

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2112241	(X3) Date Survey Completed 01/29/2026
Name of Provider or Supplier Elena Sanders Md Pc	Street Address, City, State 400 Seaview Avenue, Staten Island, NY	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of Standard Operating Procedures (SOP), personnel training records, competency evaluation documentation, as well as interview with the consultant, the laboratory failed to follow written policies and procedures to assess employee competency. FINDINGS: 1. Testing Personnel (TP) was hired November 2022 and initial competency assessment was performed, documented. However, there was no documentation of respective TP annual competency evaluation performance for 2023, 2024, and 2025. 2. This was contrary to instructions indicated in the current, approved Elena Sanders, M.D., PC SOP manual. 3. The consultant confirmed the findings on January 29, 2026, at 12:00 P.M.</p>
D5437	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a)</p> <p>(a)Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (a)(1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (a)(2) Using the criteria verified or established by the laboratory as specified in 493.1253(b) (3)-- (a)(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 (a) (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (a)(3) Whenever</p>

calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

This STANDARD is not met as evidenced by:

Based on review of SOPs, analyzer calibration and calibration verification records, as well as interview with the consultant, laboratory failed to follow the manufacturer's test system instructions with at least the frequency recommended by the manufacturer.

FINDINGS: 1. BIOTEK ELX800 ELISA Plate Reader linearity verification was performed, documented once yearly for 2023, 2024, and 2025. 2. This is contrary to instructions indicated in the current, approved, "Linearity Testing Procedure for the BIOTEK ELX800 ELISA Plate Reader" which specified linearity studies to be performed every six months. 3. The consultant confirmed the findings on January 29, 2026, at 12:00 P.M.