

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0317612	(X3) Date Survey Completed 07/23/2021
Name of Provider or Supplier Simpson General Hospital	Street Address, City, State 1842 Simpson Hwy 149, Mendenhall, 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
D0000	
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 laboratory proficiency records from 2019, 2020, and 2021 and interview with the technical consultant (TC) at 2:30 p.m. on 7/23/21, the laboratory failed to verify the accuracy of phosphorous testing at least twice annually for the year of 2020. Findings Include: 1. Review of the proficiency records from 2019, 2020 and 2021 revealed that phosphorous had not been twice verified as accurate for the year of 2020. 2. During an interview TC at 2:30 p.m. on 7/23/21, the TC confirmed that accuracy had not been verified in 2020 for the phosphorous analyte performed on the Vitros 5600 chemistry analyzer.</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.</p>

This STANDARD is not met as evidenced by:
Based on review of installation records for the RAPID Point 500 E blood gas analyzer, lack of documentation of verification of performance specifications, and interview with the Respiratory Supervisor (Testing Personnel #8) at 5:30 p.m. on 7/23/21, the respiratory department failed to ensure that performance specifications included performing comparison studies on the blood gas analyzer. The RAPID Point 500 E was installed on 3/9/21. Findings: 1. Review of installation records for the RAPID Point 500 E, installed on 3/9/21, revealed no documentation of a method comparison study performed after installation. In the installation records the Service representative stated: "Customer will perform method comparison study. TAS will complete the comparison data analysis report. 20 samples recommended." 2. Interview with Respiratory Supervisor/TP #8 on at 5:30 p.m. on 7/23/21 revealed no method comparison had been performed for the blood gas testing on the RAPID Point 500 E blood gas analyzer before testing patients on 5/27/21.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:
Based on review of the RAPID Point 500 E blood gas analyzer procedure manual and interview with the Respiratory supervisor/testing personnel (TP) #8 listed on the CMS (Center for Medicare & Medicaid Services) 209 personnel form at 5:30 p.m. on 7/23/21, the laboratory (respiratory department) failed to document as performed maintenance on the RAPID Point 500 E blood gas analyzer as required by the manufacturer. Findings include: 1. Review of the Rapid Point 500 E procedure manual revealed the following maintenance is required by the manufacturer to be performed every 10 days: a. Wash/Waste Cartridge change: The wash/waste cartridge is stable for ten days after installation on the system and contains the wash reagent which cleans the sample path after analysis and calibration and it also stores liquid waste. The cartridge should be replaced after 10 days on the instrument. There was no documentation of this maintenance performed every 10 days after cartridge install either on the maintenance log or printed from the blood gas analyzer since install on 3/9/21. 2. Interview with the Respiratory Supervisor/TP#8 at 5:30 p.m. on 7/23/21 confirmed no maintenance log was written or printed to document when the 10 day wash/waste cartridge replacement was performed on the RAPID Point 500 E.

D6019

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(iv)

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. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on review of proficiency testing (PT) records from 2019, 2020 and 2021, lack of documentation available for review and interview with the TC, the laboratory director failed to ensure an approved corrective action plan was followed when the laboratory scored below 80% (unacceptable or unsatisfactory). Findings Include: 1. Review of the laboratory proficiency result records for 2019, 2020 and 2021, revealed the following proficiency results had scores less than 80% and were not reviewed with corrective action: a. Lipase -3rd event 2019 - 40% b. Phosphorous - 1st event 2020- 60% c. Phosphorous - 2nd event 2020- 0% 2. Interview with the laboratory TC confirmed that the unsuccessful proficiency scores for lipase and phosphorous were not reviewed with corrective action taken when scores received were below 80%.