

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 01D2265506	(X3) Date Survey Completed 05/09/2023
Name of Provider or Supplier Alabama Institute For Sleep Health	Street Address, City, State 1803 Park View Dr Ne, Cullman, AL	
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
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Based on a reviews of the 2022 Chemistry records for the Opti CCA-TS Blood Gas Analyzer, the Manufacturers user manual, the patient results log, and an interview with Testing Personnel #1, the laboratory failed to document verification of the electronic output of optical electrodes. Values for the two levels of Standard Reference Cassette (SRC) checks were not documented prior to analyzing patient specimens and reporting the results; this was noted one day out of five months reviewed from July to December 2022 by the surveyor. The findings include: 1. A review of the electronic function records for the Opti CCA-TS Blood Gas analyzer revealed on 10/19/2022 there was no documentation for the low and high SRC checks, which is required before performing patient testing. 2. A review of the Opti CCA-TS user manual on page 4-3 revealed, "The multi-level Standard Reference Cassette (SRC) should be used as a control for the OPTI CCA-TS2 analyzer...SRC levels 1 and 3 frequency at least 1x [time] per day in operation." The manual further stated, "...The SRC contains a stable optical sensor simulator which is measured by the device... provides assurance that all parameters measured by the analyzer are consistent... [and] fall within limits contained in the SRC barcode.". 3. A further review of the cumulative patient log printed from the instrument revealed one patient ABG (Arterial</p>

Blood Gas) was performed on 10/19/2022. 4. During an interview on 05/09/2023 at 11:42 AM, Testing Personnel #1 confirmed the low and high SRC was not documented prior to patient testing.