

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 38D2060212	(X3) Date Survey Completed 09/07/2021
Name of Provider or Supplier Ip Eugene 1	Street Address, City, State 10 Coburg Rd, Ste 200, Eugene, OR	
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 upon review of Calibration Verification records for May 2021 and discussion with the Laboratory Director (LD), the laboratory failed to perform recalibration after Calibration Verification failed May 12, 2021. Findings include: 1. Upon review of the Calibration Verification performed on the Cobas E411 Endocrinology instrument, it was revealed that the Testosterone Calibration Verification failed the accuracy test and the reportable range test using the EP Evaluator software program used by the laboratory. 2. The LD concurred that re-calibration was not performed after the system failures noted above were reviewed during interview on 09/07/2021 at approximately 2 pm. 3. The LD signed off on the Calibration Verification for Testosterone on May 13, 2021 without noting any corrective action or re-calibration. The LD confirmed he had not performed any corrective action or recalibration of the instrument during interview 09/07/2021 at approximately 2 pm. 4. Upon review of the Interpath Calibration Verification and Validation of the Analytical Measurement range procedure for this laboratory, presented for review during survey 09/07/2021, it was revealed that the laboratory failed to follow its protocol for performing re-</p>

