

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0659993	(X3) Date Survey Completed 01/24/2025
Name of Provider or Supplier In-Vitro Diagnostics, Inc DbA Serolab	Street Address, City, State 7100 Old McGregor Road Suite A, Waco, TX	
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
D0000	An onsite recertification survey conducted January 24, 2025, found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5439	<p>CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)</p> <p>(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 review of manufacturer instructions, calibration records, and interview with laboratory personnel, the laboratory failed to perform calibration verification activities for quantitative Immunoglobulin E (IgE) measurements for two of two six-month periods in 2024. The findings included: 1. Based on review of the Immulite 2000 /2500 operator's manual, under Adjusting an Assay, stated the following: "Before using a new kit lot, an adjustment must be run. This initial adjustment corrects for any</p>

variations in performance between your Instrument and the manufacturer's Instrument. In addition, kits must be readjusted periodically. The adjustment schedule for a kit is indicated in the kits package insert. The reagent status and bead status windows indicate if an adjustment is due." 2. Based on review of the calibration records, the IgE assay has a two-point calibration called an "adjustment", where two levels of calibrators are run in four replicates, with a Low Adjustor and a High Adjustor. 3. In an interview at 12:43 hours on 1/24/2025 in the laboratory, the Laboratory Manager stated the laboratory had not run any calibration verification procedures on the IgE quantitative assay.

D5783

CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, quality control records, and interview with facility personnel, the laboratory failed to document corrective actions taken when quality control values exceeded laboratory acceptability limits for nine of nine values outside acceptable limits between February 2024 through June 2024. The findings included: 1. Based on review of the laboratory policy "Technical Procedure for Total IgE Testing", under Quality Control, the policy stated the following: "4. Controls are run daily with patient samples and confirm that they are validated to be within established ranges. If controls are out-of-range, the controls must be repeated." 2. Based on review of quality control records, the following values exceeded laboratory limits and did not have corresponding corrective actions documented: System O6459 Control 1 - TIE, Lot 044, low limit 32.0, high limit 44.0 February 2024 2/12/24 - 45.7 2/12/24 - 44.4 2/15/24 - 45.1 2/15/24 - 45.8 2/20/24 - 45.3 System O6459 Control 1 - SPE , Lot 164, low limit 1.68, high limit 2.32 May 2024 5/13/24 - 2.39 5/15/24 - 2.39 June 2024 6/17/24 - 2.45 6/26/24 - 2.35 3. In an interview at 12:22 hours on 1/24/25, the laboratory manager confirmed there were no individual corrective actions documented for the values listed above.