

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D2159558	(X3) Date Survey Completed 03/11/2021
Name of Provider or Supplier Veracyte Labs Va	Street Address, City, State 737 N 5th Street Suite 600, Richmond, VA	
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 announced CLIA Recertification on-site survey was conducted at Haliidx, Inc on March 11, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. The initial contact and entrance interview with the laboratory conducted on February 18, 2021 with off-site record review of documentation on March 4, 5, and 10, 2021 and a follow-up phone conference on March 9, 2021. Specific deficiencies cited are as follows:
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>

This STANDARD is not met as evidenced by:

Based on the review of policy and procedures (P&P), lack of documentation and interviews, the laboratory failed to follow to established policy for performing calibration verification procedures every six months in the calendar year 2020 for seven (7) of 8 therapeutic drug monitoring (TDM) analytes assayed on the Dynex Ds2 platform. Findings include: 1. Review of the P&P "Metrology and Prevention Maintenance of the Dynex DS2" (updated 04/16/19) "4.8 Calibration Verification" revealed the following statement "4.8.1 Policy- Calibration verification is required for each assay under the following conditions: At least once every six months after initial assay verification". 2. Review of available calibration verification documents revealed the lab performed the procedures for all 8 TDM's on 07/08/20. The inspector requested to review additional calibration verification documentation performed in 2020 as defined by the established policy during an interview with the associated lab director on 03/11/21 at 3:50 PM. The lab was able to produce documents for the Vedolizumab analyte (performed on 02/07/20) and lacked documentation for the Adalimumab, Infliximab, Certolizumab, Golimumab, Ustekinumab, Inflectra and Renflexis analytes (7). Additional calibration verification procedures were not performed for the 7 specified analytes. 3. An interview with the lab director and associated lab director at 4:15 PM on 03/11/21 confirmed the findings.