

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D2045786	(X3) Date Survey Completed 06/19/2019
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
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: . Based on procedure review, observation, and interview with the Technical Supervisor (TS), the laboratory failed to label the Sigma-Aldrich Modified Wright Stain with the preparation dates, expiration dates, storage requirements, and lot numbers on the secondary containers for the current lot in use. Findings include: 1. A review of the "Manual Preparation and Staining of Blood Smears in Hematology - Wright Stain" procedure revealed the section stating, "Label the stain container in use (secondary container) with the following: Wright Stain, Store at RT, Lot # and expiration date, appropriate SDS hazard pictogram." 2. On 6/19/19 at 11:05 am during a tour of the laboratory, the surveyor observed the Sigma-Aldrich Modified Wright Stain without the preparation, expiration dates, storage requirements, and lot numbers on the secondary containers for the current lot in use. 3. An interview on 6/19/19 at 11:15 am with the TS confirmed the secondary containers had not been labeled to include preparation dates, expiration dates, storage requirements, and lot numbers.</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at</p>

least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

. A. Based on observation, record review, and interview with the Technical Supervisor (TS), the laboratory failed to perform and document laboratory thermometer calibration for 2 (2017 and 2018) of 2 years. Findings include: 1. On 6/19/19 at 8:59 am the surveyor observed the following thermometer calibration expiration dates: a. Refrigerator #1 had a thermometer with a calibration expiration date of October 2016. b. The freezer had a thermometer with a calibration expiration date of October 2018. c. Refrigerator #3 had a thermometer with a calibration expiration date of October 2018. d. The storage room had a thermometer with a calibration expiration date of October 2017. 2. A review of the "Thermometer Calibration Using NIST Calibrated Thermometer" procedure revealed thermometers were to be "tested against the NIST certified thermometer before being put into use and annually thereafter." 3. A review of the "Thermometer Calibration Documentation Forms" revealed a lack of documentation of thermometer calibrations in 2017, 2018, and 2019. 4. An interview on 6/19/19 at 8:59 am with the TS confirmed the laboratory failed to perform and document thermometer calibrations for 2017 and 2018. B. Based on document review and interview with the Technical Supervisor (TS), the laboratory failed to document Beckman Coulter UniCel DxH hematology analyzer background counts for 4 (patients 2, 4, 6, and 7) out of 5 patient charts reviewed. Findings include: 1. A record review of the Beckman Coulter UniCel DxH hematology analyzer daily checks revealed a lack of documentation of background counts for the following dates reviewed: a. 12/7/18 b. 4/10/18 c. 11/7/17 d. 7/13/17 2. A review of patient charts revealed Complete Blood Counts (CBC) were reported for the following patients for the following days without documentation of background counts performed: a. Patient #2 performed on 12/7/18 b. Patient #4 performed on 4/10/18 c. Patient # 6 performed on 11/7/17 d. Patient #7 performed on 7/13/17 3. An interview on 6/19/19 at 4:06 pm with the TS confirmed the Beckman Coulter UniCel DxH hematology analyzer background counts were not documented for the 4 patient charts reviewed.

D5439

CALIBRATION AND CALIBRATION VERIFICATION
CFR(s): 493.1255(b)

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.

This STANDARD is not met as evidenced by:

. Based on record review and interview with the Technical Supervisor (TS), the laboratory failed to perform and evaluate the chemistry and endocrinology calibration verification at least once every 6 months for 1 (January 2019 event) of 4 events reviewed. Findings include: 1. When requested on 6/19/19, the laboratory was not able to provide documentation showing the calibration verification was completed at least every 6 months in 2019 for the following chemistry and endocrinology testing: a. Endocrinology- T Uptake and T4 b. Chemistry - sodium, potassium, chloride, calcium, blood urea nitrogen, creatinine, total protein, lactate dehydrogenase, magnesium, phosphorous, uric acid, cholesterol, triglycerides, high density lipoprotein, total iron binding capacity, gamma-glutamyl transferase, aspartate aminotransferase, alanine aminotransferase, total bilirubin, direct bilirubin, alkaline phosphatase, C-reactive protein, prealbumin, albumin, creatinine kinase, amylase, lipase, lithium, and ferritin. 2. An interview on 6/19/19 at 11:30 am with the TS confirmed calibration verification had not been performed at least every 6 months in 2019.