

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0120662	(X3) Date Survey Completed 05/18/2021
Name of Provider or Supplier Robert M Goldberg Md Pa	Street Address, City, State 727 Shore Road, Somers Point, NJ	
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 surveyor review of Calibration Verification (CV) records, Operators Manual (OM) and interview with the Laboratory Director (LD), the laboratory failed to perform and document Calibration procedures at least once every six months for Hematology Tests performed on the Beckman Coulter Act2 analyzer used for Hematology tests from February 2021 to the date of the survey. The findings include: 1. A review of CV records revealed that the laboratory runs CV in February and August of each year. 2. A review of CV records revealed that last time CV was performed was August 2020. 3. The LD confirmed on 5/18/21 at 11:30 am that the laboratory failed to perform and document CV in February 2021.</p>