Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1054277	01/27/2022
Name of Provider or Supplier	**Street Address, City, State**	
American Health S, Llc	7175 66th St N, Pinellas Park, FL	

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 CLIA recertification survey was conducted at American Health Associates Inc. on 01/18/2022 through 01/27/2022. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D5400-Analytic Systems 493.1250
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observations, record review, and interview the laboratory ran Patients when 2 levels of controls were not in the acceptable range for 5 days in November 2020 (11 /12/20, 11/21/20, 11/24/20, 11/26/20, and 11/27/20) and for 4 days in September 2021 (09/08/21, 09/10/21, 09/11/21, and 09/14/21). This is a repeat deficiency from the recertification survey that ended on 09/16/2019. (See D5481)
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

	This STANDARD is not met as evidenced by: Based on observation, record review, and interview the laboratory failed to ensure Pre-trigger Solution on the Architect chemistry analyzer was not expired prior to patient testing from 01/06/2022 to 01/17/2022. Findings Included: A tour of the laboratory on 01/18/2022 at 10:00 AM revealed 3 containers of Pre-trigger Solution in the refrigerator with an expiration of 01/05/2022. The expired Pre-trigger Solution was also observed in use on the Architect chemistry analyzer. It was immediately changed to an unexpired Pre-trigger Solution on 01/18/2022 at 10:15 AM. On 01/18/2022 at 10: 00 AM, the Laboratory Manager confirmed that the expired Pre-trigger Solution was on the Architect chemistry analyzer and reported no patient testing had been conducted that day. On 01/27/2022 at 8:49 AM, electronic correspondence (email) from the Laboratory Manager revealed approximately 192 Folate tests, 672 Vitamin D tests, 840 TSH (thyroid stimulating hormone) tests, 432 Vitamin B-12 tests, 24 Troponin tests, and 108 BNP (brain natriuretic peptide) tests were conducted from 01 /06/2022 to 01/17/2022 using the expired Pre-trigger Solution.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observations, record review, and interview the laboratory ran Patients when 2 levels of controls were not in the acceptable range for 5 days in November 2020 (11 /12/20, 11/21/20, 11/24/20, 11/26/20, and 11/27/20) and for 4 days in September 2021 (09/08/21, 09/10/21, 09/11/21, and 09/14/21). This is a repeat deficiency from the recertification survey that ended on 09/16/2019. Findings Included: A tour of the laboratory on 01/18/2022 at 10:00 AM revealed 2 AU 5800 Chemistry analyzers labeled AU 58 T and AU 582 T. Review of the Quality Assurance/Quality Improvement Program Manual (signed by the Laboratory Director 01/11/2022) revealed "QC (Quality Control) samples are tested and documented each day of testing for non-waived tests, as outlined in the laboratory procedure manuals. Control values are verified to be within acceptable limits before patient samples are reported." Review of QC on 11/12/2020 revealed the QC was not acceptable for CO2 (carbon dioxide) on both the AU 58 T and AU 582 T. There were 294 Patients reported on that day. Review of QC on 11/21/2020 revealed the QC was not acceptable for Calcium on both AU 58 T and AU 582 T. There were 149 Patients reported on that day. Review of QC on 11/24/2020 revealed the QC was not acceptable for Lipase on both AU 58 T and AU 582 T. There were 8 Patients reported that day. Review of QC on 11/26/2020 revealed the QC was not acceptable for Lipase on both AU 58 T and AU 582 T. There were 3 Patients reported on that day. Review of QC on 11/27/2020 revealed the QC was not acceptable for UIBC (unsaturated iron-binding capacity) on both AU 58 T and AU 582 T. There were 4 Patients reported on that day. Review of Quality Control (QC) on 09/08/2021 revealed the QC was not acceptable for CO2 for AU 58 T. There were 179 Patients reported on that day. Review of QC on 09/10/2021 revealed the QC was not acceptable for Total Bilirubin on the AU 582 T. There were 102 Patients reported on that day. Review of QC on 09/11/2021 revealed the QC was not acceptable for CO2 on the AU 58 T and the AU 582 T. There were 545 Patients reported on the AU 58 T and 212 on the AU 582 T that day. Review of QC on 09/14 /2021 revealed the QC was not acceptable for HDL (high-density lipoprotein) on the

	AU 58 T. There were 51 Patients reported on that day. On 01/26/2022 at 3:52 PM, the Laboratory Manager confirmed that there was no corrective action documented on the failed QC. Review of the plan of correction signed by the Laboratory Director on 10 /21/2019 revealed that "The Technical Supervisor and the Medical Director will be responsible for monitoring performance and compliance."