Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D2009082	11/13/2023
Name of Provider or Supplier	**Street Address, City, State**	
American Health S, Llc	5380 Hickory Hollow Parkway, Suite 120, Antioch, TN	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of test system policy's and procedures, review of the laboratory's Quality Assurance and Improvement Plan, lack of records, and staff interview, the laboratory failed to retain the complete blood count (CBC) quality control (QC) manufacturer assay sheets used to establish Quality Control (QC) ranges for the Beckman Coulter UniCel DxH 900 in 2021, 2022, or 2023. The findings include: 1. Observation of the laboratory on 11/13/23 at 8:30 a.m. revealed the following: - Two Beckman Coulter UniCel DxH 900 (SNs BD09124 & BD09125) test systems in use for hematology patient testing. - Beckman Coulter 6C commercial controls, current lots 5140 (exp 12/24/23) and 3510 exp 11/28/23 were in use for performing quality control on the DxH 900 test systems. 2. Review of the laboratory's "UniCel DxH Coulter Cellular Analysis System" policy revealed "When using the recommended Beckman Coulter commercial controls, refer to the package insert." 3. Review of the laboratory's Quality Assurance and Improvement Plan revealed "All routine laboratory records are kept for 2 years and the current one." 4. Review of laboratory records revealed no Beckman Coulter 6C commercial controls package inserts had been retained for lots used in 2021, 2022 or 2023. 5. Interview with the Technical Consultant and Director of Quality on 11/13/23 at 4:30 p.m. confirmed the manufacturer assay sheets used to establish Quality Control (QC) ranges for the Beckman Coulter UniCel DxH 900 test systems were not retained in 2021, 2022, or 2023.

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 procedure manual, testing personnel (TP) records, and staff interview, the laboratory failed to follow its own policy for documenting competency assessments for 2 of 5 testing personnel in 2021 and 2022. The findings include: 1. Review of the General Laboratory Personnel policy revealed "Competencies will be performed upon initial hire, at 6 months and annually thereafter". 2. Review of competency assessment documents for testing personnel revealed the following: - No documented initial or 6-month competency assessments for TP2 in 2022. - No documented annual competency for TP1 in 2021 and 2022. 3. Interview with the Technical Consultant and Director of Quality on 11/13/23 at 4:30 p. m. confirmed the laboratory did not follow their own policy for documenting initial, 6-month, and annual competency assessments for 2 of 5 testing personnel in 2021 and 2022.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, Laboratory Personnel Report (Form CMS-209), and staff interview, the current laboratory director failed to approve the laboratory's procedures. The findings include: 1. Review of the laboratory's written policy and procedure manuals revealed no signature or date indicating approval by the current laboratory director as listed by the laboratory on form CMS-209. 2. Interview with the Laboratory Director on 11/13/23 at 4:30 p.m. confirmed the current laboratory director began on 09/22/2023 and had not approved the policies and procedures.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the Sysmex CS2500 operator's

	manual, humidity logs, and staff interview, the laboratory failed to maintain appropriate operating humidity levels in the laboratory for the Sysmex CS2500 test system used in patient testing in 2021, 2022, and 2023 for a total of 279 days. The findings include: 1. Observation of the laboratory on 11/13/23 at 8:30 a.m. revealed two Sysmex CS2500 (SNs 21643 & 21650) coagulation analyzers in use for coagulation patient testing. 2. Review of the Sysmex CS2500 operator's manual revealed the operating humidity range for the test system to be 30% - 85%. 3. Review of the humidity logs revealed that the humidity was out of range for 96 of 365 days in 2021, 101 of 365 days in 2022, and 82 of 317 days in 2023. 4. Interview with the Technical Consultant and Director of Quality on 11/13/23 at 4:30 p.m. confirmed the laboratory failed to ensure the humidity was within manufacturer's acceptable range for the Sysmex CS2500 test system used for patient testing in 2021, 2022 and 2023 for a total of 279 days.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) 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. This STANDARD is not met as evidenced by: Citation #1 Based on observation of the laboratory and staff interview, the laboratory failed to label containers of staining reagents used for preparing patient peripheral blood smears with contents, lot numbers, preparation dates, and expiration dates. The findings include: 1. Observation of the laboratory on 11/13/23 at 08:30 a.m. revealed containers of staining solutions in use for staining patient peripheral blood. The containers were not labeled with contents, lot numbers, storage requirements or preparation and expiration dates. 2. Interview with the Technical Consultant and Director of Quality on 11/13/23 at 4:30 p.m. confirmed the laboratory did not label containers of staining reagents with contents, lot numbers, storage requirements or preparation and expiration dates. Citation #2 Based on observation of the laboratory, review of manufacturer's instructions for use, the laboratory's policies and procedure manual, and staff interview, the laboratory failed to label Beckman Coulter 6C commercial control with open dates and updated expiration dates. The findings include: 1. Observation of the laboratory on 11/13/23 at 08:30 a.m. revealed the Beckman Coulter UniCel DxH 900 (SN: BD09124 & BD09125) test systems using Beckman Coulter 6C commercial controls (lot: 5140 exp.: 12/24/23 and Lot: 3510 exp.: 11/28/23). The control vials lacked an open and an updated expiration date. 2. The Coulter 6C Control instructions for use states the controls have a 16 day open vial stability and will be "performed a maximum of 18 times within 16 days." 3. Review of the laboratory policies and procedure manual revealed the following statement under the "Laboratory Policies: General Laboratory" section: "1. All reagents, standards, controls, etc. must be labeled with Date Received, Date Opened, Expiration Date" 4. Interview with the Technical Consultant and Director of Quality on 11/13/23 at 4:30 p.m. confirmed the laboratory did not label the Beckman Coulter 6C commercial controls used for quality control of the Beckman Coulter UniCel DxH 900 hematology test systems with opened and updated expiration dates.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of the Clinical Laboratory Improvement Amendments (CLIA) certificate of compliance, CLIA Application for Certification (form CMS-116), Laboratory Personnel Report CLIA (form CMS-209), and staff interview, the laboratory director failed to ensure compliance with regulation 493.51(a)(4) by not notifying the department of Health and Human Services (HHS) state agency within 30 days of when the laboratory director personnel changed on 09/22/23. The findings include: 1. Review of the CLIA certificate of Compliance revealed the laboratory director was not the same as the laboratory director listed on the forms CMS-116 and CMS-209 completed for the survey conducted on 11/13/2023. 2. Interview on 11/13 /2023 at 4:30 p.m. with the Laboratory Director, Technical Consultant, and Director of Quality confirmed the laboratory failed to notify the HHS state agency within 30 days of when the laboratory director changed on 09/22/23.