

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  66D0675993	<b>(X3) Date Survey Completed</b>  04/27/2023
<b>Name of Provider or Supplier</b>  Commonwealth Health Center - Respiratory	<b>Street Address, City, State</b>  1178 Hinemlu' St Garapan, Saipan Mariana Islands, MP	
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 laboratory director and laboratory personnel interviews and calibration verification record review on April 27, 2023 at 10:20 am, at least once every 6 months, the laboratory failed to perform calibration verification procedures on its two blood gas instruments. Findings included: a. It was the practice of the laboratory to perform patient blood gas tests on one of two Opti CCA instruments. b. The</p>

laboratory director and laboratory personnel confirmed that the laboratory had not been performing calibration verification procedures on the two blood gas instruments. b. According to survey documents, the laboratory performed approximately 3,000 patient blood gas tests annually.

**D5775**

**COMPARISON OF TEST RESULTS**

CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:

Based on laboratory director and laboratory personnel interviews and laboratory written policies and procedures record review on April 27, 2023 at 10:10 am, the laboratory, which performs the same blood gas tests using two different instruments, failed to have written policies and procedures that detail the laboratory's system that at least twice a year evaluates and defines the relationship between test results using the different instruments. Findings included: a. It was the practice of the laboratory to perform patient blood gas tests on one of two Opti CCA blood gas instruments. b. At least twice a year and often more frequently, the laboratory tested the same sample on each of the two instruments and compared the blood gas test results. However, the laboratory maintained no written policy and procedure describing this protocol and what the laboratory considered an acceptable comparison. c. According to survey documents, the laboratory performed approximately 3,000 patient blood gas tests annually.

**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 laboratory director and laboratory personnel interviews and proficiency testing policies and procedures record review on April 27, 2023 at 10:00 am, the laboratory director, moderate complexity testing, failed to ensure that an approved corrective action plan was available when any proficiency testing results were found to be unacceptable or unsatisfactory. Findings included: a. The laboratory director and laboratory personnel confirmed that the laboratory maintained no such written policy and procedures. b. According to survey documents, the laboratory performed approximately 3,000 patient blood gas tests annually.