Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1054277	09/16/2019
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 unannounced recertification survey was conducted on 09/09/19 thru 09/13/19 and 09/16/19 at American Health Associates. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Clinical Laboratories. Based on the survey findings, an Immediate Jeopardy situation was identified and the laboratory was notified at 10:36 AM on 09/16/19. The laboratory failed to run 2 acceptable controls for T3 Uptake testing since 01/2018 (See D5400). The following Conditions were not met: D5400-Analytic Systems 493.1250 D6033-Technical Consultant-Moderate Complexity 493.1409
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of DEQAS (Vitamin D External Quality Assessment Scheme) proficiency testing documentation and interview with the Laboratory Manager the laboratory failed to have the Testing Person and Laboratory Director sign the attestation statement for 4 out 4 testing events (1st testing event 2019 and 1st, 2nd, and 3rd testing event in 2018) for Vitamin D testing. Findings Included: Review of DEQAS proficiency testing revealed no signed attestation statement signed by the Testing Person and Laboratory Director in the 1st testing event of 2019 or 1st, 2nd, or 3rd testing event in 2018. On 09/09/19 at 1:36 PM, the Laboratory Manager confirmed that there were no attestation statements for Vitamin D testing.
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 record review and interview with the Laboratory Manager the laboratory failed to run quality control that was in the reportable range of the Beckman Coulter AU5812 chemistry analyzer (See D5481), failed to use quality control of different concentrations (See D5447), failed to track shifts and trends for Hemoglobin A1C (See D5441), failed to ensure Wright's stain was removed from use after expired (See D5417), and failed to record temperatures of the refrigerator where urine samples were stored and a freezer where flu swabs were stored (See D5413).
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, lack of records, and interview with the Laboratory Manager the laboratory failed to document the temperatures of a refrigerator where urine samples were stored and a freezer where flu swabs were stored since 01/18. Findings Included: During a tour of the laboratory on 09/09/19 at 9:00 AM, a refrigerator was observed with patient urine samples and a freezer with flu swabs in it. There was no thermometer present to monitor temperatures in either the refrigerator or freezer. Review of temperature charts revealed that no temperature chart for the urine refrigerator or the flu swab freezer was maintained. Interview with the Laboratory Manager on 09/09/19 at 12:30 PM confirmed that the temperatures of the urine refrigerator and the flu swab freezer were not documented.
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 and interview with the Laboratory Manager the laboratory failed to ensure Wright's stain was removed from use after the expiration date of 01 /17. Findings Included: During a tour of the laboratory it was observed that the

	Wright's stain (used for staining blood smears to differentiate nuclear and/or cytoplasmic morphology of platelets, red blood cells, white blood cells, and parasites) expired 01/17. Interview with the Laboratory Manager on 09/09/19 at 12:00 PM confirmed that the stain was expired and had been used.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of documentation and interview with the Laboratory Manager the laboratory failed to track and trend Hemoglobin A1C testing since 01/2018. Findings Included: Review of Hemoglobin A1C quality control revealed that the laboratory was not monitoring for shifts and trends over time. On 09/10/19 at 1:00 PM, the Laboratory Manager confirmed that quality control was only being monitored daily for acceptability and not monitored for trends or shifts.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation, record review and interview with the Laboratory Manager the laboratory failed to run 2 controls of different concentration for 3 (July 2019, January 2019, and August 2018) out of 4 months (July 2019, January 2019, August 2018, and February 2018) reviewed for T3 Uptake testing. Findings Included: During a tour of the laboratory on 09/09/19 at 9:00 AM, two Beckman Coulter AU5812 Chemistry analyzers (labeled AU58-T and AU582-T) were observed. Review of validation of both chemistry analyzers revealed the reportable range for T3 Uptake was 15-50% A sample of Quality Control was reviewed from 01/2018 to include July 2019, January 2019, August 2018, and February 2018. Review of quality control (QC) for T3 Uptake in July 2019 revealed for AU58-T the mean for level 1 was 35.54% and level 2 was 39.10% and for AU582-T the mean for level 1 was 33.99% and level 2 was 36.08%. There were 84 patients ran in July 2019. Review of QC for T3 Uptake in January 2019 revealed for AU58-T the mean for level 1 was 35.91% and level 2 was 41.16% and for AU582-T the mean for level 1 was 35.67% and level 2 was 40.71%. There

	were 108 patients reported in January 2019. Review of QC for T3 Uptake in August 2018 revealed for AU58-T the mean for level 1 was 36.55% and level 2 was 41.65% and for AU582-T the mean for level 1 was 38.02% and level 2 was 42.36%. There were 103 patients reported in August 2018. The annual volume of T3 Uptake testing was 1105 in 2018 and 713 in 2019. During an interview on 09/12/19 at 4:00 PM, the Laboratory Manager confirmed that the controls being ran for T3 Uptake were not of different concentrations, and the laboratory was using the same controls as of 09/12 /19.
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 observation, record review, and interview with the Laboratory Manager the laboratory failed to run 2 controls in the reportable range for 1 (February 2018) out of 4 months (July 2019, January 2019, August 2018, and February 2018) reviewed for T3 Uptake and T4 testing. Findings Included: During a tour of the laboratory on 09/09 /19 at 9:00 AM, two Beckman Coulter AU5812 Chemistry analyzers (labeled AU58-T and AU582-T) were observed. Review of validation of both chemistry analyzers revealed the reportable range for T3 Uptake was 15-50% and for T4 was 0.7-20 ug /dL. A sample of Quality Control (QC) was reviewed from 01/2018 to current that included July 2019, January 2019, August 2018, and February 2018. Review of QC for T3 Uptake in February 2018 revealed the level 2 control for both chemistry analyzers had a mean of 55% with a standard deviation (SD) of 5%, which would make the range from 45-65%. This is greater than the upper value for the reportable range of both machines. There were 95 Patients reported in February 2018. Review of QC for T4 in February 2018 revealed the level 2 control for AU 58-T had a mean of 19.74 ug/dL with a SD of 0.310 which would make the range from 19.12--20.36 ug /dL. Review of the QC for T4 in February 2018 revealed the level 2 control for AU582-T had a mean of 19.58 ug/dL with a SD of 0.41, which would make the range from 18.76--20.4 ug/dL. These ranges are greater than the upper value for the reportable range of both machines. There were 221 patients reported in February 2018. The annual volume of T3 Uptake testing was 1105 in 2018 and 713 in 2019. The annual volume of T4 testing was 2579 in 2018 and 1750 in 2019. During an interview on 09/12/19 at 4:00 PM, the Laboratory Manager confirmed that the level 2 controls being ran for T3 Uptake and T4 were outside of the reportable range of the chemistry analyzers in February 2018.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview with the Laboratory Manager the Laboratory

	Technical Consultant failed to have oversight of the laboratory since 01/2018 (See D6036).
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Manager the Laboratory Technical Consultant failed to have oversight of the laboratory since 01/2018. Findings Included: See D5400 for failure to use quality control (QC) of different concentration, failure to use QC that is in reportable range of instrument, failure to track shifts and trends of Hemoglobin A1C, failure to ensure Wright's stain was removed from use prior to expiration, and failure to record temperatures for all refrigerators and freezers. During an interview on 09/12/19 at 4:00 PM, the Laboratory Manager (who is also the Technical Consultant) confirmed that his monthly reviews missed the aforementioned issues.