

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0651908	(X3) Date Survey Completed 11/16/2022
Name of Provider or Supplier Neshoba County General Hospital	Street Address, City, State 1001 Holland Avenue, Philadelphia, 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
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of proficiency testing records, since the last survey on 4/29/2021, for the Siemens RAPIDPoint 500 analyzer, used as a secondary analyzer for chemistry testing, the laboratory failed to verify the accuracy, at least twice annually, of ionized calcium, sodium, potassium, chloride, and glucose, when the proficiency testing provider failed to grade results for these tests for Events 1, 2, and 3 of 2022. Findings include: Review of proficiency testing records, since the last survey on 4/29/21, for the Siemens RAPIDPoint 500 analyzer, used as a secondary analyzer for chemistry testing, revealed the proficiency testing provider failed to grade the results for ionized calcium, sodium, potassium, chloride, and glucose for Events 1, 2, and 3 of 2022. There was no documentation available on the day of the survey that the laboratory had verified the accuracy of these tests at least twice annually for 2022.</p>
D5551	<p>IMMUNOHEMATOLOGY CFR(s): 493.1271(a)(f)</p> <p>(a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e). (a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells. (a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent.</p>

(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 Transfusion Log from the laboratory information system and blood bank reagent quality control records for 5/1/2021 through 4/30/2022, the laboratory failed to document performance of quality control for reagents used for ABO grouping, Rh typing, antibody detection, and compatibility testing for two days during this time frame, when testing was performed on two patients with two units of packed red blood cells (PRBC) issued for transfusion to one of these patients. Findings include: Review of the Blood Bank Transfusion Log from the laboratory information system and blood bank reagent quality control records for 5/1/2021 through 4/30/2022 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 was performed on two patients: 12/8/2021--ABO/Rh, Ab screen, and compatibility testing was performed on Patient #7000200 for two units of PRBC--#W069121134599 and #W069121149720--transfused on 12/8/2021. 12/26/2021--ABO/Rh testing was performed on Patient #7044557.

D6049

TECHNICAL CONSULTANT RESPONSIBILITIES

CFR(s): 493.1413(b)(8)(iii)

The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.

This STANDARD is not met as evidenced by:

Based on review of Siemens RAPIDPoint 500 analyzer quality control records, to include comparison testing with chemistry and hematology analyzers, calibration verification records, and proficiency testing records since the last survey on 4/29/2021, a technical consultant failed to document review of these records, for evaluation of the competency of the staff, from 4/29/2021 through the day of the survey on 11/16/2022. Findings include: Review of Siemens RAPIDPoint 500 analyzer quality control records, to include comparison testing with chemistry and hematology analyzers, calibration verification records, and proficiency testing records since the last survey on 4/29/2021 revealed no documentation of review by a qualified technical consultant from 4/29/2021 through 11/16/2022 for the following records: 1. Daily quality control of three levels of liquid control, performed every 24 hours, from 4/29/2021 through 11/16/2022. 2. Comparison testing performed for sodium, potassium, chloride and glucose with the Siemens Dimension EXL chemistry analyzer, and comparison testing for total hemoglobin performed with the Sysmex XN-1000 hematology analyzer on 9/25/2021, 2/1/2022, and 8/1/2022. 3. Calibration verification performed on 9/21/2021, 2/28/2022, and 8/25/2022. 4. Proficiency testing results for tests performed on the Siemens RAPIDPoint 500 analyzer for Events 1, 2, and 3 of 2021 and Events 1, 2, and 3 of 2022.

D6053

TECHNICAL CONSULTANT RESPONSIBILITIES

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

The technical consultant is responsible for evaluating and documenting the

performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form for respiratory department testing personnel and personnel records since the last survey on 4/29/2021, a qualified technical consultant failed to evaluate and document the performance of Respiratory Department Testing Personnel #21 and #27, for moderate complexity testing, at least semiannually during the first year these individuals tested patient specimens. Findings include: Review of the CMS 209 personnel form for respiratory department testing personnel and personnel records since 4/29/2021 revealed no semiannual evaluations, for the performance of moderate complexity testing, by a qualified technical consultant for Testing Personnel #21, date of hire March 2021, and Testing Personnel #27, date of hire January 2022.

D6054

TECHNICAL CONSULTANT RESPONSIBILITIES

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

The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form for respiratory department testing personnel and personnel records since the last survey on 4/29/2021, a qualified technical consultant failed to evaluate and document the performance of Respiratory Department Testing Personnel #16 through #26, for moderate complexity testing, at least annually since the last survey on 4/29/2021. Findings include: Review of the CMS 209 personnel form for respiratory department testing personnel and personnel records since 4/29/2021 revealed no annual evaluations, for the performance of moderate complexity testing, by a qualified technical consultant for Testing Personnel #16 through #26 since 4/29/2021.