 2024 Immunology and Immunochemistry 1st event 3. At approximately 11:10 AM on 10-07-2025, the GS presented the surveyor a designation of authority document, however the LD's signature did not match with the LD's signature on the CMS 116 and 209 forms submitted during the previous survey on 08-24-2023.

D6171

TESTING PERSONNEL QUALIFICATIONS
CFR(s): 493.1489(b)

(b) Meet one of the following requirements: (b)(1) 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; or (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical

laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii) (A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations.

This STANDARD is not met as evidenced by:

Based on a review of personnel records, and an interview with the General Supervisor, the laboratory failed to ensure one of six Testing Personnel (TP) performing high complexity patient testing met the educational requirements as specified in the CLIA regulations. The findings include: 1. A review of the 2023-2025 personnel records revealed the educational degree presented for TP1 did not meet the requirements for TP performing high complexity testing in the Specialty of Blood Bank. 2. A further review of the transcript for TP1 revealed a degree in Human Resource Management which lacked the six Chemistry hours required as per 493.1489 (b)(2)(ii)(A)(2)(i) CLIA regulatory standard. 3. The Chief Operating Officer and the GS confirmed the above findings during the Day 2 exit conference on 10-08-2025 at 4:28 PM.