

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0314742	(X3) Date Survey Completed 03/18/2024
Name of Provider or Supplier Ut Endocrinology/Lipoprotein Laboratory	Street Address, City, State 956 Court Ave, Rm A223 & A229, Memphis, TN	
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
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of manufacturer's instructions for use and calibration records, lack of documentation, review of patient test results, review of the Centers for Medicare and Medicaid Services Clinical Laboratory Improvement Amendments (CLIA) Application for Certification (Form CMS 116), and staff interview, the laboratory failed to perform calibration verification for the chemistry and endocrinology tests performed on the Siemens Immulite 1000 instrument in 2022,</p>

2023, and 2024 with approximately 600 patient tests performed during the period when calibration verification was not performed. The findings include: 1. Observation of the laboratory on 03/18/24 at 8:45 am revealed the Siemens Immulite 1000 instrument (serial number 5511) used for performing patient testing for chemistry and endocrinology on clinical research patients. The laboratory director stated during observation that the test results are released to the research team and used in the treatment decisions for patients. 2. A review of the manufacturer's package inserts and calibration records revealed the following methods were calibrated using two levels of calibrators: Cortisol, C-Peptide, Insulin, Free Thyroxine (FT4), Free Triiodothyronine (FT3), and Thyroid Stimulating Hormone (TSH). 3. No calibration verification records were available on the date of the survey for 2022, 2023, or 2024. 4. A review of patient reports revealed Insulin levels reported on two patients on 09/26/22; Cortisol, TSH, FT4, and FT3 reported on three patients on 08/07/23, Cortisol, TSH, and FT4 reported on 11/28/23 on two patients. 5. A review of Form CMS 116 revealed the laboratory performs approximately 300 tests per year for the six analytes performed on the Siemens Immulite 1000. 6. The laboratory director confirmed during an interview on 03/18/24 at 12:05 pm that the laboratory failed to verify the calibration of the six analytes performed on the Siemens Immulite 1000 chemistry instrument in 2022, 2023 and 2024.