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	(X3) Date Survey Completed
	25D1047462	01/04/2024
Name of Provider or Supplier	**Street Address, City, State**	
Greene County Hospital	1017 Jackson Avenue, Leakesville, MS	
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
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 review of manufacturer's instructions for the Instrumentation Laboratories (IL) HemosIL normal and abnormal controls and ACL Elite Patient and Quality Control (QC) Worksheets from 3/1/2023 through 1/3/2024, the laboratory failed to follow manufacturer's instructions for establishing target values and acceptance ranges for HemosIL Normal Control, Lot #N0320752, and HemosIL Abnormal Control, Lot #N0321366, when the current lot of RecombiPlasTin 2G prothrombin time reagent, Lot #N1127272, was put in use on 3/28/2023, for performing prothrombin time (PT) testing on the ACL Elite coagulation system. Findings include: 1. The manufacturer's instructions for the IL HemosIL normal and abnormal controls state, "The mean of the control range determined in your laboratory may vary due to the lot of reagent used. Due to differences in reagents and instrumentation, each laboratory should establish its own target value and acceptance range." 2. There was no documentation available on the day of the survey, 1/4/2024, of the establishment of ranges for the current lots of HemosIL Normal Control, Lot #N0320752, and HemosIL Abnormal Control, Lot #N0321366, when the current lot of RecombiPlasTin 2G PT reagent, Lot #N1127272, was put in use on 3/28/2023, for performing prothrombin time (PT) testing on the ACL Elite coagulation system. These lots of normal and abnormal control were used for ten months without establishing acceptance ranges for the current lot of RecombiPlasTin 2G PT reagent, 3. Review of ACL Elite Patient and QC Worksheets from 3/1/2023 through 1/3/2024 revealed the acceptance ranges for HemosIL Normal Control, Lot #N0320752, and HemosIL Abnormal Control, Lot #N0321366, were the

	ranges established for RecombiPlasTin 2G PT reagent, Lot # N0512868, taken out of use on 3/28/2023.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (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 review of calibration verification records since the last survey on 3/30/2022 and confirmation by the general supervisor on 1/4/2024 at 4:30 p.m., the laboratory failed to perform calibration verification on the Instrumentation Laboratories (IL) GEM Premier 3500 analyzer for blood gas testing - pH, pO2, and pCO2 - at least every six months since the last survey on 3/30/2022. The laboratory's annual volume for blood gases is 270. Findings include: 1. Review of calibration verification records since the last survey on 3/30/2022 revealed calibration verification was not documented as performed for blood gas testing on the IL GEM Premier 3500 analyzer for ten months, from 3/30/2022 until 2/1/2023, and for eleven months, from 2/1/2023 through the day of the survey on 1/4/2024. 2. The general supervisor confirmed in an interview on 1/4/2024 at 4:30 p.m. that there was no documentation of calibration verification for the IL GEM Premier 3500 analyzer from 3/30/2022 until 2/1/2023, and no documentation of calibration verification from 2/1/2023 through 1/4/2024. The laboratory's annual volume for blood gases is 270.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are

	reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Fortenberry, Deborah Based on review of the Transfusion Service Testing Record and blood bank reagent quality control (QC) records from 4/19/2022 through 12/21/2023, the laboratory failed to document performance of quality control for the reagents used for ABO grouping, Rh typing, antibody detection, and compatibility testing for two of four days, during this time frame, when testing was performed on two patients with one unit of packed red blood cells (PRBC) issued for transfusion to each of these patients. Findings include: Review of the Transfusion Service Testing Record and blood bank reagent QC records from 4/19/2022 through 12/21/2023 revealed that quality control for the blood bank reagents was not documented, as performed, on the following days when ABO grouping, Rh typing, antibody detection (Ab screen), and compatibility testing were performed on two patients: 4/19/2022--ABO/Rh, Ab screen, and compatibility testing performed on Patient #000237198 for one unit of PRBC transfused on 4/19/2022. 1/10/2023--ABO/Rh, Ab screen, and compatibility testing performed on Patient #000240051 for one unit of PRBC transfused on 1/10 /2023.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: 1. Based on review of manufacturer's instructions for the Instrumentation Laboratories (IL) HemosIL normal and abnormal controls and ACL Elite Patient and Quality Control (QC) Worksheets from 3/1/2023 through 1/3/2024, the technical consultant failed to ensure the prothrombin time (PT) quality control program was maintained throughout the entire testing process when the laboratory failed to follow manufacturer's instructions for establishing target values and acceptance ranges for HemosIL Normal Control, Lot #N0320752, and HemosIL Abnormal Control, Lot #N0321366, for ten months after the current lot of RecombiPlasTin 2G prothrombin time reagent, Lot #N1127272, was put in use on 3/28/2023, for performing prothrombin time (PT) testing on the ACL Elite coagulation system. Refer to D5411 (Failure to follow manufacturer's instructions for establishing quality control acceptance ranges). 2. Based on review of calibration verification records since the last survey on 3/30/2022 and confirmation by the general supervisor on 1/4/2024 at 4: 30 p.m., the technical consultant failed to ensure the blood gas testing quality control program, to include calibration verification on the Instrumentation Laboratories (IL) GEM Premier 3500 analyzer, was maintained throughout the entire testing process when calibration verification was not performed for blood gas testing for ten months, from 3/30/2022 until 2/1/2023, and for eleven months, from 2/1/2023 through the day of the survey on 1/4/2024. Refer to D5439 (Failure to perform calibration verification at least every six months).

D6092	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv) The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of the six chemistry proficiency testing events performed since 3/30/2022, lack of documentation of corrective action for a score of 60% for phosphorus for Event 1 of 2023 and 60% for Troponin T for Event 2 of 2023, and interview with the technical consultant on 1/4/2024 at 5:00 p.m., the laboratory director failed to ensure that an approved corrective action plan was followed when proficiency testing results were found to be unsatisfactory. Findings include: 1. Review of the chemistry proficiency testing scores for Events 1, 2 and 3 of 2022 and Events 1, 2, and 3 of 2023 revealed a score of 60% for phosphorus for Event 1 of 2023 and 60% for Troponin T for Event 2 of 2023. 2. There was no documentation of corrective action for the unsatisfactory score of 60% for phosphorus for Event 1 of 2023 and 60% for Troponin T for Event 2 of 2023 available for review on the day of the survey, 1/4/2023. 3. In an interview on 1/4/2024 at 5:00 p.m., the technical consultant confirmed there was no documentation of corrective action for the unsatisfactory scores.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) The technical supervisor is responsible for establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results. This STANDARD is not met as evidenced by: Based on review of the Transfusion Service Testing Record and blood bank reagent quality control (QC) records from 4/19/2022 through 12/21/2023, the technical supervisor of immunohematology failed to ensure that acceptable levels of analytic performance were maintained throughout the entire testing process when the laboratory failed to document performance of quality control for the reagents used for ABO grouping, Rh typing, antibody detection, and compatibility testing for two of four days, during this time frame, when testing was performed on two patients with one unit of packed red blood cells (PRBC) issued for transfusion to each of these patients. Findings include: Review of the Transfusion Service Testing Record and blood bank reagent QC records from 4/19/2022 through 12/21/2023 revealed that quality control for the blood bank reagents was not documented, as performed, on the following days when ABO grouping, Rh typing, antibody detection (Ab screen), and compatibility testing were performed on two patients: 4/19/2022--ABO/Rh, Ab screen, and compatibility testing performed on Patient #000237198 for one unit of PRBC transfused on 4/19/2022. 1/10/2023--ABO/Rh, Ab screen, and compatibility testing performed on Patient #000240051 for one unit of PRBC transfused on 1/10/2023. Refer to D5559 (Failure to document performance of blood bank reagent quality control).