

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  40D0673783	<b>(X3) Date Survey Completed</b>  02/22/2018
<b>Name of Provider or Supplier</b>  Sur -Med Medical Center, Corp	<b>Street Address, City, State</b>  8 Colon Pacheco, Salinas, PR	
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>D5439</b>	<p><b>CALIBRATION AND CALIBRATION VERIFICATION</b> CFR(s): 493.1255(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of calibration, calibration verification records and interview with the laboratory supervisor , it was determined that the laboratory did not perform calibration verification procedures for albumin or cholesterol each six months, from April 2017 to January 2018. The findings include: a. The laboratory performed comprehensive metabolic panel (CMP) by the Fusion 5.1 instrument. b. Review of the calibration records for years 2016 to 2018 on February 22, 2018 at 10:00 AM, showed</p>

	<p>the following: i. cholesterol test: last two calibration done on May 16, 2017 and January 14, 2018. ii. albumin test: the last two calibrations done on April 19, 2017 and January 12, 2018. c. The laboratory did not perform calibration verification procedures for albumin or cholesterol. d. The laboratory reported 122,100 (CMP) patient's tests from April 2017 to January 2018.. e. The laboratory supervisor stated that the she was not aware of the situation.</p>
<p><b>D5791</b></p>	<p><b>ANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1289(a)(c)</p> <p>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of Quality Assessment (QA) manual , Q.A, records and interview with the laboratory supervisor, it was determined that the laboratory did not follow the established Quality Assessment Program to monitor and evaluate the following requirements for analytic systems: control procedures. The findings include: a. Review of the QA procedure manual on February 22, 2018 at 1:15 PM, showed that a calibration procedures must be monitored each year. A page was provided for documentation. b. Review of the QA procedures for years 2016 to 2018 showed that the laboratory did not document, in the provided page, the monitoring of the calibration verification procedures since year 2018 c. The laboratory supervisor stated that they omitted to review the QA procedure.</p>
<p><b>D5891</b></p>	<p><b>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT</b> CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on quality assessment (QA) procedures manual, quality assessment records review (2014-2016) and laboratory supervisor interview on February 22, 2018 at 1:15 PM, it was determined that the laboratory failed to follow the established Quality Assessment Program to monitor and evaluate the following post-analytic systems requirement: Test report. The findings include: a. Review of the quality assessment program showed that evaluations to patient's final test reports must be evaluated every year and the evaluation must include twenty patient reports. b. Review of the quality assessment records showed that the laboratory did not evaluate the patient report during year 2016 or 2017. c. The laboratory supervisor stated that the laboratory did not perform evaluations to patient's final test reports during years 2016 and 2017.</p>
<p><b>D6094</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(5)</p> <p>The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to</p>

identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

Based on Quality Assessment (QA) records review and laboratory supervisor interview on February 22, 2018 at 1:15 PM, it was determined that laboratory director did not ensure compliance with quality assessment (QA) requirements. The findings include: a. Quality Assessment records showed that the laboratory did not monitor the calibration verification assessment not the test report either. Refer to D5791 and D5891.

**D6177**

**TESTING PERSONNEL RESPONSIBILITIES**

CFR(s): 493.1495(b)(3)

Each individual performing high complexity testing must adhere to the laboratory's quality control policies, document all quality control activities, instrument and procedural calibrations and maintenance performed.

This STANDARD is not met as evidenced by:

Based on review of calibration and verification records, it was found that the testing personnel did not perform calibration verification procedures for cholesterol or albumin each six months since year 2017. The findings include: a. The calibration records showed that for cholesterol the testing personnel performed calibration on May 16, 2017 and February 14, 2018. b. The calibration records showed that for albumin the testing personnel performed calibration on April 19, 2017 and February 14, 2018. c. Review of the calibration verification records on February 22, 2018 at 10:00 AM did not included calibration verification procedures for cholesterol or albumin. Refer to D5439.