Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D1080642	05/19/2026
Name of Provider or Supplier	**Street Address, City, State**	
American Health Associates, Inc	1070 Asheville Highway, Spartanburg, SC	

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
D0000	An announced onsite CLIA recertification survey was conducted on May 19, 2026, at American Health Associates, LLC dba American Health Associates of Spartanburg by the South Carolina Department of Public Health (SC DPH) Bureau of Nursing Homes and Medical Services. The laboratory was found to be out of compliance with Medicare condition 42 CFR Part 493, CLIA requirements for laboratories. The following are a list of STANDARD LEVEL deficiencies cited as a result of recertification survey conducted on May 19, 2026:
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on record review, lack of documentation of written procedures, and staff interview, the laboratory failed to have updated written policies and procedures to follow that ensure optimum integrity of patient's specimen from the time of collection or receipt of the specimen through completion of testing and the reporting of results for 3 out of 3 specialties/subspecialities reviewed (Diagnostic Immunology, Chemistry, and Hematology). Findings included: 1. Review of CMS 116 application reveals the laboratory performs testing in the specialty and subspecialty of diagnostic immunology, chemistry, and hematology. 2. A review of random patient chemistry results revealed the following: a. Instrument printout dated October 31, 2023, 06:02, S. No.0048 S.ID B1969744, Na/l 129, GLUC 58, K/L 3.8, BUN 16, Cl/1 105, CRE 0.75, CO2 28 b. Instrument printout dated October 31, 2023, 06:02, S. No. H0007 S. ID B1969692 c. Instrument printout dated October 31, 2023, 06:02, S.No.0052 S. ID B1969750, Na/l 143, k/L 4.3, Cl/1 105, co2 24, ALT 4, GLUC 62, BUN 29, CRE

	0.98, TP 6.3, ALB 2.87 d. Instrument printout dated October 31, 2023, 06:02, S. No. 0053 S. ID Na/2 141, K/2 4.5, Cl/l 100, co 28,GLUC 68, BUN 17, CRE 0.94 e. Instrument printout dated October 31, 2023, 06:02, S. No.0057 S. ID B1969755, Na/2 135, K/2 4.5, cl/2 95, co2 31, GLUC 79, BUN 16, CRE 0.75 f. Instrument printout dated July 18, 2025, 06:02, S. No. H0006 S. ID B2100168, Na/l 147, GLUC 41 The above test results are examples of tests that were potentially affected due to a lack of updated policies and procedures (last updated June 2010) for current analyzers following the manufacturer's instructions for processing of clinical specimens. 3. In an interview on May 19, 2026, at 3:07 pm in the office with the testing personnel (TP) TP2 the above findings were confirmed.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on records review, lack of documentation and staff interview, the laboratory failed to document twice annual accuracy accessment of the Laboratory Information System (LIS) as part of the Quality Assurance Plan (QA). Findings including: 1. Review of the laboratory's QA plan (dated June2010) reveals a lack of policy and procedure requirement for twice annual accuracy assessment for the LIS. 2. Review of laboratory records reveals a lack of documentation for twice annual accuracy assessments for the LIS.(signed off 6/17/10) 3. In an interview with the testing personnel (TP2) on May 19, 2026, in the office at 3:08pm, the findings were confirmed.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on records review, lack of documentation, and staff interview, the laboratory failed to establish and/or follow written policies and procedures based on manufacturer's instructions for specimen submission, handling, referral requirements, preservation, and transportation as outlined by the manufacturer as required 493.1242 (a) (4) (5) (6) in the for 4 out of 4 (Calcium, Glucose, Potassium, and Activated Partial Thrombin Time) analytes requiring specified specimen handling prior to testing. Findings included: 1. Review of Beckman Coulter 5800 user manual reveals specific specimen requirements for the following analytes: a. Calcium -separate from the red cells as soon as possible b. Glucose-separate red cells rapidly to minimize loss of glucose through glycolysis c. Potassium-sample free from hemolysis; separate red cells from serum as soon as possible 2. A review of Siemens Healthcare Diagnostics Sysmex CS-2500 System Installation Package Rev 1.0 reveals Activated Partial

	Thromboplastin Time (APTT)- use heparinized sample, centrifuge within 1 hour, 18-24 Celsius, test within 4 hours of collection. 3. The surveyor requested from the laboratory and the laboratory failed to provide written procedures for staff/specimen collectors, and/or clients noting the specific specimen requirements for 4 out of 4 (Calcium, Glucose, Potassium, and APTT) analytes on the day of inspection. 4. In an interview on May 19, 2026, at 3:07 pm in the office with the testing personnel (TP) TP2 the above findings were confirmed.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) (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, lack of documentation, and staff interview, the laboratory failed to have an established written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified as required 493.1241 through 493.1242 for the 3 out of 3 years reviewed (2023, 2024, and 2025). Findings included: 1. Review of policy and procedure titled "Quality Assurance and Improvement Plan"(dated 6/17/2010) reveals section IV, Quality Assurance Plan, A. Procedure Manuals, lack a section and/or procedure for collection/transportation of specimens. 2. Review of patient results reveals the following results were potentially affected due to specimen handling and /or transportation. a. Instrument printout dated October 31, 2023, 06:02, S.No.0048 S. ID B1969744, Na/l 129, GLUC 58, K/L 3.8, BUN 16, Cl/1 105, CRE 0.75, CO2 28 b. Instrument printout dated October 31, 2023, 06:02, S. No. H0007 S. ID B1969692 c. Instrument printout dated October 31, 2023, 06:02, S.No.0052 S. ID B1969750, Na/l 143, k/L 4.3, Cl/1 105, co2 24, ALT 4, GLUC 62, BUN 29, CRE 0.98, TP 6.3, ALB 2.87 d. Instrument printout dated October 31, 2023, 06:02, S. No. 0053 S. ID Na/2 141, K/2 4.5, Cl/l 100, co 28,GLUC 68, BUN 17, CRE 0.94 e. Instrument printout dated October 31, 2023, 06:02, S. No.0057 S. ID B1969755, Na/2 135, K/2 4.5, cl/2 95, co2 31, GLUC 79, BUN 16, CRE 0.75 f. Instrument printout dated July 18, 2025, 06:02, S. No. H0006 S. ID B2100168, Na/l 147, GLUC 41 Sodium=Na/ Potassium= K /l Chloride=Cl Carbon Dioxide= CO2 Alanine Transaminase=ALT Glucose=GLUC Blood urea nitrogen=BUN Creatinine=CRE TOTAL PROTEIN=TP ALBUMIN=ALB
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on direct observation, lack of documentation, and staff interview, the laboratory failed to establish approved procedures for new/current analyzers in use, and date the initial use and discontinuance of procedures not in use as required 493.1251 for 3 out

	of 3 years reviewed (2023, 2024, and 2025). Findings included: 1. During a laboratory tour on May 19, 2026, at 11:20 am the following instrumentation was observed: a. Beckman Coulter AU5800 Chemistry Analyzer b. Beckman Coulter DXH 900 Hematology Analyzer c. iSED ESR Analyzer d. Sysmex Coagulation CS-2500 Analyzer e. Beckman Coulter Automated Urinalysis Solution DXU Iris 2. The surveyor requested and the laboratory failed to provide procedures approved by laboratory director for the following instrumentation: a. Beckman Coulter AU5800 Chemistry Analyzer b. Beckman Coulter DXH 900 Hematology Analyzer c. iSED ESR Analyzer d. Sysmex Coagulation CS-2500 Analyzer e. Beckman Coulter Automated Urinalysis Solution DXU Iris 3. In an interview on May 19, 2026, at 3:07 pm in the office with the testing personnel (TP) TP2 the above findings were confirmed.
D5409	PROCEDURE MANUAL CFR(s): 493.1251(e) (e) The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2). This STANDARD is not met as evidenced by: Based on direct observation, lack of documentation, and staff interview, the laboratory failed to date the initial use and discontinuance of procedures not in use as required 493.1251 for 3 out of 3 years reviewed (2023, 2024, and 2025). Findings included: 1. During a laboratory tour on May 19, 2026, at 11:20 am the following instrumentation was observed: a. Beckman Coulter AU5800 Chemistry Analyzer b. Beckman Coulter DXH 900 Hematology Analyzer c. iSED ESR Analyzer d. Sysmex Coagulation CS-2500 Analyzer e. Beckman Coulter Automated Urinalysis Solution DXU Iris 2. Review of the procedure manual reveals a lack of documentation for the new instrumentation observed and noted in the laboratory on the day of inspection. 3. In an interview on May 19, 2026, at 3:07 pm in the office with the testing personnel (TP) TP2 the above findings were confirmed.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on records review (testing personnel competency records) and staff interview, the TC failed to document initial and annual competency assessments for 2 out of 2 TP. Findings included: 1. Review of the Quality Assurance and Improvement Plan dated 6/17/10 reveals the requirement of initial and annual competency for staff 2. Review of competency documentation reveals a lack of initial and annual competency assessments for TP1 and TP2. 3. Review of personnel competency documentation identifies each competency evaluation as being semiannaul. 4. In an interview with the TP2 on May 19, 2026 at 3:08pm in the office, the findings were confirmed.