

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D1093815	(X3) Date Survey Completed 10/22/2021
Name of Provider or Supplier Margaret R Pardee Memorial Hospital	Street Address, City, State 800 North Justice Street, Hendersonville, NC	
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
D5211	<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> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's CAP(College of American Pathologists) PT (Proficiency testing) records and absence of documentation 10/22/21, the laboratory failed to ensure that all PT reports were reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. Findings: Review of 2019, 2020, and 2021 CAP PT records revealed the laboratory failed to review and evaluate the PT reports for the following: 1. 2019 AQ-A -Critical Care Blood gas: graded report not reviewed; 2. 2019 AQ-B- Critical Care Blood gas: graded report not reviewed; 3. 2019 AQ-C- Critical Care Blood gas: graded report not reviewed; 4. 2019 SO-A- Blood Oximetry: 60% score for total hemoglobin, 40% score for Oxyhemoglobin and Carboxyhemoglobin with no corrective action documented; 5. 2019 SO-B- Blood Oximetry: graded report not reviewed; 6. 2019 SO-C- Blood Oximetry: graded report not reviewed; 7. 2020 AQ-A Critical Care Blood gas: graded report not available; 8. 2020 AQ-B Critical Care Blood gas: graded report not reviewed; 9. 2020 AQ-C Critical Care Blood gas: graded report not reviewed; 10. 2020 SO-A- Blood Oximetry: graded report not reviewed and results not evaluated for Code[22] -Results outside the method/instrument reportable range for Carboxyhemoglobin; 11. 2020 SO-B Blood Oximetry: graded report not reviewed; 12 2021 AQ-A Critical Care Blood gas: no corrective action for 80% score for pH and results not evaluated for code[42] -no credit assigned due to absence of response; 13. 2021 SO-A Blood Oximetry: results not evaluated for code [42]-no credit assigned due to absence of response. 14. 2021 SO-B Blood Oximetry: graded report not available.</p>

D5413

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT

CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's procedures, observation, and interview with the Respiratory therapy Manager 10/22/21, the laboratory failed to monitor and document the room temperature for reagents in storage. Findings: The "Policy and Procedure for Blood Gases, Competency Validation and Procedure Manual for Blood Gas, Electrolyte and Co-Oximetry Measurements on the ABL80 Series Analyzer" states, "Stability and Storage: Solution packs and sensor cassettes are stable at room temperature until the expiration date. Location: All room-temperature reagents and consumables are stored at the ABG machine location....Temperature log: The temperature of both blood gas labs will be checked on a daily basis and recorded on the BLOOD GAS LAB TEMPERATURE LOG form located in each blood gas lab beside the thermometer. The blood gas lab temperature is to be kept between 65-77 degrees Fahrenheit." During tour at approximately 10:30 a.m., the surveyor observed reagents located in the respiratory department storage room. The manufacturer's requirement for storage temperatures was reviewed by the surveyor from each reagent package. The upper limit for the room temperature requirement is 77degrees F (Fahrenheit)/ 25 degrees C(Celsius) for each of the following: a. ABL80 SC80 Co-Ox Reagent pack- lot# 324736, expiration date: 12/15/21; b. ABL80 SC80 Co-Ox Reagent pack- lot# 324192, expiration date: 1/7/22; c. cHb Calibration solution- lot #R0266, expiration date: 1/31/23; d. Quality Control Level 1 Qualicheck 5- lot # R0198, expiration date: 5/31/23; e. Quality Control Level 2 Qualicheck 5 - lot # R0200, expiration date: 6/30/23; f. Quality Control Level 3 Qualicheck 5- lot # R0194, expiration date: 5/31/23. The respiratory manager confirmed at approximately 10:30 am that temperatures are not being monitored in the storage room.