Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0706889	02/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Sml Inc Dba Solis Medical Laboratory	4200 Twelve Oaks Place, Houston, TX	

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	The laboratory was found out of compliance with the CLIA regulations. The condition not met was: D2000 - 42 C.F.R. 493.801 Condition: Enrollment and testing of [proficiency testing] samples; D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; Noted deficiencies and plans of correction were discussed with the laboratory representative at the exit conference. The facility representatives were given an opportunity to provide evidence of compliance with noted deficiencies and no such evidence was provided prior to survey exit.
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on a review of the laboratory's records and staff interview, it was revealed that the laboratory failed to have documentation of being enrolled in an HHS approved proficiency testing program for the analyte Human Chorionic Gonadotropin- Serum in 2022. Findings include: 1. A review of the laboratory's testing records revealed the laboratory performed Human Chorionic Gonadotropin (HCG) testing using patient's serum specimens. 2. A review of the laboratory's records revealed the laboratory failed to provide documentation of enrollment in an HHS approved proficiency testing program for the analyte Human Chorionic Gonadotropin- Serum in 2022. 3. Further review of the laboratory's records revealed the laboratory estimated performing 546

	HGC tests using patient's serum specimens in 2022. 4. An interview with the technical director on 2/1/23 at 2:30 p.m. in the laboratory, after review of the records, confirmed the above findings. Key: HHS= Health and Human Services
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 a review of the laboratory's test records and staff interview, it was revealed that the laboratory failed to have documentation of performing twice annual accuracy assessments in 2022 for two unregulated analytes tested on the Beckman Coulter DxC 700 chemistry analyzer. Findings include: 1. A review of the laboratory's test records revealed the laboratory tested for C- Reactive Protein (CRP) and CRP- high sensitivity on the Beckman Coulter DxC 700 chemistry analyzer. 2. The laboratory was asked to provide documentation of assessing the accuracy, twice annually, for CRP and CRP- high sensitivity. No documentation was provided. 3. Further review of the laboratory's test records revealed the laboratory estimated performing 1,364 CRP tests and 40 CRP- high sensitivity tests in 2022. 4. An interview with the technical director on 2/1/23 at 2:30 p.m. in the laboratory, after review of the records, confirmed that the laboratory overlooked these two tests when re-enrolling for proficiency testing samples in 2022.
D5219	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(2) At least twice annually, the laboratory must verify the accuracy of any test or procedure listed in subpart I of this part for which compatible proficiency testing samples are not offered by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on a review of the laboratory's test menu, the laboratory's records, and staff interview, it was revealed that the laboratory failed to have documentation of verifying the accuracy of one non-regulated toxicology analyte, Levitiracetam, at least twice annually in 2022. Findings include: 1. A review of the laboratory's test menu revealed the following non-regulated toxicology analyte Levitiracetam was tested by the laboratory using the Beckman Coulter DxC 700 chemistry analyzer. 2. A review of the laboratory's records revealed the laboratory failed to have documentation of performing twice annual accuracy assessments for Levitiracetam in 2022. 3. Further review of the laboratory's records revealed the laboratory estimated performing 896 Levitiracetam tests in 2022. 4. An interview with the technical director on 2/1/23 at 2: 30 p.m. in the laboratory, after review of the records, confirmed the above findings.
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 a review of manufacturer's instructions, review of laboratory records, and staff interview, it was revealed the laboratory failed to identify issues with analytic systems. Findings include: 1. The laboratory failed to follow the manufacturer's instructions by ensuring patients run using the Abbott Determine HIV-1/2 Ag/Ab Combo test were greater than twelve years of age. (refer to 5411I) 2. The laboratory failed to follow the manufacturer's instructions by ensuring patient's samples were tested within 30 minutes of collection for the Chem 8+ and CTnI cartridges. (refer to 5411 II) 3. The laboratory failed to follow the manufacturer's instructions for compatible viral transportation mediums for SARS-CoV-2 (COVID) testing on the Quidel Solana instrument. (refer to 5411 III) 4. The laboratory failed to follow the manufacturer's instruction to perform PTT testing within 4 hours on the Siemens CA620 coagulation instrument. (refer to 5411 IV) 5. The laboratory failed to document the revised expiration date on individual Abbott i-STAT cartridges found in the laboratory being stored at room temperature. (refer to D5415) 6. The laboratory failed to have documentation of performing precision studies for 2 test cartridges used on the Abbott i-STAT analyzer. (refer to D5421) 7. The laboratory failed to have documentation of evaluating the calibration verification records for analytes run on the Beckman Coulter DxC 700 chemistry analyzer in December 2022. (refer to D5439) 8. The laboratory failed to establish an IQCP (Individualized Quality Control Plan) to support the modification in quality control testing for two cartridges(CHEM 8+ and CTnI) run on the Abbott i-STAT analyzer. (refer to D5445) 9. The laboratory failed to perform qualitative QC to include a positive and a negative QC on the Quidel Solana instrument. (refer to D5449) 10. The laboratory failed to have documentation to perform at least two levels of control materials each eight hours of operation for Prothrombin time testing on the Siemens CA620 coagulation instrument. (refer to D5545)
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: I. Based on review of the Instructions for Use for the Abbott Determine HIV-1/2 Ag /Ab Combo test, a review of patient test records from January 2022 to January 2023, and staff interview, it was revealed that the laboratory failed to follow the manufacturer's instructions by ensuring that three patients run using the Abbott Determine HIV-1/2 Ag/Ab Combo test were greater than twelve years of age. Findings include: 1. A review of the Instructions for Use for the Abbott Determine HIV-1/2 Ag/Ab Combo test (IN02732530 Rev. 8 2021/06) revealed the following: "Limitations of the Test: This assay has not been evaluated for newborn screening, cord blood specimens, or individuals less than 12 years of age." 2. A review of the laboratory's patient test records from January 2022 to January 2023 revealed the

following 3 patient's samples were run using the Abbott Determine HIV-1/2 Ag/Ab Combo assay: - Patient ID: 2467722 Date of birth: 12/6/11 Test run: 4/1/22 Patient age at time of testing: 10 years, 3 months, 26 days - Patient ID: 2497620 Date of birth: 3/22/11 Test run: 7/22/22 Patient age at time of testing: 11 years, 4 months, 11 days - Patient ID: 2551287 Date of birth: 11/24/13 Test run: 1/18/23 Patient age at time of testing: 9 years, 1 month, 25 days 3. An interview with the technical director on 2/2 /23 at 3:40 p.m. in the office, after review of the records, confirmed the above findings. II. Based on a review of the Procedure Manual for the i-STAT System, the laboratory's test records, and staff interview, it was revealed that the laboratory failed to follow the manufacturer's instructions by ensuring three patient's samples were tested within 30 minutes of collection for the Chem 8+ and CTnI cartridges. Findings include: 1. A review of the Procedure Manual for the i-STAT System (714446-00C, rev date:07/12/04) revealed the following: "For the glucose and other cartridge tests, test sample within 30 minutes of collection." 2. A review of the laboratory's test records revealed the following 3 patient samples were tested greater than 30 minutes from the time of collection using the Chem 8+ or CTnI cartridges: Patient ID: 2555885 Collection date and time: 2/1/23 14:00 Tested on CTnI cartridge at 14:37 Elapsed time: 37 minutes Patient ID: 2551035 Collection date and time: 1/17/23 15:55 Tested on Chem 8 + cartridge at 16:28 Elapsed time: 33 minutes Patient ID: 2551664 Collection date and time: 1/19/23 11:25 Tested on Chem 8 + cartridge at 12:06 Elapsed time: 41 minutes 3. An interview with the technical director on 2/2/23 at 15: 44 p.m. in the office, after review of the records, confirmed the above findings. 44697 III. Based on the direct observation of the surveyor, the manufacture's instructions, and confirmed in an interview found the laboratory failed to follow the manufacturer's instructions for compatible viral transportation mediums for SARS-CoV-2 (COVID) testing on one of one Quidel Solana instrument. The findings were: 1. Review of the manufacturer's instructions titled Quidel Solana SARS-CoV-2 Assay that the laboratory director signed on 7/22/2022 under SPECIMEN COLLECTION, STORAGE, AND HANDLING revealed "Specimens collected in BD/Copan UTM, Remel M4RT, or Quidel QTM are stable at room temperature (RT), 2C to 8C or -70C or below for up to 4 days." 2. Direct observation of the surveyor on 2/1/2023 at 12:00 pm revealed three patients specimens collected in Healthlink UTM-RT, Lot#2204180, Exp. 2023-09-02 for the SARS-CoV-2 testing on one of one Quidel Solana (SN: 21022272). Collected 1/31/2023 Patient#: 1108284 Sample ID: 2555318 Cov-2 RNA RT-HAD Nasopharynx result: Not Detected Collected 1/31/2023 Patient#: 1110229 Sample ID: 2555500 Cov-2 RNA RT-HAD Nasopharynx result: Not Detected Collected 2/1/2023 Patient#: 1110284 Sample ID: 2555762 Cov-2 RNA RT-HAD Nasopharynx result: Not Detected 3. Requested the laboratory to provide validation documentation for Healthlink UTM-RT. No documentation was provided. 4. An interview with the technical supervisor on 2/1/2023 at 1:05 pm in the lab confirmed the above findings. IV. Based on the review of the manufacturer's package insert, the laboratory's patient PTT reports from 12/30/22 to 2/2/2023, and confirmed in an interview found the laboratory failed to follow the manufacturer's instruction to perform PTT testing within 4 hours on one of one Siemens CA620 coagulation instrument. The findings were: 1. Review of the manufacturer's package insert titled Dade Actin FS Activated PTT Reagent (11541731_en Rev, 08-USA only. 2021-06) under Storing the Specimen revealed "Plasma containing unfractionated heparin should be centrifuged within one hour of blood collection, stored at room temperature and tested within 4 hours." 2. Random review of the laboratory's patient PTT test results from 12/30/22 to 2/2/2023 revealed three patient with PTT tesing were performed over 4 hours on Siemens CA620 coagulation instrument (SN: 11145). Patient #:1104343 Collected time: 2/2/2023 at 12:07 am Resulted time: 2/2/2023 at 9: 16 am Elapsed time: 9 hours 9 mins Patient #:1092256 Collected time: 12/30/2022 at

	3:15 pm Resulted time: 12/30/2022 at 7:38 pm Elapsed time: 4 hours 23 mins Patient #:1107738 Collected time: 12/30/2022 at 4:20 am Resulted time: 12/30/2022 at 9:12 am Elapsed time: 4 hours 52 mins 3. An interview with the technical supervisor on 2/2 /2023 at 1:40 pm in the office confirmed the above findings. Key: PTT=Partial thromboplastin time
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 a review of the Procedure Manual for the i-STAT system, surveyor observation of the laboratory, a review of the laboratory's test records, and staff interview, it was revealed that the laboratory failed to document the revised expiration date on 26 of 26 individual Abbott i-STAT cartridges found in the laboratory being stored at room temperature. Findings include: 1. A review of the Procedure Manual for the i-STAT system (714446-00C, revision date: 07/12/04) revealed the following: "Room Temperature Cartridges - Verify that all boxes of cartridges at room temperature have been out of the refrigerator less than two weeks." 2. Surveyor observation of the laboratory on 2/2/23 at 2:55 p.m. revealed the following Abbott i-STAT cartridges on the counter being stored at room temperature: - 9 Chem 8+ cartridges lot: H22281 expiation: 4/6/23 - 9 CTnI cartridges lot: A22226 expiration: 3 /15/23 - 2 EG7+ cartridges lot: N22170 expiration: 2/16/23 - 6 CREA cartridges lot: A22260A expiration: 3/16/23 3. Further review of the 26 cartridges revealed no open date or revised expiration date were documented on the packs, ensuring the cartridges were used within 14 days. 4. A review of the laboratory's test records revealed the laboratory ran 33 i-STAT cartridges (Chem 8+, CREA, and CTnI) from January 6,2023 to the time of the inspection. 5. An interview with the technical director on 2/2 /23 at 3:00 p.m. in the office, after review of the records, confirmed the above findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i) (B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the laboratory's verification records, the laboratory's test records, and staff interview, it was revealed that the laboratory failed to have documentation of performing precision studies for 2 test cartridges used on the Abbott i-STAT analyzer.

	Findings include: 1. A review of the laboratory's verification records for the Abbott i-STAT analyzer (Serial number 350779) revealed verification studies were performed in December 2022. 2. Further review of the i-STAT verification records revealed the laboratory failed to have documentation of a precision study for the following cartridges: - Chem 8+ - CTnI 3. A random review of the laboratory's test records revealed the following patients were run on the i-STAT using either the Chem 8+ or CTnI cartridges and there was no documentation that a precision study was performed: - Patient ID: 2548598 Chem 8+ and CTnI cartridges run on 1/10/23 - Patient ID: 2550325 CTnI cartridge run on 1/16/23 - Patient ID: 2551035 Chem 8+ cartridge run on 1/17/23 - Patient ID: 2552714 Chem 8+ and CTnI cartridges run on 1 /21/23 - Patient ID: 2555712 CTnI cartridge run on 2/1/23 4. An interview with the technical director on 2/2/23 at 3:40 p.m. in the office, after review of the records, confirmed the above findings.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of the laboratory's calibration verification records from 2022, the laboratory's test records, and staff interview, it was revealed that the laboratory failed to have documentation of evaluating the calibration verification records for six of 38 analytes run on the Beckman Coulter DxC 700 chemistry analyzer in December 2022. Findings include: 1. A review of the laboratory's calibration verification records from December 2022 revealed the following 6 analytes were tested on the Beckman Coulter DxC 700 chemistry analyzer: - Iron - Lipase - Magnesium - Ammonia - Triglyceride - Lactate Dehydrogenase 2. Further review of the records revealed the laboratory failed to have documentation of sending the results into Strek for an evaluation to determine if the results from the 6 assays listed above were linear. 3. A review of the laboratory's test records revealed the laboratory estimated performing 6,576 tests (Iron, Lipase, Magnesium, Ammonia, Triglyceride, Lactate Dehydrogenase) on the Beckman

	Coulter DxC 700 chemistry analyzer in 2022. 4. An interview with technical director on 2/2/23 at 10:00 a.m. in the office, after review of the records, confirmed the above findings.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the laboratory's i-STAT Verification Studies, the laboratory's quality control records for the i- STAT from January 2023 to February 2023, the laboratory's test records, and staff interview, it was revealed that the laboratory failed to establish an IQCP (Individualized Quality Control Plan) to support the modification in quality control testing for two cartridges(CHEM 8+ and CTnI) run on the Abbott i-STAT analyzer. Findings include: 1. A review of the laboratory's i-STAT Verification Studies revealed the laboratory started testing the CHEM 8+ and CTnI cartridge on the i-STAT analyzer (Serial number: 350779) on January 6, 2023. 2. A review of the laboratory's quality control records for the CHEM 8+ and CTnI cartridges run on the i-STAT analyzer revealed the laboratory ran 2 levels of control material (levels 1 and 3) on the following dates: - Chem 8+ 1/10/23 - CTnI 1/30/23 3. A review of the laboratory's records revealed there was no documentation of the laboratory developing an IQCP for the CHEM 8+ or CTnI cartridges run on the i-STAT analyzer, modifying the frequency of quality control testing from two levels of quality control material every day of patient testing to two levels of quality control material with every new shipment of test cartridges or every 30 days. 4. A random review of patient test records revealed the following 8 patients were run on the i-STAT when there was no documentation of the laboratory running 2 levels of quality control material each day of patient testing: Patient's initials: PO tested on 1/7/23 using Chem 8+ cartridge Patient's initials: TS tested on 1/13/23 using CTnI cartridge Patient's initials: TD tested on 1/14/23 using CTnI cartridge Patient ID: 2550325 tested on 1/16/23 using CTnI cartridge Patient ID: 2551035 tested on 1/17/23 using Chem 8+ cartridge Patient ID: 2552011 tested on 1/20/23 using Chem 8+ and CTnI cartridges Patient ID: 323234 tested on 1/23/23 using CTnI cartridge Patient ID: 2555712 tested on 2/1/23 using CTnI cartridge 5. An interview with the technical director on 2/2/23 at 2:00 p.m. in the office, after review of the records, confirmed the above findings.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on the review of the laboratory's COVID QC records from August 2022 to January 2023, COVID patient logs, and confirmed in an interview found the laboratory failed to perform qualitative QC to include a positive and a negative QC for 33 of 150 days reviewed for one of one Quidel Solana instrument. The findings were: 1. Review of the laboratory's COVID QC records from August 2022 to January 2023 revealed the following dates did not have documentation of a positive and a negative qualitative QC performed for 33 of 150 days reviewed. 8/09/22 8/10/22 8/11/22 8/17/22 9/02/22 9/08/22 9/09/22 9/15/22 10/31/22 11/17/22 11/26/22 11/27/22 12/04/22 12/11/22 12/13/22 12/17/22 12/18/22 12/24/22 12/25/22 12/29/22 12/31/22 1/01/23 1/07/23 1/12/23 1/13/23 1/15/23 1/18/23 1/21/23 1/22/23 1/24/23 1/26/23 1/28/23 1/29/23 2. Review the patient logs for the dates above revealed 132 patients had COVID testing on Quidel Solana instrument (SN: 21022272). 8/09/22 ID: 2503199U Result: Negative 8/10/22 ID: 2503504U Result: Negative 8/10/22 ID: 2503508U Result: Negative 8/11/22 ID: 2503893U Result: Negative 8/11/22 ID: 2503896U Result: Negative 8/17/22 ID: 2505391U Result: Positive 9/02/22 ID: 2509957U Result: Negative 9/08/22 ID: 2511185U Result: Negative 9/08/22 ID: 2511186U Result: Negative 9/08/22 ID: 2511254U Result: Negative 9/09/22 ID: 2511577U Result: Positive 9/15/22 ID: 2513329U Result: Negative 10/31/22 ID: 2526114BU Result: Negative 10/31/22 ID: 2526118CU Result: Negative 10/31/22 ID: 2526123U Result: Negative 10/31/22 ID: 2526471U Result: Negative 10/31/22 ID: 2526572U Result: Negative 11/17/22 ID: 2532012U Result: Negative 11/17/22 ID: 2532013U Result: Negative 11/17/22 ID: 2532063U Result: Negative 11/26/22 ID: 2534307BU Result: Positive 11/26/22 ID: 2534307CU Result: Negative 11/27/22 ID: 2534405BU Result: Negative 11/27/22 ID: 2534438BU Result: Positive 12/04/22 ID: 2536513U Result: Negative 12/04/22 ID: 2536519U Result: Positive 12/04/22 ID: 2536526U Result: Negative 12/04/22 ID: 2536527U Result: Negative 12/11/22 ID: 2538927BU Result: Negative 12/11/22 ID: 2538964U Result: Negative 12/13/22 ID: 2539664U Result: Negative 12/13/22 ID: 2539722BU Result: Positive 12/13/22 ID: 2539772U Result: Positive 12/13/22 ID: 2539773BU Result: Negative 12/13/22 ID: 2539795U Result: Negative 12/13/22 ID: 2539878U Result: Negative 12/13/22 ID: 2539894U Result: Positive 12/13/22 ID: 2539897U Result: Negative 12/13/22 ID: 2539898U Result: Negative 12/13/22 ID: 2539945U Result: Positive 12/17/22 ID: 2541228U Result: Negative 12/17/22 ID: 2541233U Result: Negative 12/17/22 ID: 2541235U Result: Negative 12/17/22 ID: 2541037U Result: Negative 12/17/22 ID: 2541238U Result: Negative 12/17/22 ID: 2541239U Result: Negative 12/17/22 ID: 2541240U Result: Negative 12/17/22 ID: 2541243U Result: Negative 12/18/22 ID: 2541248U Result: Negative 12/18/22 ID: 2541288U Result: Negative 12/18/22 ID: 2541289U Result: Negative 12/24/22 ID: 2543300U Result: Negative 12/25/22 ID: 2543342BU Result: Negative 12/25/22 ID: 2543344U Result: Negative 12/25/22 ID: 2543345U Result: Negative 12/25/22 ID: 2543346U Result: Positive 12/25/22 ID: 2543347U Result: Positive 12/25/22 ID: 2543348U Result: Negative 12/25/22 ID: 2543378U Result: Negative 12/25/22 ID: 2543386U Result: Positive 12/29/22 ID: 2544584U Result: Negative 12/29/22 ID: 2544585U Result: Negative 12/29/22 ID: 2544628U Result: Negative 12/29/22 ID: 2544630U Result: Negative 12/29/22 ID: 2544633U Result: Negative 12/29/22 ID: 2544647U Result: Negative 12/29/22 ID: 2545368U Result: Negative 12/31/22 ID: 2545369U Result: Negative 1/01/23 ID: 2545482U Result: Positive 1/01/23 ID: 2545483U Result: Negative 1/01/23 ID: 2545484U Result: Positive 1/01/23 ID: 2545512U Result: Negative 1/07/23 ID: 2547502U Result: Negative 1/07/23 ID: 2547535U Result: Negative 1/07/23 ID: 2547536U Result: Negative 1/07/23 ID: 2547538U Result: Negative 1/07/23 ID: 2547564U

	Result: Negative 1/07/23 ID: 2547619U Result: Negative 1/07/23 ID: 2547628U Result: Positive 1/12/23 ID: 2548891U Result: Negative 1/12/23 ID: 2549097U Result: Negative 1/12/23 ID: 2549100U Result: Negative 1/12/23 ID: 2549101U Result: Positive 1/12/23 ID: 2549120U Result: Negative 1/12/23 ID: 2549191U Result: Negative 1/12/23 ID: 2549252U Result: Negative 1/12/23 ID: 2549253U Result: Negative 1/13/23 ID: 2549631U Result: Negative 1/15/23 ID: 2550147U Result: Negative 1/15/23 ID: 2550149U Result: Negative 1/15/23 ID: 2550150U Result: Negative 1/18/23 ID: 2551025U Result: Negative 1/18/23 ID: 2551026U Result: Negative 1/18/23 ID: 2551121U Result: Negative 1/18/23 ID: 2551128BU Result: Negative 1/21/23 ID: 2552020U Result: Negative 1/21/23 ID: 2552022U Result: Negative 1/21/23 ID: 2552044FU Result: Negative 1/21/23 ID: 2552045U Result: Negative 1/21/23 ID: 2552046U Result: Negative 1/21/23 ID: 2552115U Result: Negative 1/22/23 ID: 2552237U Result: Negative 1/22/23 ID: 2552285BU Result: Negative 1/22/23 ID: 2552287U Result: Negative 1/22/23 ID: 2552288U Result: Negative 1/22/23 ID: 2552289U Result: Negative 1/22/23 ID: 2552290U Result: Negative 1/22/23 ID: 2552291U Result: Negative 1/24/23 ID: 2552746U Result: Negative 1/24/23 ID: 2552773U Result: Negative 1/24/23 ID: 2552886U Result: Negative 1/24/23 ID: 2552893U Result: Negative 1/24/23 ID: 2552904U Result: Negative 1/24/23 ID: 2553141U Result: Negative 1/26/23 ID: 2553592U Result: Negative 1/26/23 ID: 2553634U Result: Negative 1/26/23 ID: 2553642U Result: Negative 1/26/23 ID: 2553643U Result: Negative 1/28/23 ID: 2554265U Result: Negative 1/28/23 ID: 2554266U Result: Negative 1/28/23 ID: 2554413BU Result: Negative 1/28/23 ID: 2554435 Result: Negative 1/28/23 ID: 2554443U Result: Negative 1/29/23 ID: 2554568BU Result: Negative 1/29/23 ID: 2554579U Result: Positive 1/29/23 ID: 2554581U Result: Negative 1/29/23 ID: 2554582U Result: Positive 1/29/23 ID: 2554583U Result: Negative 1/29/23 ID: 2554627U Result: Negative 1/29/23 ID: 2554629U Result: Positive 1/29/23 ID: 2554630U Result: Negative 1/29/23 ID: 2554632U Result: Negative 3. An interview with the technical supervisor on 2/1/2023 at 11:00 am in the office confirmed the above findings. Key: QC=Quality Control
D5545	HEMATOLOGY CFR(s): 493.1269(b)(d) (b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on the review of the laboratory's CMS 116 application, Prothrombin time QC records from October 2022 to January 2023, patient records, and confirmed in an interview found the laboratory failed to have documentation to perform at least two levels of control materials each eight hours of operation for Prothrombin time testing on one of one Siemens CA620 coagulation instrument. The findings were: 1. Review of the laboratory's CMS 116 application revealed the laboratory's operation hours were 24 hours, seven days a week, including weekends and holidays. 2. Random review of the laboratory's Prothrombin time QC records from Octrober 2022 to January 2023 revealed 10 of 30 days reviewed did no have docuentation of at least two levels of QC every 8 hours of opearation for Prothrombin time testing. 10/21 /2022 QC tested: 11:10 am QC due: 7:10 pm Next QC run: 10/22/2022 8:26 am Elapsed time from 8 hour QC expiration time: 13 hrs 16 mins 11/3/2022 QC tested: 5:

45 am QC due: 1:45 pm Next QC run: 11/3/2022 4:45 am Elapsed time from 8 hour QC expiration time: 3 hrs 11/16/2022 QC tested: 3:52 am QC due: 11:52 am Next QC run: 11/17/2022 7:15 am Elapsed time from 8 hour QC expiration time: 19 hours 23 mins 11/21/2022 QC tested: 3:04 am QC due: 11:04 am Next QC run: 11/22/2022 11: 07 am Elapsed time from 8 hour QC expiration time: 24 hours 3 mins 11/24/2022 QC tested: 6:24 am QC due: 2:24 pm Next QC run: 11/25/2022 5:20 am Elapsed time from 8 hour QC expiration time: 14 hrs 56 mins 12/1/2022 QC tested: 8:21 am QC due: 4:21 pm Next QC run: 12/1/2022 9:18 pm Elapsed time from 8 hour QC expiration time: 4 hrs 57 mins 12/7/2022 QC tested: 4:52 am QC due: 12:52 pm Next QC run: 12/7/2022 7:22 pm Elapsed time from 8 hour QC expiration time: 7 hours 12 /15/2022 QC tested: 5:15 am QC due: 1:15 pm Next QC run: 12/16/2022 3:47 am Elapsed time from 8 hour QC expiration time: 14 hrs 32 mins 1/13/2023 QC tested: 3: 19 am QC due: 11:19 am Next QC run: 1/13/2023 3:38 pm Elapsed time from 8 hour QC expiration time: 4 hrs 19 mins 1/28/2023 QC tested: 4:48 am QC due: 12:48 pm Next QC run: 1/28/2023 8:19 pm Elapsed time from 8 hour QC expiration time: 7 hrs 31 mins 3. Review the patients records for the above dates revealed 77 patients had prothrombin time testing. 10/21/2022 Patient ID: 2523774 Time run: 9:04 pm QC due: 10/21/2022 7:10 pm 10/21/2022 Patient ID: 2523779 Time run: 9:04 pm QC due: 10/21/2022 7:10 pm 10/21/2022 Patient ID: 2523754 Time run: 11:27 pm QC due: 10 /21/2022 7:10 pm 10/21/2022 Patient ID: 2523773 Time run: 11:28 pm QC due: 10/21 /2022 7:10 pm 11/3/2022 Patient ID: 2527384 Time run: 2:08 pm QC due: 11/3/2022 1:45 pm 11/3/2022 Patient ID: 2527376 Time run: 3:29 pm QC due: 11/3/2022 1:45 pm 11/3/2022 Patient ID: 2527379 Time run: 3:29 pm QC due: 11/3/2022 1:45 pm 11 /3/2022 Patient ID: 2527384 Time run: 3:43 pm QC due: 11/3/2022 1:45 pm 11/3 /2022 Patient ID: 2527377 Time run: 3:44 pm QC due: 11/3/2022 1:45 pm 11/3/2022 Patient ID: 2527630 Time run: 3:47 pm QC due: 11/3/2022 1:45 pm 11/3/2022 Patient ID: 2527632 Time run: 4:07 pm QC due: 11/3/2022 1:45 pm 11/16/2022 Patient ID: 2531464 Time run: 12:00 pm QC due: 11/16/2022 11:52 am 11/16/2022 Patient ID: 2531393 Time run: 12:01 pm QC due: 11/16/2022 11:52 am 11/16/2022 Patient ID: 2531501 Time run: 12:13 pm QC due: 11/16/2022 11:52 am 11/16/2022 Patient ID: 2531563 Time run: 1:41 pm QC due: 11/16/2022 11:52 am 11/16/2022 Patient ID: 2531418 Time run: 2:24 pm QC due: 11/16/2022 11:52 am 11/16/2022 Patient ID: 2531511 Time run: 2:24 pm QC due: 11/16/2022 11:52 am 11/16/2022 Patient ID: 2531395 Time run: 6:22 pm QC due: 11/16/2022 11:52 am 11/16/2022 Patient ID: 2531629 Time run: 6:22 pm QC due: 11/16/2022 11:52 am 11/16/2022 Patient ID: 2531740 Time run: 7:47 pm QC due: 11/16/2022 11:52 am 11/16/2022 Patient ID: 2531725 Time run: 7:50 pm QC due: 11/16/2022 11:52 am 11/16/2022 Patient ID: 2531740 Time run: 8:10 pm QC due: 11/16/2022 11:52 am 11/21/2022 Patient ID: 2532587 Time run: 11:34 am QC due: 11/21/2022 11:04 am 11/21/2022 Patient ID: 2532732 Time run: 12:25 pm QC due: 11/21/2022 11:04 am 11/21/2022 Patient ID: 2532945 Time run: 1:26 pm QC due: 11/21/2022 11:04 am 11/21/2022 Patient ID: 2532763 Time run: 1:41 pm QC due: 11/21/2022 11:04 am 11/21/2022 Patient ID: 2532754 Time run: 1:41 pm QC due: 11/21/2022 11:04 am 11/21/2022 Patient ID: 2532669 Time run: 2:58 pm QC due: 11/21/2022 11:04 am 11/21/2022 Patient ID: 2532730 Time run: 6:56 pm QC due: 11/21/2022 11:04 am 11/21/2022 Patient ID: 2532770 Time run: 6:56 pm QC due: 11/21/2022 11:04 am 11/21/2022 Patient ID: 2532769 Time run: 6:57 pm QC due: 11/21/2022 11:04 am 11/21/2022 Patient ID: 2532750 Time run: 6:57 pm QC due: 11/21/2022 11:04 am 11/21/2022 Patient ID: 2532999 Time run: 6:58 pm QC due: 11/21/2022 11:04 am 11/21/2022 Patient ID: 2532883 Time run: 9:44 pm QC due: 11/21/2022 11:04 am 11/22/2022 Patient ID: 2533177 Time run: 11/22/2022 12:08 am QC due: 11/21/2022 11:04 am 11 /22/2022 Patient ID: 2532799 Time run: 11/22/2022 12:08 am QC due: 11/21/2022 11: 04 am 11/22/2022 Patient ID: 2533198 Time run: 11/22/2022 12:09 am QC due: 11/21

	/2022 11:04 am 11/22/2022 Patient ID: 2533259 Time run: 11/22/2022 1:25 am QC due: 11/21/2022 11:04 am 11/24/2022 Patient ID: 2533961 Time run: 11/24/2022 11: 10 pm QC due: 11/24/2022 2:24 pm 12/1/2022 Patient ID: 2535704 Time run: 12/1 /2022 4:26 pm QC due: 12/1/2022 4:21 pm 12/1/2022 Patient ID: 2535724 Time run: 12/1/2022 4:26 pm QC due: 12/1/2022 4:21 pm 12/1/2022 Patient ID: 2535711 Time run: 12/1/2022 4:27 pm QC due: 12/1/2022 4:21 pm 12/1/2022 Patient ID: 2535714 Time run: 12/1/2022 4:27 pm QC due: 12/1/2022 4:21 pm 12/1/2022 Patient ID: 2535726 Time run: 12/1/2022 4:28 pm QC due: 12/1/2022 4:21 pm 12/1/2022 Patient ID: 2535704 Time run: 12/1/2022 4:40 pm QC due: 12/1/2022 4:21 pm 12/1/2022 Patient ID: 2535724 Time run: 12/1/2022 4:40 pm QC due: 12/1/2022 4:21 pm 12/1 /2022 Patient ID: 2535961 Time run: 12/1/2022 4:56 pm QC due: 12/1/2022 4:21 pm 12/1/2022 Patient ID: 2535960 Time run: 12/1/2022 4:58 pm QC due: 12/1/2022 4:21 pm 12/1/2022 Patient ID: 2535963 Time run: 12/1/2022 5:01 pm QC due: 12/1/2022 4:21 pm 12/1/2022 Patient ID: 2535710 Time run: 12/1/2022 5:46 pm QC due: 12/1 /2022 4:21 pm 12/1/2022 Patient ID: 2536000 Time run: 12/1/2022 5:59 pm QC due: 12/1/2022 4:21 pm 12/1/2022 Patient ID: 2535715 Time run: 12/1/2022 7:25 pm QC due: 12/1/2022 4:21 pm 12/1/2022 Patient ID: 2536029 Time run: 12/1/2022 9:01 pm QC due: 12/1/2022 4:21 pm 12/7/2022 Patient ID: 2537771 Time run: 12/7/2022 1:33 pm QC due: 12/7/2022 12:52 pm 12/7/2022 Patient ID: 2537716 Time run: 12/7/2022 1:42 pm QC due: 12/7/2022 12:52 pm 12/7/2022 Patient ID: 2537716 Time run: 12/7 /2022 1:50 pm QC due: 12/7/2022 12:52 pm 12/7/2022 Patient ID: 2537581 Time run: 12/7/2022 4:37 pm QC due: 12/7/2022 12:52 pm 12/7/2022 Patient ID: 2537841 Time run: 12/7/2022 5:26 pm QC due: 12/7/2022 12:52 pm 12/7/2022 Patient ID: 2537857 Time run: 12/7/2022 5:43 pm QC due: 12/7/2022 12:52 pm 12/15/2022 Patient ID: 2540385 Time run: 12/15/2022 1:56 pm QC due: 12/7/2022 1:15 pm 12/15 /2022 Patient ID: 2540391 Time run: 12/15/2022 1:56 pm QC due: 12/7/2022 1:15 pm 12/15/2022 Patient ID: 2540392 Time run: 12/15/2022 1:57 pm QC due: 12/7 /2022 1:15 pm 12/15/2022 Patient ID: 2540409 Time run: 12/15/2022 1:57 pm QC due: 12/7/2022 1:15 pm 12/15/2022 Patient ID: 2540385 Time run: 12/15/2022 2:07 pm QC due: 12/7/2022 1:15 pm 12/15/2022 Patient ID: 2540409 Time run: 12/15 /2022 2:07 pm QC due: 12/7/2022 1:15 pm 12/15/2022 Patient ID: 2540412 Time run: 12/15/2022 2:40 pm QC due: 12/7/2022 1:15 pm 12/15/2022 Patient ID: 2540411 Time run: 12/15/2022 2:41 pm QC due: 12/7/2022 1:15 pm 12/15/2022 Patient ID: 2540603 Time run: 12/15/2022 3:04 pm QC due: 12/7/2022 1:15 pm 12/15/2022 Patient ID: 2540641 Time run: 12/15/2022 5:20 pm QC due: 12/7/2022 1:15 pm 12/15 /2022 Patient ID: 2540390 Time run: 12/15/2022 5:20 pm QC due: 12/7/2022 1:15 pm 1/13/2023 Patient ID: 2549721 Time run: 1/13/2023 11:58 am QC due: 1/13/2023 11:19 pm 1/13/2023 Patient ID: 2549596 Time run: 1/13/2023 12:08 am QC due: 1/13 /2023 11:19 pm 1/13/2023 Patient ID: 2549591 Time run: 1/13/2023 12:31 am QC due: 1/13/2023 11:19 pm 1/13/2023 Patient ID: 2549807 Time run: 1/13/2023 2:02 pm QC due: 1/13/2023 11:19 pm 1/13/2023 Patient ID: 2549802 Time run: 1/13/2023 2:02 pm QC due: 1/13/2023 11:19 pm 1/13/2023 Patient ID: 2549795 Time run: 1/13 /2023 2:08 pm QC due: 1/13/2023 11:19 pm 1/28/2023 Patient ID: 2554430 Time run: 1/28/2023 1:28 pm QC due: 1/28/2023 12:48 pm 4. An interview with the technical supervisor on 2/2/2023 at 11:32 am in the office confirmed the above findings Key: CMS=Center of Medicare and Medicaid Services QC=Quality Control
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where

	the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on a random review of patient's microbiology test reports from January 2023 and staff interview, it was revealed that the laboratory failed to include the correct address of the testing facility on two of two patient's microbiology test reports reviewed from January 2023. Findings include: 1. A random review of patient's microbiology test reports from January 2023 revealed the laboratory failed to include the correct address of the testing facility on the following 2 patient's test reports: Patient ID: 027913 Wound culture resulted 1/31/23 Patient ID: 06031940 Urine culture resulted 1/31/23 *The above listed patient reports indicated the testing was performed at the address: 7501 Fannin St. Suite 800 Houston, TX 77054. Actual address for the laboratory is 4200 Twelve Oaks Place Houston, TX 77027. 2. An interview with the technical director on 2/2/23 at 3:35 p.m. in the office, after review of the records, confirmed the above findings.
D5807	TEST REPORT CFR(s): 493.1291(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results. This STANDARD is not met as evidenced by: Based on the review of the laboratory's records, patient's final reports, and confirmed in an interview found the laboratory failed to provide the accurate normal reference range for PT for two of two months reviewed on one of one Siemens CA620 coagulation instrument. The findings were: 1. Review of the laboratory's records for new PT reagent, Innovin, lot#564621, expiration date 4/21/2025, the laboratory director signed on 11/29/2022, revealed the new normal reference range for PT was 9.3-11.5. 2. Random review of the patient final reports from December 2022 to January 2023 revealed 2 patients reports with the reference range of 8.4-11.5. Collection Date: 1/25/23 Patient #: 1103365 Prothrombin Time (PT) Result: 10.4 INR Result: 1.06 Collection Date: 1/27/23 Patient #: 1109975 Prothrombin Time (PT) Result: 10.8 INR Result: 1.10 3. An interview with the technical supervisor on 2/2 /2023 at 3:00 pm in the office confirmed the above findings. Key: PT=Prothrombin Time
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's proficiency testing records and staff interview, it was revealed that the laboratory director failed to ensure the laboratory was enrolled in an HHS approved proficiency testing program for the analyte Human Chorionic Gonadotropin in 2022. (Refer to D2000)
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 review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure a quality control program was established and maintained (refer to D5445, D5449, and D5545).
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) 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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on a review of the laboratory's personnel records and staff interview, it was revealed that the laboratory director failed to ensure that testing personnel had documentation of training to perform moderate complexity testing (refer to D6066).
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:

	Based on a review of the laboratory's records and staff interview, it was revealed that the technical consultant failed to ensure a quality control program was established and maintained (refer to D5445, D5449, and D5545).
D6050	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iv) The procedures for evaluation of the competency of the staff must include, but are not limited to direct observation of performance of instrument maintenance and function checks. This STANDARD is not met as evidenced by: Based on a review of the laboratory's competency assessment forms for 2022, the laboratory's personnel records, and staff interview, it was revealed that the technical consultant failed to ensure the competency assessments performed on five of ten testing personnel included the direct observation of instrument maintenance and function checks on the six analyzers used in the laboratory. Findings include: 1. A review of the laboratory's competency assessment forms revealed the technical consultant assessed competency for the following 6 analyzers: - DXC 700 - DXI 800 - Sysmex XS-1000i - Clinitek Advantus - Sysmex CA 620 - Solana 2. Further review of the laboratory's competency assessment forms revealed the technical consultant failed to include the direct observation of instrument maintenance and function checks for the above listed analyzers. 3. A review of the laboratory's personnel records revealed the following testing personnel (as indicated on the CMS 209 form) had competency assessments performed by the technical consultant in 2022 that failed to include the direct observation of instrument maintenance and function checks on the 6 laboratory analyzers: - Testing person #2 assessment performed: 4/21/22 - Testing person #3 assessment performed: 11/21/22 - Testing person #4 assessment performed: 7/21/22 - Testing person #5 assessment performed: 5/20/22 - Testing person #6 assessment performed: 5/20/22 4. An interview with technical director on 2/2/23 at 3:30 p.m. in the office, after review of the records, confirmed the above findings.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of the verification studies for the Beckman Coulter DxH 690 hematology analyzer, the laboratory's personnel files, and staff interview, it was revealed that the technical consultant failed to evaluate and document the performance of five of ten testing personnel following a change in instrumentation in March 2022. Findings include: 1. A review of the laboratory's verification studies revealed the laboratory received a new instrument, a Beckman Coulter DxH 690 hematology analyzer (serial number: BFO3003) in March 2022. 2. A review of the laboratory's personnel files revealed that testing performance for the Beckman Coulter DxH 690 had not been evaluated and documented prior to reporting patient test results for the

	following testing personnel (as indicated on the CMS 209 form): - Testing person #2 - Testing person #3 - Testing person #4 - Testing person #5 - Testing person #6 3. An interview with the technical director on 2/2/23 at 3:30 p.m. in the office, after review of the records, confirmed the above findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted CMS 209 form, review of the laboratory's personnel records, and staff interview, it was revealed that the laboratory failed to have documentation of training prior to performing patient testing for the following: a) four of five testing personnel for COVID testing on the Solana analyzer. b) two of five testing personnel for Complete Blood Count (CBC) testing on the Beckman Coulter DxH 690 hematology analyzer. c) one of five testing personnel for Clostridium difficile (cdiff) testing on the Solana analyzer. d) five of five testing personnel for Chem 8+ and Troponin cartridge testing on the Abbott i-STAT analyzer. Findings include: 1. A review of the laboratory's submitted CMS 209 form revealed the laboratory identified ten testing personnel performing moderate complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of training prior to performing patient testing on the following: a) Covid testing on the Solana analyzer began July 2022 - Missing training for testing personnel #2, #3, #4, #6 b) CBC testing on the Beckman Coulter DxH hematology analyzer began March 2022 - Missing training for testing personnel #5, #6 c) Cdiff testing on the Solana analyzer began April 2022 - Missing training for testing personnel #2 d) Chem 8+ and Troponin cartridge testing on the Abbott i-STAT analyzer began January 2023 - Missing training for testing personnel #2, #3, #4, #5, #6 3. An interview with the technical director on 2/2/23 at 3:00 p.m. in the office, after review of the records, confirmed the above findings.