Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0942072	06/25/2025
Name of Provider or Supplier	**Street Address, City, State**	
Arizona Endocrinology Center Plc	15640 N 28th Dr, Phoenix, AZ	

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	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) (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 calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on lack of calibration records from December 2024 for Thyroid-stimulating Hormone (TSH) testing and interview with the Testing Personnel (TP-1), the laboratory failed to perform and document calibration procedures with at least the frequency recommended by the manufacturer. Findings include: 1. The laboratory utilizes the Beckman Coulter DxC 600 analyzer to perform patient testing in the subspecialty of Endocrinology, with an approximate annual test volume of 39,354. 2. The instrument manufacturer requires a calibration for TSH every 28 days. 3. The laboratory failed to provide evidence of calibration records for TSH from December 2024. 4. Calibration records reviewed for the DxC 600 analyzer for the analyte, TSH, indicated calibration procedures were performed on 11/22/24 and the next calibration was performed on 1/09/25, exceeding the 28-day requirement. 5. TP-1 interviewed on June 25, 2025 at 11:45 AM confirmed the laboratory failed to provide evidence of calibration procedures for TSH during the timeframe referenced above.

D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of quality control (QC) and patient test records from 1/02/25 for Thyroid-stimulating Hormone (TSH), review of the instrument's troubleshooting guide and interview with the Testing Personnel (TP-1), the laboratory failed to perform and document corrective action for the error flag, CLX, generated by the analyzer. Findings include: 1. The laboratory utilizes the Beckman Coulter DxC 600 analyzer to perform patient testing in the subspecialty of Endocrinology, with an approximate annual test volume of 39,354. 2. Quality control and patient test records reviewed for TSH on the testing date of 1/02/25 revealed an instrument error flag, CLX, was generated for each level of QC performed (ImmunoLvl1 and ImmunoLvl3) and each patient's TSH test result. 3. The manufacturer's troubleshooting documentation reviewed during the survey indicated the error flag, CLX, is defined as "Calibrator Lot Expired", and states, "For patient and QC tests, the calibrator lot may have expired after a successful calibration. Corrective Action - For patient and QC tests: Review the Calibration Data screen to determine whether replicates of the active calibration are associated with the CLX flag. Then take one of the following actions: - If the calibration is not associated with the flag, the patient or QC test result is a valid result. - If the calibration is associated with the flag, and you did not intend to run QC or patient test using this calibration, calibrate the assay again with a calibrator lot that has not expired. Request the QC or patient test again. - If the calibration is associated with the flag, and you intended to run the QC or patient test using this calibration, no corrective action is necessary." 4. No evidence of corrective action was presented for review to indicate the laboratory investigated, corrected and determined if patient and /or QC results were affected by the error flag, CLX, generated by the analyzer on 1/02 /25. 5. The laboratory performed 59 patient tests on 1/02/25 for TSH. 6. The TP-1 interviewed on 6/25/25 at 11:55 AM acknowledged that the laboratory failed to take corrective action as described above for the CLX error flag for TSH testing on 1/02 /25.