Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2039533	07/12/2023
Name of Provider or Supplier	**Street Address, City, State**	
American Health, S Llc Dba American Health Associa	10270 Old Columbia Road Suite 600, Columbia, MD	

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	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's delegation of duties and written competency procedure, the laboratory failed to establish and follow written procedures to assess the competency of the laboratory manager. Findings: 1. The document titled "Delegation of Duties" was submitted with the second allegation of compliance (AoC) on 03/31/2023. It delegated the following duties to the "General Supervisor": Review of proficiency testing, quality control review, review of maintenance logs, review of temperature logs, competency assessments, training, corrective action reports, review of specimen in-take logs and monitoring systems, and review of abnormal test values. 2. The procedure titled "Employee Competency and Training" was submitted with the third (current) AoC on 06/09/2023 and stated that "The Laboratory Director will complete competency checks for the Laboratory Manager annually. This will include competency checks on all instrumentation and assays performed." 3. The laboratory did not have a written procedure for assessing the competency of the laboratory manager/general supervisor for their duties as a laboratory manager/general supervisor including the delegated duties.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems

	identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory's preanalytic quality assurance procedures did not ensure that the laboratory maintained an ongoing mechanism to assess and correct preanalytic test problems. Findings: 1. The laboratory did not have written procedures that ensured the laboratory contact someone from the patient care facility and the phlebotomist to obtain information concerning specimen contamination and that the communication was documented. The laboratory policy described by the technical consultant during interview on the afternoon of July 12, 2023 was for the laboratory to make three phone calls to the patient care facility and if no one answered or returned the call then the laboratory sent the test report to the care facility stating that a new request for re-collection was needed. 2. During the month of June 2023, three (M3203397, M3204984 and M3205215) of six specimens reviewed were identified as contaminated, for two (M3203397 and M3204984) of these specimens, the laboratory was unable to contact someone from the patient care facility and the phlebotomist to determine the source of contamination. 3. The source of contamination was not identified for these two specimens, and since the source of contamination could not be identified, the laboratory could not take steps to monitor the severity of the problem and take corrective action(s) to correct the problem causing contamination.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the allegation of compliance (AoC) submitted for the current recertification survey, the quality control (QC) procedure, and QC records from the onsite revisit survey, and interview with the technical consultant (TC), the laboratory failed to implement the AoC by failing to perform monthly QC reviews. Findings: 1. The initial AoC received on 02/07/2023 stated that "Quality Control will continue to be monitored on the monthly QA [quality assessment] checklist." 2. Section II.D. of the procedure titled "Quality Control (Internal) - Selection, Set-up and Review v1. 2M" stated that "Each month a comprehensive review of the past month's quality control data is performed by the department supervisor or designee" and "The review and corrective action as indicated are documented." 3. The laboratory's practice was to print the chemistry QC monthly and document review on the "Monthly QC Review" worksheets. 4. The "Monthly QC Review" worksheets were not completed in 2023 for the AU-5800 and Architect chemistry analyzers. 5. During the onsite revisit survey on 07/12/2023 at 7:30 PM, the TC confirmed that QC review for the AU-5800 and Architect analyzers was not documented on the "Monthly QC Review" worksheets in 2023.