

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D2175248	(X3) Date Survey Completed 12/14/2023
Name of Provider or Supplier Smg Pediatric Clinic Hardin Valley	Street Address, City, State 2587 Willow Point Way, Knoxville, TN	
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
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of manufacturer's instruction manual, laboratory records, and interview with the laboratory liaison, the laboratory failed to follow manufacturer's instructions for calibration in 2022. The findings include: 1. Observation of the laboratory on December 14, 2023 at 9:30 a.m. revealed the Advanced Instruments BR2 Bilirubin Stat Analyzer on the counter in use for pediatric patient testing for total bilirubin. (Serial number 19060894C). 2. Review of the manufacturer's instruction manual revealed the following, "The BR2 requires calibration upon installation and at least every six months, unless quality control data indicates the need for earlier calibration". 3. Review of laboratory records revealed that calibration was due April 2022 and was not performed. 4. Interview with the laboratory liaison on December 14, 2023 at 12:20 p.m. confirmed the laboratory failed to follow the manufacturer's instructions for calibration of the BR2 Bilirubin Stat Analyzer every six months in 2022.</p>