

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2045786	(X3) Date Survey Completed 06/22/2021
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
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 record review and interview with the General Supervisor, the laboratory failed to perform calibration verification activities at least every 6 months in 2020. Findings include: 1. A review of the laboratory's "Linearity Verification" procedure revealed a section stating, "As mandated by CLIA, laboratories must validate the Analytical Measurement Range (AMR) or method linearity initially, every six</p>

months, and/or when calibration verification fails to meet the laboratories acceptable limits." 2. A review of the laboratory's calibration verification data revealed the following analytes did not have calibration verification performed at least every 6 months in 2020: a. Alkaline Phosphatase (ALP) had calibration verification performed on 9/4/20 and 5/11/21. b. Alanine Aminotransferase (ALT) had calibration verification performed on 9/4/20 and 5/11/21. c. Amylase had calibration verification performed on 9/4/20 and 5/11/21. d. Aspartate Aminotransferase (AST) had calibration verification performed on 9/4/20 and 5/11/21. e. Creatine Kinase had calibration verification performed on 9/4/20 and 5/11/21. f. Gamma-Glutamyl Transferase (GGT) had calibration verification performed on 9/4/20 and 5/11/21. g. Lactate Dehydrogenase (LD) had calibration verification performed on 9/4/20 and 5/11/21. h. Lipase had calibration verification performed on 9/4/20 and 5/11/21. i. Total Bilirubin had calibration verification performed on 5/8/20 and 5/8/21. j. Direct Bilirubin had calibration verification performed on 5/8/20 and 5/8/21. k. High-Density Lipoproteins (HDL) had calibration verification performed on 6/17/20 and 5/8/21. l. Ferritin had calibration verification performed on 6/17/20. m. Albumin had calibration verification performed on 6/30/20 and 5/15/21. n. Blood Urea Nitrogen (BUN) had calibration verification performed on 6/30/20 and 5/15/21. o. Calcium had calibration verification performed on 6/30/20 and 5/15/21. p. Total Cholesterol had calibration verification performed on 6/30/20 and 5/15/21. q. Chloride had calibration verification performed on 6/30/20 and 5/15/21. r. Creatinine had calibration verification performed on 6/30/20 and 5/15/21. s. Glucose had calibration verification performed on 6/30/20 and 5/15/21. t. Potassium had calibration verification performed on 6/30/20 and 5/15/21. u. Lithium had calibration verification performed on 6/30/20 and 5/15/21. v. Magnesium had calibration verification performed on 6/30/20 and 5/15/21. w. Sodium had calibration verification performed on 6/30/20 and 5/15/21. x. Phosphorus had calibration verification performed on 6/30/20 and 5/15/21. y. Total Protein had calibration verification performed on 6/30/20 and 5/15/21. z. Triglycerides had calibration verification performed on 6/30/20 and 5/15/21. aa. Carbon Dioxide had calibration verification performed on 7/1/20. bb. Iron had calibration verification performed on 7/1/20. cc. Ammonia had calibration verification performed on 7/1/20. dd. Uric Acid had calibration verification performed on 7/1/20. 3. An interview on 6/22/21 at 3:10 pm with the General Supervisor confirmed the laboratory did not perform calibration verification activities at least every 6 months for the above analytes. *** This is a repeated deficiency from the previous two surveys (6/19/19 and 10/19/16)***

D5775

COMPARISON OF TEST RESULTS
CFR(s): 493.1281(a)(c)

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities.

This STANDARD is not met as evidenced by:
. Based on record review and interview with the General Supervisor, the laboratory failed to evaluate the correlation between different instruments performing the same testing at least twice annually for 1 of 2 events required in 2020. Findings include: 1. A review of the laboratory's "Instrument Correlations" procedure revealed a section stating, "The laboratory monitors and evaluates all methods for the same test

performed on different instruments. This evaluation is done at least twice a year, using five samples of each analyte monitored. The laboratory will monitor this policy using Proficiency Testing (PT) Acceptability Criteria and recording on an Instrument Correlation Log." 2. A review of the laboratory's instrument correlation data revealed the following instruments did not have instrument correlations twice annually in 2020:

- a. Beckman AU5800 Unit 1 System ID 42793798 chemistry analyzer had instrument correlations performed in 6/2020
- b. Beckman AU5800 Unit 2 System ID 45196208 chemistry analyzer had instrument correlations performed in 6/2020
- c. CA 1500 A SYS 1 SN 8816 coagulation analyzer had instrument correlations performed in 6/2020
- d. CA 1500 A SYS 1 SN 8818 coagulation analyzer had instrument correlations performed in 6/2020
- e. DxH A System ID 3820959 hematology analyzer had instrument correlations performed in 6/2020
- f. DxH B System ID 3792459 hematology analyzer had instrument correlations performed in 6/2020
- g. DxH C System ID 59545753 hematology analyzer had instrument correlations performed in 6/2020

3. An interview on 6/22/21 at 3:10 pm with the General Supervisor confirmed the laboratory did not perform instrument correlations as least twice annually for the instruments listed above. in 2020