Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2039533	10/03/2022
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
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory failed to successfully participate in a proficiency testing program (refer to D2107).
D2107	ENDOCRINOLOGY CFR(s): 493.843(f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is

	unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of proficiency testing (PT) records and interview with the regional manager (RM), the laboratory failed to achieve satisfactory performance for triiodothyronine (T3) in three consecutive testing events. Findings: 1. The laboratory was enrolled with College of American Pathologists (CAP) in two different PT programs that tested for T3 in three annual events (A, B, and C): 1) General Chemistry /Therapeutic Drugs (C) and 2) Ligand-General (K). 2. The laboratory received the following grades for the following CAP PT events: a. 2021 C-C, T3, 0% b. 2022 K-A, T3, 40% c. 2022 K-B, T3, 0% 3. The "Action Taken to Prevent Recurrence" section of the investigation form for the 2021 C-C event stated "TT3 = Result Not Multiplied by 100." The investigation also indicated that results from PT samples CHM-13 and CHM-15 were switched. Had the results been converted correctly, sample CHM-13 would have been within the acceptable range for sample CHM-15, but sample CHM-15 would have been out of the acceptable range for sample CHM-13. There was no further investigation into why specimen CHM-15 was out of the acceptable range. There was no indication on the form who performed the investigation and when. There was no signature and date of approval from the laboratory director (LD) or designee to indicate that the investigation had been reviewed. 4. The original results evaluation form for the 2022 K-A PT event was released by CAP on 05/06/2022 and signed by the LD on 06/01/2022. There was no investigation on file during day 1 of the on-site recertification survey on 09/28/2022. A copy of an investigation was received via email on 11/03/2022 at 5:50 PM. The investigation was signed by the supervisor and LD on 11/03/2022. The investigation stated that three of five samples were not converted correctly, but would have been within acceptable range if they were converted correctly. Laboratory results for specimen K-03, if converted correctly, were 270 nanograms per deciliter (ng/dL). The acceptable range from CAP was 277.2-407.6 ng/dL. There was no further investigation into why specimen K-03 was out of the acceptable range. Attached to the investigation was a memo to the testing personnel (TP) dated 09/30/2022 instructing the TP to multiply the T3 instrument results by 100. 5. The original results evaluation form for the 2022 K-B PT event was released by CAP on 08/19/2022. There was no investigation on file during the on-site recertification survey on 09/28/2022. A copy of an investigation was received via email on 11/03/2022 at 5:50 PM. The investigation stated that results were not calculated correctly, but were within the acceptable range. The investigation was signed by the LD, but not dated. Attached to the investigation was a memo to the TP dated 09/30/2022 instructing the TP to multiply the T3 instrument results by 100. 6. During day 2 of the survey on 10/03/2022 at 7:45 PM, the RM confirmed that the laboratory had three consecutive failures for T3 in the CAP PT program.
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: Note: This is a repeat deficiency. The laboratory was cited during the complaint survey completed on 11/12/2022 for not maintaining all testing records from the

	chemistry analyzer. The laboratory's allegation of compliance received on 12/08/2020 stated that the laboratory director or designee would conduct bi-annual audits of all laboratory records to assure that the laboratory remained compliant. Based on laboratory record review and interview with the regional manager (RM), the laboratory failed to retain all analytic systems records for at least 2 years. Findings: 1. A review of monthly temperature logs from January through August 2022 showed that temperature logs for "Refrigerator #6," "Storage Room #1," "Dry Bath Incubator," "Incubator," and "C-Diff Incubator" were missing for 2 of 8 months reviewed; and 2. The second page of the August 2022 "AU 5800 Maintenance Logsheet" which documents monthly and quarterly chemistry instrument maintenance was not present at the time of the survey. 3. During an interview on 10/03/2022 at 7:45 PM, the RM confirmed that the laboratory did not retain all analytic system records for at least 2 years.
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the regional manager (RM), the laboratory did not ensure that a copy of all PT documents was maintained by the laboratory for a minimum of two years from the date of the PT testing event. Findings: 1. A review of chemistry PT records from 2021 to 2022 showed that not all of the chemistry instrument printouts from 1 of 3 "Ligand-General" PT events (K-B 2022) were available for review at the time of the survey; and 2. The "Original Evaluation Report" which contains PT scores from the same event was not present. 3. During an interview on 10/03/2022 at 7:45 PM, the RM confirmed that the laboratory did not maintain all PT documents for a minimum of two years from the date of the PT testing event.
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: Note: This is a repeat deficiency. The laboratory was cited during the complaint survey completed on 11/12/2020 for not consistently documenting notification of the laboratory manager when transport coolers were out of range (OOR) and supervisory review of the check-in logs. The laboratory's allegation of compliance (AOC) received on 12/08/2020 stated that the laboratory director or designee would conduct monthly audits of the check-in logs to ensure that the supervisory staff were performing daily reviews and any errors requiring quality assurance or staff retraining were being performed. Based on review of the previous AOC, client services (CS) procedure manual, and facility check-in logs and interview with the CS staff and regional manager (RM), the laboratory failed to follow procedures for monitoring specimen transport temperatures. Findings: 1. The laboratory documented the time

	specimens were dropped off at the laboratory and the temperature of the transport coolers each day on facility check-in logs. There were five different facility check-in log templates based on facility location. 2. The "CS Specimen In-Take" procedure stated that on "the Facility Check-In Log, the phlebotomist must record their initial's and record the drop off time for each facility that is being dropped off", that if the transport cooler temperature "is NOT within acceptable range, the staff working at the specimen in-take area must notify the laboratory manager and fill in the Specimen In-Take Problem Log", that "the Facility Check-In Logs and Specimen In-Take problem logs must be review by supervisor staff", and that the "Medical Director will review the Facility Check-In Logs and Specimen In-Take Problems logs during their monthly visit." 3. The acceptable temperature range for specimen coolers was 40-77 F and there was a section at the bottom of each check-in log for the "Supervisory Review Signature." 4. The "VA Facility Check-In" log dated 08/03/2021 showed a transport cooler carrying specimens from four facilities as received at 34.4 F. The column labeled "Acceptable Y or N" was blank. There was no documentation of the OOR cooler temperatures on the problems log. Review of one of the four facilities showed that patient results were reported. The log was signed as reviewed on 08/03/2021. 5. The "MG County Facility Check-In" log dated 08/07/2021 showed a transport cooler carrying specimens from five facilities as received at 39 F. The column labeled "Acceptable Y or N" stated "Y" (yes) when it was not acceptable. The "Supervisor Review Signature" was missing. 6. All five daily facility check-in logs from May 2022 were reviewed for a total of 24 days. Of 24 days of logs, 17 days had no signatures on any of the five logs. 7. The "Baltimore Facility Check-In" logs dated 05 /10/2022 and 05/17/2022 were missing transport cooler temperatures for six facilities and five facilities, respectively. The "Supervisor Review Signature" was missing for both logs. 8. The "PA County Facility Check-In" log dated 07/26/2022 was blank. Patient samples from one of the PA County facilities listed on the log were received, tested, and reported. The "Supervisor Review Signature" was missing on the log. 9. The "MG Facility Check-In" log dated 08/31/2022 showed that samples from three facilities were received in a transport cooler with a recorded temperature of 96.3 F. There was no documentation of the OOR specimens in the problems log. At 12:30 PM on 10/03/2022, the CS staff member stated that the temperature was erroneously entered as 96.3 F instead of 46.3 F and the laboratory manager was notified, but no response was received back. The Check-In log was signed as reviewed on 08/31/2022 with no additional notes. 10. There was no documentation that the facility check-in logs were reviewed by the medical director on a monthly basis as stated in the "CS Specimen In-Take" procedure. 11. During day 2 of the survey on 10/03/2022 at 7:45 PM, the RM confirmed that the laboratory was not consistently documenting daily supervisor review of the facility check-in logs, was not documenting corrective actions performed when transport cooler temperatures were OOR, and was not documenting monthly medical director reviews as instructed in the procedure.
D5215	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2) The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results). This STANDARD is not met as evidenced by:

	Based on review of proficiency testing (PT) records, the laboratory failed to document a self-evaluation of chemistry PT scores that were ungraded by the College of American Pathologists (CAP) PT program. Findings: 1. The laboratory was enrolled with CAP in three annual events (A, B, and C) for General Chemistry/Therapeutic Drugs (C) and Ligand-General (K) PT programs. 2. Events 2021 C and 2022 A and B for both programs were reviewed for a total of six PT events. 3. The CAP PT program used reason codes when a PT sample was not graded. 4. Reason code [20] was "Response was not formally graded due to insufficient peer group data" and was used for the following analytes: a. Triiodothyronine (T3) percent uptake in events C-C 2021, C-A 2022, and C-B 2022 b. Ferritin in events K-A 2022 and K-B 2022 5. Reason code [22] was "Result is outside the method/instrument reportable range" and was used for the following analytes: a. Ferritin in event K-B 2022 b. Folate in event K-B 2022 c. T3 percent uptake in event K-B 2022 d. Vitamin B-12 in event K-B 2022 6. Reason code [11] was for "Unable to analyze (documentation to be provided by the laboratory)" and was used for the following analytes: a. Folate in event K-A 2022 b. T3 percent uptake in event K-A 2022 c. Vitamin B-12 in event K-A 2022 7. There was no indication on any of the PT documentation that the laboratory's results for analytes with ungraded PT results were compared with results listed in CAP's participant summary to verify accuracy.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and interview with the regional manager (RM), the laboratory did not ensure that unsatisfactory PT scores were investigated and corrective actions taken. Findings: 1. A review of PT records from 2021 to 2022 showed that the laboratory received a score of 60% for the test thyroid stimulating hormone and a score of 40% for the test phenobarbital during the 3rd PT event of 2021 for "General Chemistry/Therapeutic Drugs" (C-C 2021). 2. A review of PT records showed that there was no documentation of an investigation by the laboratory as to the cause of the unsatisfactory scores, or of corrective actions performed. 3. The laboratory did not document what investigation was performed for failed PT for the test triiodothyronine for 2 of 2 PT events in 2022 for "Ligand-General" (K-A 2022 and K-B 2022). Cross-refer to D2107, findings #4 and #5 for details. 4. During an interview on 10/03/2022 at 7:45 PM, the RM confirmed that unsatisfactory PT scores had not been investigated.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493.1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by:

	Based on record review and interview, the laboratory failed to implement corrections concerning the preanalytic process from the previous survey (see D5311 for findings).
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on review of the previous allegation of compliance (AOC) and the client services (CS) procedure manual, the laboratory's written procedure describing the stability requirements for specimens collected for lactase dehydrogenase (LDH) testing was not corrected as described in the previous survey AOC. Findings: 1. The CS staff check-in, accession, process, and perform data entry for patient specimens received for laboratory testing. 2. The "Stability Studies of Chemistry Analytes" performed by the laboratory on 12/15/2020 and submitted as part of the AOC received on 01/16/2021 for the complaint survey completed on 11/12/2020 determined that specimens to be tested for LDH were stable for four hours when uncentrifuged. 3. The "Criteria for Specimen Rejection" procedure (CS procedure) included a chart listing all chemistry analytes tested at the laboratory and the specimen stability when uncentrifuged. The chart listed LDH as stable for eight hours when uncentrifuged. 4. On 10/03/2022, a CS staff member confirmed that they were trained using the CS procedure containing the incorrect stability requirements for LDH. II. Based on review of the previous AOC, the phlebotomy procedure manual, and the CS procedure manual and interview with the regional manager (RM) and the regional phlebotomy manager (RPM), the laboratory failed to incorporate practices that were implemented as part of the AOC into the written policies and procedures. Findings: 1. The AOC received on 01/16/2021 for the complaint survey completed on 11/12/2020 stated that as "of 12/20/2020 the Maryland laboratory phlebotomists have begun drawing Sodium fluoride/Potassium oxalate tubes for all glucose testing if centrifugation will not take place within 2 hours of collection." This policy change was not documented in the "Phlebotomy Manual of Policies and Procedures." 2. The AOC also stated that any "specimen that is received, for glucose analysis, that has not been centrifuged within 2 hours after collection that is not collected in a Sodium fluoride/Potassium oxalate must be highlighted on the label in order to alert the technologist to DNR [do not report] the glucose." 3. The RM stated that some of the phlebotomists have since been issued portable centrifuges and the laboratory rarely received specimens in sodium fluoride/potassium oxalate tubes for glucose testing. 4. Unless a specimen was received uncentrifuged, there was no way for CS staff to determine if specimens not collected in a sodium fluoride/potassium oxalate tube should be flagged for not being spun within 2 hours after collection as the time the phlebotomists centrifuged the specimens was not documented. 5. It was unknown to the RPM at the time of the survey how many of the phlebotomists were issued portable centrifuges. 6. The laboratory did not perform quality assurance activities to assess and monitor centrifugation of specimens by phlebotomists.
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, the laboratory failed to ensure laboratory personnel followed written procedures for test performance (refer to D5401); failed to monitor and document laboratory reagent refrigerator, freezer, and incubator temperatures to ensure proper reagent storage and reliable test system operation (refer to D5413); failed to label reagents to ensure they are not used when deteriorated or expired (refer to D5415); failed to ensure reagents were not used when deteriorated or expired (refer to D5417); failed to perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer (refer to D5429); failed to perform calibration procedures (refer to D5437); failed to perform control procedures to monitor the accuracy and precision of the complete analytic process (refer to D5441); failed to document quality control checks of culture plates used for patient testing (refer to D5477); failed to ensure quality control test results met the laboratory's criteria for acceptability before reporting patient test results (refer to D5481); and failed to document corrective actions (refer to D5783). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(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 standard operating procedure manual (SOPM) and laboratory record review, and interview with the regional manager (RM), the laboratory did not follow written procedures for performing microbiology cultures on clinical laboratory reagent water (CLRW). Findings: 1. The laboratory uses an Evoqua Water System to provide CLRW for use with the laboratory's clinical chemistry analyzers. 2. The procedure "Evoqua Water System" in the SOPM states, "Water cultures are performed monthly at each point of use for deionized water" and "A copy of the culture report is to be filed in the department." The procedure instructs the user that "These cultures should be entered into the LIS (Laboratory Information) system with the appropriate CAP account number." 3. A review of "Evoqua Water Filtration System Maintenance Checklist" logs from January through August 2022 showed that the "Water Culture Result" on the CLRW was not documented for 2 out of 8 months. 4. During an interview on 10/03/2022 at 11:00 AM, the RM stated that a testing person told them

	that the CLRW culture is not ordered in the LIS, but when the culture results are interpreted the result is recorded on the "Evoqua Water Filtration System Maintenance Checklist." The RM confirmed that the laboratory did not follow the written SOPM.
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 temperature log record review and interview with the regional manager (RM), the laboratory failed to monitor and document laboratory refrigerator, freezer, and incubator temperatures to ensure proper reagent storage and reliable test system operation. Findings: 1. A review of monthly temperature logs from January through August 2022 showed that in January 2022 temperatures were not documented 22 out of 26 days for "Refrigerator #6," and 1 out of 26 days for "Refrigerator #5" and "Freezer #8"; 2. In June 2022 temperatures were not documented 1 out of 26 days for "Refrigerator #2" and "Freezer #8"; 3. In July 2022 incubator temperatures were not documented 3 out of 26 days for "C-Diff Incubator"; 4. In August 2022 temperatures were not documented 3 out of 27 days for "Refrigerator #3"; and 5. Two different logs labeled "Incubator" were found from August 2022. One of 2 logs showed that temperatures were not documented 2 out of 27 days. 6. During an interview on 10/03 /2022 at 7:45 PM, the RM confirmed that the laboratory failed to ensure reliable test system operation by documenting refrigerator, freezer, and incubator temperatures in the laboratory.
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: Based on observation and interview with the regional manager, the laboratory did not label reagents to ensure they are not used when deteriorated or expired. Findings: 1. The laboratory discontinued use of the Tosoh analyzer, but the analyzer still had reagent lines attached during the survey; 2. The hemolysis and lyse reagent bottle had two different opened dates on the one bottle (April 13 and 22, 2022). The regional manager when interviewed was unable to determine why two open dates were recorded on one bottle; and 3. The analyzer and reagents were not marked to show that they were not to be used for testing patient specimens.

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, the laboratory did not ensure that supplies were not used past expiration. Findings: 1. The laboratory lens fluid that was observed on the counter near the back of the laboratory had an opened date of February 19, 2020 and an expiration date of February 19, 2021.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on chemistry instrument maintenance record review and interview with the regional manager (RM), the laboratory did not ensure that all instrument maintenance was performed on the chemistry analyzer as recommended by the manufacturer. Findings: 1. The laboratory uses an AU 5800 chemistry analyzer to perform chemistry testing. The "AU 5800 Maintenance Logsheet" has sections to document the maintenance performed under "Daily," "Weekly," "Every Two Weeks," "Monthly," and "Quarterly." 2. A review of monthly "AU 5800 Maintenance Logsheets" from January through August 2022 showed that "Every Two Weeks" maintenance was not documented 2 out of 8 months, and was documented 1 time a month on 4 out of 8 months. 3. The log showed that "Quarterly" instrument maintenance was to be performed "MAR-JUN-SEP-DEC." Record review showed that it was documented once in July 2022. 4. During an interview on 10/03/2022 at 7:45 PM, the RM confirmed that chemistry analyzer maintenance was not performed and documented with at least the frequency specified by the manufacturer.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification.

	This STANDARD is not met as evidenced by: Note: This is a repeat deficiency. The laboratory was cited during the recertification survey completed on 03/25/2020 for not performing and documenting the Tosoh hemoglobin A1c calibrations with at least the frequency recommended by the manufacturer. The laboratory's allegation of compliance received on 05/01/2020 stated that the calibrations were scheduled to occur weekly on Mondays and the laboratory manager would review the maintenance log on Mondays to ensure the calibrations were performed. Based on review of the manufacturer's operator's manual, the laboratory's standard operating procedure (SOP), monthly maintenance logs, and monthly quality control (QC) logs, and interview with the regional manager (RM), the laboratory failed to ensure that calibrations were performed, documented, and instrument printouts retained with the frequency recommended by the manufacturer for hemoglobin A1c testing. Findings: 1. The laboratory used a Tosoh G8 analyzer to test patient specimens for hemoglobin A1c. 2. The Tosoh "G8 Variant Analysis Mode Operator's Manual", version 3.2, stated that they "recommend calibrating the analyzer once a week" and that the "laboratory may establish a longer calibration interval based on daily QC results." 3. The laboratory SOP titled "HEME v11-307M Tosoh G8 Hemoglobin A1c" stated that hemoglobin A1c "must be calibrated every 7 days" and "Printed or electronic calibration records are stored a minimum of 2 years." 4. The monthly maintenance log included a row titled "Calibrate system. Record on QC log when performed" followed by boxes to check off the days when calibration was performed. 5. The laboratory recorded results of QC each month on the "QC Review Logsheet" and taped the Tosoh G8 instrument printouts containing the QC and calibration results from each month to sheets of paper that were stored behind each month's QC Review Logsheet in a binder. 6. Monthly maintenance and QC Review Logsheets were reviewed from 01/2021 through 01 /2022 for a total of 13 months. 7. There were four of 13 months (01/2021, 02/2021, 03 /2021, and 05/2021) when calibration was documented weekly on the monthly maintenance logs but the printed calibration records were not retained. 8. There were two of 13 months (04/2021 and 12/2021) when calibration was documented for all but one week on the monthly maintenance logs and the printed calibration records were not retained. 9. The monthly maintenance log for 06/2021 was missing and printed calibration records were not retained. 10. The monthly maintenance log for 11/2021 had no calibration documented and the printed calibration records were not retained. 11. The month of 07/2021 had no calibration documented on the monthly maintenance log and no printed calibration records for two of four weeks. 12. There were two of 13 months (10/2021 and 01/2022) that had calibration documented on the monthly maintenance logs for only a single week but retained the printed calibration records for all but a single week. 13. There were two of 13 months (08/2021 and 09 /2021) when the laboratory retained all weekly printed calibration records but did not document the calibrations on the maintenance logs for each week performed. 14. During survey on 10/03/2022 at 7:45 PM, the RM confirmed that the laboratory did not consistently record when weekly calibrations were performed on the maintenance logs and did not retain all printed calibration records as stated in the SOP.
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: I. Based on record review and interview with the technical consultant, the laboratory did not maintain quality control records for routine chemistry. Findings: 1. The laboratory's quality control test results for the month of November 2021 were missing for the second level of control for the following analytes: unsaturated iron-binding capacity (UIBC), C-reactive protein, and direct low density lipoprotein (DLDL) tested on the Architect analyzer; 2. The laboratory's quality control test results for the month of November 2021 were missing for the first level of control for the following analytes: alkaline phosphatase, albumin, alanine transaminase, ammonia, amylase, aspartate aminotransferase, direct bilirubin, total bilirubin, calcium, and cholesterol; and 3. During an interview with the technical consultant on the afternoon of October 3, 2022 concerning the missing quality control records, the technical consultant was not able to provide them. II. Based on record review, the laboratory did not check the negative reactivity of the Clostridium difficile (C. diff) control as required in the laboratory's written procedures. Findings: 1. On April 1, 2022 (nine patient specimens tested) and April 2, 2022 (three patient specimens tested) the laboratory did not have an approved negative control for C. diff to check the negative reactivity of the test and instead used a patient specimen for the negative quality control reagent; and 2. The laboratory did not have written procedures to validate the patient sample for use as a negative control, the written procedure did not have procedures to identify the source and assign an expiration date to the negative patient specimen used as a negative control, and the patient specimen was only identified as "patient neg control" on the testing record. A lot number and expiration date had not been assigned to identify the source of this patient negative control.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the standard operating procedure (SOP) and culture plate sterility check logs and interview with the regional manager (RM), the laboratory failed to document quality control checks of culture plates used for patient testing. Findings: 1. The laboratory inoculated patient specimens onto sheep blood agar / MacConkey agar bi-plates. 2. The SOP titled "Quality Monitoring of Sheep Blood Plate (BAP) - MacConkey Agar Plate (MAC)" gave instructions for observing each new shipment /lot number of plates for defects and performing a sterility check. 3. The SOP stated to complete "the QC Sheep Blood / MacConkey (BAP/MAC) Bi-Plate Sterility Check

	log, for each lot received within the shipment." 4. The sterility check log included columns to record the culture plate lot numbers, expiration dates, media condition, sterility results, testing person's initials, and the supervisor's initials. 5. The laboratory was unable to provide completed sterility check logs for 2021 and 2022. 6. During the survey on 10/03/2022 at 7:45 PM, the RM confirmed that the laboratory did not have completed sterility check logs for 2021 and 2022.
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 review of Clostridium difficile (C. diff) test records, the laboratory reported patient test results when quality control results failed to meet the laboratory's criteria for acceptability and prior to performing corrective actions including retesting of quality control reagents that failed. Findings: 1. On July 7, 2022 at 1402 hours the negative control result for C. diff failed to meet the laboratory's criteria for acceptability, three patients were also tested at 1402 hours, two of the patients were re-tested at 1506 hours after the initial test results were invalid. The laboratory retested the failed negative control at 1633 hours, after patient test results were accepted; 2. On July 12, 2022 at 1622 hours the negative control result for C. diff failed to meet the laboratory's criteria for acceptability, two patients were also tested at 1622 hours and results were reported. The laboratory retested the failed negative control at 1717 hours, after patient test results were accepted; and 3. On July 22, 2022 at 1721 hours the negative control result for C. diff failed to meet the laboratory's criteria for acceptability, eight patients were also tested at 1721 hours and test results reported. The laboratory retested the negative control at 1818 hours, after the patient test results were accepted.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: I. Based on record review, the laboratory did not take corrective actions when chemistry quality control (QC) results did not meet the laboratory's criteria for acceptability. Findings: 1. On November 25 and 27, 2021 the level two QC test result for the analyte iron (tested on the Architect analyzer) was greater than three standard deviations from the mean, and there was no corrective action documented on the "Monthly QC Review"; 2. On November 27, 2021, the level three QC test result for the analyte phenytoin (PHNY) (tested on the Architect analyzer) was greater than

	three standard deviations from the mean value, and there was no corrective action documented on the "Monthly QC Review"; 3. On November 23 and 27, 2021, the level three QC test result for the analyte phenobarbital (PHNO) (tested on the Architect analyzer) was greater than three standard deviations from the mean value, and there was no corrective action documented on the "Monthly QC Review"; 4. On November 23, 24, 25, and 26, 2021 the level one QC test result for the analyte rheumatoid factor (tested on the Architect analyzer) was greater than three standard deviations from the mean, and there was no corrective action documented on the "Monthly QC Review" for these dates; and 5. The "Monthly QC Review" was initialed and dated as reviewed by a staff member, but the reviewer failed to reconcile the daily QC results with the corrective actions documented on the monthly report. The corrective action documented for the failed QC recorded on the review sheet was not complete, did not include the level of the control that failed, and did not include review of the previous control results. There were no troubleshooting actions documented, and the person providing the corrective action was not documented. II. Based on record review, the corrective actions documented for chemistry were incomplete. Findings: 1. The October "Monthly QC Review" log was identified as being reviewed by a staff member December 30, 2021. The report did not include the identity of the individual making corrective actions, the corrective action column was not completed, the name and serial number of the analyzer was not identified, and the year was only identified because the reviewer wrote the complete date on the day of review; and 2. Corrective actions for theophylline patient testing were not documented when results for both the level five and level six quality control reagents fell below 2 standard deviations (SD) on October 28 and 29, 2021 and on October 30, 2021, the level five control was out 2SD and the level six was out 3SD.
D5800	POSTANALYTIC SYSTEMS CFR(s): 493.1290 Each laboratory that performs nonwaived testing must meet the applicable postanalytic systems requirements in 493.1291 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 postanalytic systems and correct identified problems as specified in 493. 1299 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on record review, the laboratory failed to ensure test results are interpreted and reported in an accurate and reliable manner (see D5801 for findings).
D5801	TEST REPORT CFR(s): 493.1291(a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

	This STANDARD is not met as evidenced by: I. Based on record review and interview, the laboratory failed to report bacteriology test results in an accurate and reliable manner. Findings: 1. On July 22, 2022 a patient stool sample was tested for Clostridium difficile (C. diff), the analyzer reported the patient test as indeterminate, but the laboratory reported the test as rejected, even though the specimen was accepted and tested. The procedure for the C. diff test states that indeterminate test results are to be reported as indeterminate; 2. The laboratory inaccurately reported the result as specimen rejected, when it should have been reported as indeterminate; 3. The manufacturer states to report results as either positive, negative, or indeterminate; and 4. The findings were verified during interview with the regional manager at 1:00 PM on October 3, 2022. II. Based on record review, the laboratory reported erythrocyte sedimentation rates (ESR) for patient samples as contaminated even though the source of contamination was not identified. Findings: 1. On December 8, 2021 the results of the ESR for specimens M2868362, M2876999, and M2885071 were identified as possible contamination in the test records, but there was no test report generated; 2. The source of the contamination was not identified; and 3. The laboratory did not ensure that written procedures were available to staff to identify and confirm sources of contamination and to document it in the testing records.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the laboratory director failed to approve validation studies (refer to D6013); failed to ensure an approved corrective action plan was followed for failed proficiency testing results (refer to D6019); failed to ensure that the quality control program was maintained (refer to D6020); and failed to ensure the quality assessment programs were established and maintained (refer to D6021). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by:

	Based on record review, the laboratory director did not review, sign, and date the brain natriuretic peptide validation studies performed October 26, 2020 for simple precision, linearity, and method comparison studies.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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. (e) The laboratory director must-- (e)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory director failed to ensure that an investigation was performed in a timely manner and an approved corrective action plan was implemented when proficiency testing results were found to be unacceptable or unsatisfactory. Cross-refer to tags D2107 and D5221 for findings.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on procedure and record review and interview with the regional manager, the laboratory director (LD) failed to ensure that the quality control program was maintained to assure the quality of laboratory services provided. Findings: 1. The LD did not ensure that the laboratory maintained quality control test records and did not ensure that laboratory approved quality control reagents were used for patient testing (see D5441 cite # I and II for findings); 2. The LD did not ensure that quality and sterility checks were performed and documented for new lot numbers and shipments of blood agar / MacConkey agar bi-plates received into the laboratory for patient testing. Cross-refer to tag D5477 for findings. 3. The LD did not ensure quality control testing identified control failures and retested patient samples after remedial action was performed and quality control results were found to be acceptable (see D5481 for findings)
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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. (e) The laboratory

director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
I. Based on review of the previous recertification survey completed on March 25, 2020 and the previous complaint survey completed on November 12, 2020, the laboratory director (LD) failed to ensure that the allegations of compliance (AOC) were implemented and monitored to assure the quality of laboratory services provided. Findings: 1. The LD failed to ensure that all testing records were retained (cross refer to tags D3031 and D5477 for findings). 2. The LD failed to ensure that specimen transport conditions were continually monitored (cross-refer to tag D5203 for findings). 3. The LD failed to ensure that practices implemented as part of the AOC were written into laboratory policies and procedures (cross-refer to tag D5311 for findings). 4. The LD failed to ensure that calibrations for the Tosoh analyzer were performed with at least the frequency recommended by the manufacturer (cross-refer to tag D5437). II. Based on standard operating procedure manual (SOPM), quality assurance (QA), and proficiency testing (PT) record review and interview with the regional manager (RM), the laboratory director (LD) failed to follow the established QA program to assure the quality of laboratory services provided and to identify failures in quality as they occur. Findings: 1. The procedure, "QUAL v6 - 101.6M Quality Management Plan" "II. Quality Assessment Plan" "A. Select QA Metrics (Annual), Perform Ongoing Assessment" states, "To meet Quality Assessment objectives, key performance indicator quality metrics (KPI) are selected annually and approved by the Laboratory Director, then monitored, reviewed at monthly or quarterly meetings (or other defined increment) and documented in meeting minutes." 2. QA record review from 2020 to 2022 showed that there was a "QM Indicator List" which listed 9 KPI which was "Reviewed and approved" by the LD on 02/26/2020, however there was no documentation that KPI were selected and approved by the LD for 2021 and 2022 as required by the Quality Management Plan. 3. The SOPM states, "After metrics are selected and the mode of data collection defined, the lab manager and supervisors coordinate data collection" and "Data is submitted to the lab manager, who prepares the monthly or quarterly QM report and schedules the QM meeting." QA record review showed that the last available "QM Indicator Report" was from "July-September 2021", was signed by the LD on 12/30/2021, and was missing the documentation used to determine whether the KPI goals were met. The laboratory was unable to provide the "QM Indicator Report" for the 3rd quarter of 2021 and the 1st, 2nd, and 3rd quarters of 2022. 4. The laboratory documented the agenda, attendees, and minutes from the "QM meetings" on the "AHA Maryland Lab Director and Management Site Visit Agenda and Notes" form. These forms were not available after 10/27/2020. 5. The SOPM states, "Data is compiled monthly or quarterly (or other defined increment) and plotted over time against the target to evaluate for shifts or trends." There was no documentation that QA KPI were evaluated for shifts and trends. 6. The LD recorded monthly site visits and documentation reviews on the "AHA Maryland Lab Director Site Visit Log" (LD Log). The LD Log was missing for 2021 and the LD log for 2022 was incomplete. It did not include dates of review and did not include documentation of records used for the review of "QA Indicators Report"; "Incident Reports"; "Proficiency Testing Results"; "Laboratory Competency"; "Phlebotomy Concerns"; and "Instrument Validations Reviewed." 7. The 2022 LD Log documented that the LD reviewed and approved the "QA Indicators Report", but QA record review showed that there were no "QA Indicator Reports" from 2022 available for review. 8. The 2022 LD Log documented that the LD reviewed and approved the "Incident Reports", but QA record review showed that the

	last "Incident Report" was from 06/2019. 9. The 2022 LD Log documented that the LD reviewed and approved the "Proficiency Testing Results", but PT record review showed that PT documents were not retained (cross-refer to tag D3037) and that the laboratory did not ensure that unsatisfactory PT scores were investigated and corrective action taken (cross-refer to tag D5221). 10. The surveyors requested the documents that were reviewed by the LD to complete the LD Log, but the documents were not available for review during the survey. 11. During an interview on 10/03 /2022 at 3:45 PM, the RM stated that there were no other QA documents available for review. The RM also confirmed that LD site visits from 2021 were not documented and the LD did not ensure that quality assessment programs were established and maintained to assure the quality of laboratory services provided. III. Based on record review, the laboratory director did not ensure the quality assurance program identified failures interpreting test results when a specimen for Clostridium difficile tested as indeterminate but was interpreted as contaminated (see D5801 cite I for findings).
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, the laboratory technical consultant failed to ensure quality control checks are performed for microbiology test media (refer to D6042); failed to document staff training (refer to D6045) and failed to document and ensure staff competency to perform patient testing (refer to D6046). The cumulative effect of these systemic problems resulted in the laboratory's inability to ensure the accuracy and reliability of patient test results.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: I. Based on record review, the technical consultant failed to ensure procedures were written, approved, and referenced to use patient specimens as Clostridium difficile quality control reagents and failed to maintain quality control records (see D5441 cites I and II for findings). II. Based on procedure and record review and interview, the technical consultant failed to ensure that quality and sterility checks were performed and documented for new lot numbers and shipments of blood agar / MacConkey agar bi-plates received into the laboratory for patient testing (see D5477 for findings). III. Based on record review, the technical consultant failed to ensure that bacteriology patient testing was performed after corrective actions and quality control results met

	the laboratory's criteria for acceptability (see D5481 for findings). IV. Based on record review, the technical consultant failed to ensure quality control failures were identified and corrective actions taken (see D5783 cite I for findings).
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (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 review of staff training records and interview with the regional manager, the technical consultant failed to ensure that training records were completed for testing staff. Findings: 1. Testing Person #1: a) The trainer did not date and initial the June 2021 AU800 training checklist for 17 training activities observed for Testing Person 1. b) The trainer did not complete page three of the AU800 May 18, 2022 training record. How the competency was determined (observation, record review, etc) was not recorded and the trainer initials were indicated with a "-" mark and not initials. c) The C. difficile assay training record dated June 12, 2021 was not initialed by the trainer. 2. Testing Person #2: a) The trainer did not complete the August 2021 erythrocyte sedimentation rate (ESR) training record. Day 1 and day 2 were not dated and initialed (on the chart) by the trainer, instead a check mark was used for eleven activities. The trainee did not sign that Testing Person 2 completed training. b) The trainer did not complete the August 2021 AU800 checklist for 17 activities observed for both day 1 and day 2, but recorded check marks instead of dating and initialing the activities. The trainee did not date their training next to the signature where indicated and the supervisor did not date and sign that employee was trained where indicated. c) The trainer and dates of observation for day 1 and day 2 were identified on the August 2021 Architect checklist, instead checkmarks were used. 3. Testing Person #3: a) The trainer was not identified on the ESR evaluation b) The signatures of trainee, and supervisor review were not signed. c) The observation dates were not documented, instead checkmarks were used. 4. Testing Person #5: a) CS2500 trainee signatures and dates were not recorded where indicated. b) Instead of observation dates for day 1 and 2, checkmarks were used. c) The supervisor did not date and sign that procedures were reviewed with the trainee.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of staff competency check records and interview with the regional manager, the technical consultant failed to ensure that competency check records were completed when evaluating testing staff. Findings: 1. Testing Person #4: a) The

	technical consultant did not perform a competency check in 2021 2. The trainers and supervisor were not evaluated for their ability to train and complete training and competency records for staff to ensure that their training was complete.