

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 04D0689262	<b>(X3) Date Survey Completed</b> 08/24/2018
<b>Name of Provider or Supplier</b> Dallas County Medical Center	<b>Street Address, City, State</b> 201 Clifton Street, Fordyce, AR	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:  . Through a review of manufacturer's instruction, temperature records, observations made during a tour of laboratory, as well as interviews with staff, it was determined the laboratory failed to store quality control material consistent with manufacturer's recommendations to achieve accurate and reliable test results as evidenced by: A. A review of Bio-Rad Immunoassay Quality Control package inserts revealed the storage requirement for the analyte Folate as "-20 to -70 degrees Celsius." B. A review of laboratory's temperature records January-August of 2018 revealed the temperature range of freezer #2 as -10 to -20 degrees Celsius. C. During a tour of the laboratory on 8/22/2018 at 1330, the surveyor observed two vials of Bio-Rad Immunoassay controls (Level I lot # 40921 expire 10/31/2018 and Level III lot #40923 expires 10/23/2018) stored in freezer #2. D. In an interview on 8/22/2018, the general supervisor (as listed on form CMS 209) confirmed the control materials were stored in freezer #2.</p>
<b>D5421</b>	<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</p>

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.

This STANDARD is not met as evidenced by:

. 1. Through a review of the new instrument validation, which was performed 4/18/2018 for the Siemens Epoch Blood Gas analyzer and interviews with staff, it was determined the laboratory failed to validate the reportable range established by the manufacturer for four of eight chemistry tests validated on the Siemens Epoch. As evidenced by: A. The manufacturer's analytic range listed on the Analytical Range Verification Summary dated 04/18/2018 includes the following analytic ranges: pCO<sub>2</sub> 5.0-250.00; pO<sub>2</sub> 5.0-750.0; Glucose 20.0-700.0 and Hematocrit 10.0-75.00. B. The Analytical Range Verification Summary dated 04/18/2018 include the following ranges validated by testing standard solutions: pCO<sub>2</sub> 17.0-141.4; pO<sub>2</sub> 26.7-595.3; Glucose 15.0-638.0 and Hematocrit 9.0-66.00. The laboratory did not validate the full analytic range claimed by the manufacturer. C. In an interview on 08/22/2018 at 1330, general supervisor (as listed on the form CMS-209) confirmed the laboratory did not validate the full reportable range claimed by the manufacturer of the Siemens Epoch. 2. Through a review of new instrument validation which was performed on 4/18/2018, lack of documentation as well as interviews with staff, it was determined the Blood Gas laboratory failed to perform method correlation for the Siemens Epoch Blood Gas Analyzer to verify that the manufacturer's reference intervals are appropriate for the laboratory's patient population. As evidenced by: A. The new instrument validation for the Siemens Epoch Blood Gas analyzer revealed the analyzer validation was performed on 4/18/2019 and revealed that no data was present to verify that the manufacturer's reference intervals (normal ranges) are appropriate for the laboratory's patient population. B. Upon request, the laboratory was unable to provide method correlation data for the validation of the Siemens Epoch Blood Gas analyzer. C. In an interview, at 1400 on 8/22/2018, the general supervisor (as listed on the form CMS-209) confirmed that method correlation was not performed as part of the validation of the Siemens Epoch analyzer.

**D5431**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

. Through a review of the Sysmex CA-600 Daily Maintenance Checklist and interviews with laboratory staff, it was determined the laboratory failed to ensure function checks for the Coagulation analyzer were within manufacturer's established limits before testing patients. As evidenced by: A. A review of the Sysmex CA-600 Maintenance Checklist revealed the temperature range of the Detector as 36-38 degrees Celsius. The Sysmex CA-600 Maintenance Checklist includes the following dates when the Detector temperature was documented outside of the acceptable range: in December 2017 detector temperature was below 36 degrees Celsius on 2 of 31

days; in January 2018 detector temperature was below 36.0 on 1 of 31 days; in February 2018 detector temperature was below 36.0 on 1 of 28 days; in March 2018 detector temperature was below 36.0 degrees Celsius on 2 of 31 days; in April 2018 detector temperature was below 36.0 on 1 of 30 days; in May 2018 detector temperature was below 36.0 on 3 of 31 days; in June 2018 detector temperature was below 36.0 on 4 of 30 days and in July 2018 2 of 31 days. B. In an interview on 8/22 /2018 at 10:30, general supervisor (as listed on the form CMS-209) confirmed the function checks were documented outside of acceptable limits.