

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 04D0466587	(X3) Date Survey Completed 02/23/2021
Name of Provider or Supplier Pediatric Clinic, The	Street Address, City, State 1525 Country Club Road, Sherwood, AR	
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: . Through a review of the Reichert Unistat user manuel, laboratory policy and procedure manual, lack of documentation as well as interview with staff, it was determined the laboratory failed to perform calibration verification for the Reichert Unistat Bilirubinometer with at least the frequency required by the manufacturer. Survey finding follow: A. A review of the Reichert Unistat Bilirubinometer user manual revealed the requirement for calibration: "Calibration is required upon installation and then at least at six month intervals." B. A review of the laboratory policy and procedure manual revealed the calibration procedure for Total Bilirubin: "Calibration of the instrument is performed every six months following manufacturer's instructions." C. The surveyor requested Calibration verification for the Reichert Unistat Bilirubinometer. None was provided. D. In an interview on 2/23/21 at 1205 pm, the technical consultant confirmed the laboratory did not perform six month Calibration verifications as required by the manufacturer.</p>