

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2045786	(X3) Date Survey Completed 12/12/2022
Name of Provider or Supplier American Health Associates	Street Address, City, State 39205 Country Club Drive Suite C30, Farmington Hills, MI	
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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview with the General Supervisor, the laboratory failed to establish policies to assess Clinical Consultant competency for 1 (Clinical Consultant #1) of 1 Clinical Consultant listed on Form CMS-209. Findings include: 1. A review of the laboratory's personnel records on 12/13/22 revealed a lack of competency assessment for Clinical Consultant #1 with a hire date of June 2021. 2. A review of the laboratory's competency assessment policies on 12/13/22 revealed a lack of policy for the performance of competency assessments for Clinical Consultants. 3. An interview on 12/13/22 at 1:08 pm with the General Supervisor revealed no competency assessment had been performed for Clinical Consultant #1.</p>
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</p>

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.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the General Supervisor, the laboratory failed to perform calibration verification for its unsaturated iron-binding capacity (UIBC) testing at least every six months for 1 (December 2021 to December 2022) of 1 year reviewed. Findings include: 1. A review of the laboratory's calibration verification records revealed the UIBC analyte was absent from the following calibration verification testing events: a. December 2021 b. May 2022 c. November 2022 2. A review of the laboratory's "Beckman Coulter AU Series Unsaturated Iron Binding Capacity (UIBC)" procedure on 12/13/22 revealed the test system uses less than thee calibrators to perform its routine calibrations showing calibration verification is required. 3. An interview on 12/13/22 at 2:44 pm with the General Supervisor confirmed the laboratory failed to perform UIBC calibration verification at least every six months. **This is a repeated deficiency from the 6/22/21, 6/19/19, and 10/19/16 recertification surveys**