Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	32D2162365	05/04/2021
Name of Provider or Supplier	**Street Address, City, State**	
Modern Vascular Navajo Albuquerque	7800 Constitution Ave Ne, Albuquerque, NM	
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	During an initial certification survey completed on 05/04/2021 for 42 CFR part 493 Laboratory Requirements, the facility was found out of compliance with the following conditions: 42 CFR Part 493.801 Enrollment and testing of proficiency samples 42 CFR Part 493.1250 Analytic Systems 42 CFR Part 493.1403 Laboratories Performing Moderate Complexity Testing; Laboratory Director 42 CFR Part 493.1409 Laboratories Performing Moderate Complexity Testing; Technical Consultant 42 CFR Part 493.1421 Laboratories Performing Moderate Complexity Testing; Testing Personnel
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 the review of Centers for Medicare and Medicaid Services (CMS) CASPER (Certification and Survey Provider Enhanced Reporting) Report 155 (historical report containing a summary of proficiency test (PT) scores), manufacturer instructions and interview with the Laboratory Manager, the laboratory failed to enroll in proficiency testing for Sodium, Potassium, Chloride, TCO2 (Total Carbon Dioxide), Ionized Calcium, Glucose, Urea Nitrogen, Creatinine, Hematocrit (human electrolytes, metabolites, and coagulaton markers) testing performed using the i-STAT Chem 8+ Abbott Chemistry handheld, in vitro analyzer. The laboratory tested 166 patients from

	May 1, 2020 to April 28, 2021. Findings are: A. Review of the CMS CASPER 155 Report revealed no proficiency testing scores for 2020 and 2021. B. During interview on 4/22/21 at 9:54 am the Laboratory Manager stated the laboratory was not enrolled in proficiency testing. C. Review of the manufacturer's Urgent Product Corrective Action notices APOC2020-001 and APOC2020-001 dated January 2020 revealed the BLUE Chem 8+ cartridges (which replaced the WHITE Chem 8+) did not have FDA (Food & Drug Administration) authorization to be used in laboratories with a Certificate of Waiver or Certificate of Provider Performed Microscopy and informed all users of the test system to transition to alternative waived methods or use a reference laboratory for testing. D. Review of the laboratory's application history (CMS Form 116) revealed: 1. The laboratory applied for and received a Certificate of Waiver on 02/21/2019 for the i-STAT Chem 8+ cartridge, pregnancy tests, and fingerstick glucose testing. 2. On 04/24/2020, the laboratory submitted a request to change to a Certificate of Compliance for the I-STAT Chem 8+ cartridge and Activated Clotting Time but failed to enroll in proficiency testing. E. Review of the CMS document, "Frequently Asked Questions (FAQ), Abbott i-STAT," updated on 04 /29/2020 and available on the CMS website indicated: 1. The Chem 8+ cartridge was classified by the FDA as moderate complexity for arterial (blood found in the lungs, left chambers of the heart and in the arteries) or venous whole blood (blood found in veins, right chambers of the heart and pulmonary artery) as of 02/28/2020. 2. Laboratories need to follow all CLIA regulations that apply to non-waived testing, including enrollment in Proficiency Testing.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on the review of laboratory policies, manufacturer's instructions, CMS (Centers for Medicare & Medicaid) notices, quality control records, and interview with the Laboratory Manager, the laboratory failed to meet the condition for Analytic Systems. The laboratory used the Abbott i-STAT Chemistry, handheld, in vitro analyzer, used the Chem 8+ cartridge, to perform Sodium, Potassium, Chloride, Total Carbon Dioxide, Ionized Calcium, Glucose, Blood Urea Nitrogen, Creatinine, and Hematocrit testing. The laboratory tested 166 patients May 1, 2020 to April 28, 2021. Findings are: A. The laboratory failed to have approved written policies for all aspects of laboratory testing. See D5401 B. The laboratory failed to perform and document verification/validation studies for the Abbott i-STAT Chemistry Analyzer Chem 8+ cartridges. See D5421 C. The laboratory failed to follow the manufacturer's instructions and use heparinized whole blood (Blood in which none of the blood elements have been removed and which has been treated with a blood thinner that prevents the formation of blood clots) for patient testing. See D5411 D. The laboratory failed to maintain documentation of the required semi-annual calibration verification, as per regulatory requirement. See D5439 E. The laboratory failed to perform two levels of controls each day of patient testing, as per regulatory requirement. See D5447 F. The laboratory failed to ensure proper storage of the

	Abbott i-STAT Chem 8+ analyzer, Chem 8+ cartridges, and the quality control reagents as required by the manufacturer. See D5413
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 the review of laboratory policies and interview with the Laboratory Manager, the laboratory failed to have approved written policies for all aspects of laboratory testing. The laboratory used the Abbott i-STAT handheld in vitro analyzer, used Chem 8+ cartridges to perform Sodium, Potassium, Chloride, Total Carbon Dioxide, Ionized Calcium, Glucose, Blood Urea Nitrogen, Creatinine, and Hematocrit testing. The laboratory tested 166 patients May 1, 2020 to April 28, 2021. Findings are: A. During interview on 04/22/2021 at 10:50 am, the Laboratory Manager stated the policies were not sent to the laboratory from their corporate office until 04/21 /2021. She stated that the laboratory did not perform Activated Clotting Times. B. Review of the laboratory policies indicated an effective date of 05/26/2020 but there was no signature indicating the Laboratory Director had reviewed and approved the following policies: 1. i-STAT Kaolin Activated Clotting Time & Applicable Quality Control. 2. i-STAT Chem 8+ Cartridge & Applicable Quality Control. 3. Quality Assessment Plan for Lab draws (i-STAT). 4. Personnel Competency and New Employee Training Policy for i-STAT lab draws.
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: Based on review of manufacturer's Product letter, the Standard Operating Procedure for the Abbott i-STAT Chemistry analyzer, and interview with the Laboratory Manager, the laboratory failed to follow the manufacturer's instructions and use proper sample collection for use with the Abbott i-STAT Chemistry Analyzer, Chem 8+ cartridges used to perform Sodium, Potassium, Chloride, Total Carbon Dioxide, Ionized Calcium, Glucose, Blood Urea Nitrogen, Creatinine, and Hematocrit tests. The laboratory tested 166 patients May 1, 2020 - April 28, 2021. Findings are: A. During interview on 04/22/2021 at 11:00 am, the Laboratory Manager stated the laboratory collected whole blood samples in a plain syringe (no anticoagulant such as heparin added to prevent clotting) for use with the Chem 8+ cartridges. B. Review of the Standard Operating Procedure for i-STAT, effective date 05/26/2020, indicated "Whole blood heparinized green top sample" was required for Chem 8+ tests. This policy had not been reviewed or approved by the Laboratory Director. See D5401 C. Review of the manufacturer's Chem 8+ (BLUE) Product Letter, dated February 2020,

	revealed "Samples must be collected in syringes with balanced heparin or tubes with lithium heparin anticoagulant (a blood thinner that prevents the formation of blood clots). Use of a sample collected without an anticoagulant is not supported."
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 the review of the Standard Operating Procedure for the i-STAT (Policy Clin#101), Abbott i-STAT Reference guide, Procedure manual for the Abbott i-STAT system, interview and follow-up telephone call with the Laboratory Manager, the laboratory failed to ensure proper temperature storage of the i-STAT Chemistry analyzer, its testing cartridges, and components as required by the manufacturer. Findings are: A. During interview with Laboratory Manager on 04/22/21 at 10:30 am, she stated that the temperatures were kept electronically and that she would have to retrieve the data but she didn't know if she was going to be able to because their computer system had become inoperable. B. On 05/3/21 during a follow-up telephone call at 12:25 pm, the surveyor asked for the temperature documentation and the Laboratory Manager stated that she was not able to provide any temperature logs for the facility. C. Review of the Standard Operating Procedure for the i-STAT (Policy Clin#101), Section D, page 11, titled "Reagents/Materials" lists the following temperature requirements; 1. i-STAT Test Cartridges: "Store the cartridges in the manufacturer sealed pouches at 2-8 C (degree Celsius). Do not allow cartridge to freeze. Refrigerated cartridges are stable until the expiration date listed on the cartridge box. Cartridges may be stored at room temperature (18-30C or 64-86F (degree Fahrenheit)) for 14 days." 2. i-STAT Level 1 and Level 3 Liquid Tri Controls (Quality Control Reagents): "Store control vials at 2-8C. Allow control vials to warm to room temperature for a minimum of 30 minutes. Control solutions may be stored at room temperature for up to 5 days at 18-30C or 64-86F. Prolonged storage at temperatures greater than 30 degrees may cause changes in the values of some analytes." D. Review of the Abbott i-STAT Reference guide and the procedure manual, lists the following temperature requirements; 1. i-STAT Test Cartridges: "Store at temperatures between 2-8C (35-46F). Store cartridges at room temperature for the timeframe indicated on the cartridge box. Do not expose to temperatures above 30C (86F)." 2. For new shipments of test cartridges: "Immediately check temperature strip enclosed with each shipment of cartridges. Follow the instructions on the card." The laboratory failed to monitor, document, and provide evidence that the temperature of new cartridge shipments received in the laboratory were being recorded. 3. i-STAT Analyzer: " Storage/Transport temperature: -10 to 46C (14-115F). The handheld's operating temperature range is 16 to 30C (61-86F). Store handhelds near the testing location or in an area close to the temperature of the testing area. Do not store handhelds near equipment that gives off heat or in direct sunlight." 4. i-STAT

	External Electronic Simulator's storage temperature is at room temperature (-20-50C or -4-122F) and requires an "operating ambient Humidity of 0-90% RH (Relative Humidity) non-condensing."
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 review of manufacturer's Urgent Corrective Action notices, CMS (Centers for Medicare & Medicaid) publication, the laboratory's application history, and interview with the Laboratory Manager, the laboratory failed to perform and document validation/verification studies for the Abbott i-STAT Chemistry Analyzer, using the Chem 8+ cartridges to perform Sodium, Potassium, Chloride, Total Carbon Dioxide, Ionized Calcium, Glucose, Blood Urea Nitrogen, Creatinine, and Hematocrit tests. The laboratory tested 166 patients May 1, 2020 - April 28, 2021. Findings are: A. During interview on 04/22/2021 at 9:57 am, the Laboratory Manager stated the laboratory did not perform a validation study after the Chem 8+ cartridge was reclassified from waived to moderate complexity in February 2020. B. Review of the manufacturer's Urgent Product Corrective Action notices APOC2020-001 and APOC2020-002 dated January 2020 revealed the BLUE Chem 8+ cartridges (which replaced the WHITE Chem 8+) did not have FDA (Food & Drug Administration) authorization to be used in laboratories with a Certificate of Waiver or Certificate of Provider Performed Microscopy and informed all users of the test system to transition to alternative waived methods or use a reference laboratory for testing. C. Review of the laboratory's application (CMS 116) history revealed: 1. The laboratory applied for and received a Certificate of Waiver on 02/21/2019 for the i-STAT Chem 8+ cartridge, pregnancy tests, and fingerstick glucose testing. 2. On 04/24/2020, the laboratory submitted a request to change to a Certificate of Compliance for the I-STAT Chem 8+ cartridge. D. Review of the CMS publication, Frequently Asked Questions (FAQ), Abbott i-STAT updated on 04/29/2020 and available on the CMS website indicated: 1. The Chem 8+ cartridge was classified by the FDA as moderate complexity for arterial or venous whole blood as of 02/28/2020. 2. Laboratories need to follow all CLIA regulations that apply to non-waived testing.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by:

	43577 Based on the review of the Standard Operating Procedure for the i-STAT (Policy Clin#101), Procedure manual for i-STAT system, and interview with the Laboratory Manager, the laboratory failed to perform and document the required function checks each day of patient testing, as specified by the manufacturer. Findings are: A. During interview on 04/22/21 at 11:15 am, the Laboratory Manager stated that the External Electronic simulator (Quality Control device specific for the i-STAT analyzer, used to confirm analyzer performance) was not being used to verify the performance of the i-STAT analyzer during each day of patient testing. 1. Laboratory manager was unable to provided documentation of the i-STAT External Electronic Simulator checks. B. Review of the Standard Operating Procedure for the i-STAT (Policy Clin#101), indicated that Quality control is designed to verify performance of the analyzer and of the cartridges. 1. In Section F, page 12, Titled Quality Control indicated that "Quality Control frequency is defined as every day of patient testing using simulator checks." 2. The laboratory failed to perform and record the Internal or External Simulator checks on each day of patient testing as stated in their Standard Operating Procedure. C. Review of the The i-STAT procedure manual provided by Abbott, the manufacturer of the i-STAT analyzer, indicated "Verify the performance of each analyzer in the i-STAT System using the Internal or External Electronic Simulator every 24 hours of use." 1. The laboratory failed to follow the manufacturer instructions related to the use of the Internal or External Electronic Simulators.
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: 43577 Based on the review of the Standard Operating Procedure for the i-STAT (Policy Clin#101), Procedure manual for i-STAT system, i-STAT Technical Bulletin, and interview with the Laboratory manager, the laboratory failed to record/document the performance of the required manufacturer's software upgrade, the twice a year calibration (also known as "CLEW") process, for updating the system software. Findings are: A. During interview with the Laboratory Manager on 04/22/21 at 11:15 am, she stated that they did perform the CLEW updates as needed but did not keep

	any documentation related to the calibration updates. B. Review of the Standard Operating Procedure for the i-STAT (Policy Clin#101), indicated that the laboratory is to perform CLEW software updates; 1. To validate the Calibration Verification /Analytical Measurement ranges. 2. To be performed at six month intervals. 3. To be recorded on the Verification Log Sheet. C. Review of the the i-STAT procedure manual provided by Abbott, the manufacturer of the i-STAT analyzer, indicated that the Update of the Analyzer's software as a procedure to be performed every 6 months. See page 12, Section labeled "Every 6 Months Procedures." D. Review of the Abbott i-STAT Technical Bulletin, revision date of 07-10-2020, titled "Instructions for updating i-STAT handheld software using www.pointofcare.abbott," revealed the importance of the update and the frequency at which it must be completed. 1. The Bulletin states the importance of the update: "Due to the continuous manufacturing process improvements to the i-STAT System, it is necessary to update standardization values from time to time to maintain long-term consistency of performance. These updates are equivalent to manually adjusting calibration on a traditional laboratory analyzer." 2. The Bulletin states the frequency: "New CLEW software - delivered twice a year - re-establishes these standardization values and incorporates refinements to the internal quality monitoring system."
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: 43577 Based on the review of the Standard Operating Procedure for the i-STAT (Policy Clin#101), the Excel patient list attached to email received from Laboratory Manager[Name of] on 05/04/21 at 3:51 pm, and interview, confirmed the laboratory failed to perform and document the two levels of Quality Control each day of patient testing for 158 of 166 (PT#2-PT#20, PT#22-PT#50, PT#52-PT#80, PT#82-PT#96, PT#98-PT#139, PT#143-PT#166) patients tested May 1, 2020 to April 28, 2021. Findings are: A. During interview with Laboratory Manager on 04/22/21 at 9:50 am she stated that the i-STAT Level 1 and Level 3 Liquid Tri Controls (Quality Control Reagents) were run once a month and when receiving a new lot of cartridges but not every time a patient sample was run as as per regulatory requirement. She stated that approximately 8-10 i-STAT tests were performed each month. B. Review of the Standard Operating Procedure for the i-STAT (Policy Clin#101), states that the laboratory verifies each new lot number and new shipment of cartridges using the i-STAT Level 1 and Level 3 Liquid Tri Controls, prior to running patient testing. C. During interview on 04/22/2021 at 10:00 am, the Laboratory Manager stated the laboratory had not developed an Individualized Quality Control Plan (IQCP) to qualify for reduced frequency of performing Quality Control. D. Review of the email received on 05/04/21 at 3:51 pm revealed the total number of patients tested was 166, from May 2020 to April 2021, the timeframe when the laboratory changed their Certificate of Waiver to a Certificate of Compliance. 1. In May 2020, 6 of 7 (PT#2 - PT#7) patients tested did not have the two levels of Quality Controls performed on the day of testing. I-STAT Tri Level Liquid Quality Controls (Level 1-Lot 301119 and Level 3-Lot 321119) were performed on 05/04/2020. 05/04/2020 PT#1 05/11/2020

PT#2 05/12/2020 PT#3 05/18/2020 PT#4 05/26/2020 PT#5 05/27/2020 PT#6 05/28/2020 PT#7 In June 2020, 11 of 11 (PT#8 - PT#18) patients tested did not have the two levels of Quality Controls performed on the day of testing. No i-STAT Tri Level Liquid Quality Controls (Level 1 and Level 3) recorded for the month of June. 06/04/2020 PT#8 06/04/2020 PT#9 06/10/2020 PT#10 06/15/2020 PT#11 06/16/2020 PT#12 06/17/2020 PT#13 06/17/2020 PT#14 06/22/2020 PT#15 06/22/2020 PT#16 06/23/2020 PT#17 06/24/2020 PT#18 In July 2020, 17 of 18 patients (PT#19 - PT#20 and PT#22 - PT#36) tested did not have the two levels of Quality Controls performed on the day of testing. I-STAT Tri Level Liquid Quality Controls (Level 1-Lot 301119 and Level 3-Lot 321119) were performed on 07/02/2020. 07/01/2020 PT#19 07/01/2020 PT#20 07/02/2020 PT#21 07/09/2020 PT#22 07/06/2020 PT#23 07/13/2020 PT#24 07/15/2020 PT#25 07/15/2020 PT#26 07/16/2020 PT#27 07/16/2020 PT#28 07/21/2020 PT#29 07/21/2020 PT#30 07/23/2020 PT#31 07/28/2020 PT#32 07/28/2020 PT#33 07/30/2020 PT#34 07/30/2020 PT#35 07/30/2020 PT#36 In August 2020, 6 of 6 (PT#37 - PT#42) patients tested did not have the two levels of Quality Controls performed on the day of testing. Tri Level Liquid Quality Controls (Level 1-Lot 301119 and Level 3-Lot 321119) were performed on 08/04/2020 and on 08/31/2020 (QC test strip of results manually labeled with a date of 09/01/2020 and recorded in log as the monthly QC for the month of September 2020. 08/05/2020 PT#37 08/11/2020 PT#38 08/13/2020 PT#39 08/17/2020 PT#40 08/19/2020 PT#41 08/24/2020 PT#42 In September 2020, 8 of 8 (PT#43 - PT#50) patients tested did not have the two levels of Quality Controls performed on the day of testing. No i-STAT Tri Level Liquid Quality Controls (Level 1 and Level 3) were run for the month of September 2020. 09/03/2020 PT#43 09/08/2020 PT#44 09/09/2020 PT#45 09/15/2020 PT#46 09/16/2020 PT#47 09/16/2020 PT#48 09/16/2020 PT#49 09/21/2020 PT#50 In October 2020, 2 of 3 patients (PT#52 - PT#53) tested did not have the two levels of Quality Controls performed on the day of testing. I-STAT Tri Level Liquid Quality Controls (Level 1-Lot 301119 and Level 3-Lot 321119) were performed on 10/01/2020. 10/01/2020 PT#51 10/05/2020 PT#52 10/19/2020 PT#53 In November 2020, 10 of 10 (PT#54 - PT#63) patients tested did not have the two levels of Quality Controls performed on the day of testing. I-STAT Tri Level Liquid Quality Controls (Level 1-Lot 301119 and Level 3-Lot 321119) were performed on 11/02/2020. 11/03/2020 PT#54 11/05/2020 PT#55 11/09/2020 PT#56 11/10/2020 PT#57 11/11/2020 PT#58 11/11/2020 PT#59 11/11/2020 PT#60 11/19/2020 PT#61 11/24/2020 PT#62 11/25/2020 PT#63 In December 2020, 17 of 17 (PT#64 - PT#80) patients tested did not have the two levels of Quality Controls performed on the day of testing. I-STAT Tri Level Liquid Quality Controls (Level 1-Lot 301119 and Level 3-Lot 321119) were performed on 12/01/2020. 12/02/2020 PT#64 12/08/2020 PT#65 12/09/2020 PT#66 12/14/2020 PT#67 12/15/2020 PT#68 12/17/2020 PT#69 12/21/2020 PT#70 12/21/2020 PT#71 12/21/2020 PT#72 12/22/2020 PT#73 12/22/2020 PT#74 12/28/2020 PT#75 12/28/2020 PT#76 12/29/2020 PT#77 12/29/2020 PT#78 12/29/2020 PT#79 12/31/2020 PT#80 In January 2021, 15 of 16 (PT#82 - PT#96) patients tested did not have the two levels of Quality Controls performed on the day of testing. I-STAT Tri Level Liquid Controls (Level 1-Lot 301128 and Level 3-Lot 321128) were performed on 01/04/2021. 01/04/2021 PT#81 01/06/2021 PT#82 01/11/2021 PT#83 01/12/2021 PT#84 01/12/2021 PT#85 01/13/2021 PT#86 01/13/2021 PT#87 01/14/2021 PT#88 01/14/2021 PT#89 01/18/2021 PT#90 01/19/2021 PT#91 01/20/2021 PT#92 01/20/2021 PT#93 01/21/2021 PT#94 01/25/2021 PT#95 01/28/2021 PT#96 In February 2021, 19 of 20 (PT#98 - PT#116) patients tested did not have the two levels of Quality Controls performed on the day of testing. I-STAT Tri Level Liquid Controls (Level 1-Lot 301128 and Level 3-Lot 321128) were performed on 02/01/2021. 02/01/2021 PT#97 02/02/2021 PT#98 02/02/2021 PT#99 02/03/2021 PT#100 02/04/2020 PT#101 02/08/2021 PT#102 02/09/2021 PT#103 02/09/2021 PT#104 02/10/2021 PT#105 02/11

	/2021 PT#106 02/17/2021 PT#107 02/17/2021 PT#108 02/17/2021 PT#109 02/17 /2021 PT#110 02/18/2021 PT#111 02/22/2021 PT#112 02/23/2021 PT#113 02/23 /2021 PT#114 02/24/2021 PT#115 02/25/2021 PT#116 In March 2021, 23 of 23 (PT#117 - PT#139) patients tested did not have the two levels of Quality Controls performed on the day of testing. I-STAT Tri Level Liquid Controls (Level 1-Lot 301128 and Level 3-Lot 321128) were performed on 03/01/2021. 03/02/2021 PT#117 03/02/2021 PT#118 03/03/2021 PT#119 03/03/2021 PT#120 03/04/2021 PT#121 03 /08/2021 PT#122 03/09/2021 PT#123 03/09/2021 PT#124 03/10/2021 PT#125 03/11 /2021 PT#126 03/11/2021 PT#127 03/11/2021 PT#128 03/15/2021 PT#129 03/16 /2021 PT#130 03/17/2021 PT#131 03/18/2021 PT#132 03/22/2021 PT#133 03/23 /2021 PT#134 03/24/2021 PT#135 03/29/2021 PT#136 03/30/2021 PT#137 03/31 /2021 PT#138 03/31/2021 PT#139 In April 2021, 24 of 27 (PT#143 - PT#166) patients tested did not have the two levels of Quality Controls performed on the day of testing. I-STAT Tri Level Liquid Controls (Level 1-Lot 301128 and Level 3-Lot 321128) were performed on 04/01/2021. 04/01/2021 PT#140 04/01/2021 PT#141 04 /01/2021 PT#142 04/05/2021 PT#143 04/05/2021 PT#144 04/05/2021 PT#145 04/07 /2021 PT#146 04/07/2021 PT#147 04/08/2021 PT#148 04/08/2021 PT#149 04/08 /2021 PT#150 04/08/2021 PT#151 04/13/2021 PT#152 04/13/2021 PT#153 04/13 /2021 PT#154 04/14/2021 PT#155 04/14/2021 PT#156 04/14/2021 PT#157 04/15 /2021 PT#158 04/20/2021 PT#159 04/20/2021 PT#160 04/21/2021 PT#161 04/21 /2021 PT#162 04/27/2021 PT#163 04/27/2021 PT#164 04/28/2021 PT#165 04/28 /2021 PT#166 .
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 the review of the CMS (Centers for Medicare & Medicaid Services) Personnel Report Form 209, laboratory policies, personnel records, manufacturer's Urgent Product Corrective Action notices, and interview with the Laboratory Manager, the Laboratory Director failed to provide overall management and direction of the laboratory. Findings are: A. The Laboratory Director failed to ensure the laboratory employed a qualified Technical Consultant to provide the technical oversight of the laboratory. See D6004 B. The Laboratory Director failed to ensure validation studies were performed and documented for the Abbott i-STAT Chemistry Analyzer Chem 8+ cartridges. See D6013 C. The Laboratory Director failed to ensure laboratory personnel were following manufacturer's instructions for the Abbott i-STAT Chemistry Analyzer Chem 8+ cartridges. See D6014 D. The Laboratory Director failed to ensure the laboratory had documentation of training and competency for 4 Testing Personnel (TP #1 - TP#4) of 4 (TP#1 - TP#4) testing personnel. See D6029 E. The Laboratory Director failed to ensure the laboratory established and followed approved policies for evaluating competency of Testing Personnel. See D6030 F. The Laboratory Director failed to ensure the laboratory had approved policies/procedures prior to 04/21/2021. See D6031 G. The Laboratory Director failed to ensure the all testing personnel had the education or experience to perform moderate complexity testing. See D6028
D6004	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based review of the CMS (Centers for Medicare & Medicaid Services) Personnel Report Form 209, and interview with the Laboratory Manager, the Laboratory Director failed to ensure the laboratory employed a qualified Technical Consultant to provide the technical oversight of the laboratory. Findings are: A. Review of the CMS Personnel Report Form 209 signed by the Laboratory Director on 04/21/2021 revealed no one designated as the laboratory's Technical Consultant. B. During interview on 04 /22/2021 at 9:45 am, the Laboratory Manager stated that she was unaware of the function of the Technical Consultant and confirmed the Laboratory Director did not perform the responsibilities of the Technical Consultant. She further stated she used the i-STAT at her previous job but was not responsible for the technical oversight. C. The Laboratory Director was not available for interview during the survey.
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 interview with the Laboratory Manager, the laboratory failed to perform and document validation studies for the Abbott i-STAT Chemistry Analyzer Chem 8+ cartridges to perform: Sodium, Potassium, Chloride, Total Carbon Dioxide, Ionized Calcium, Glucose, Blood Urea Nitrogen, Creatinine, and Hematocrit. The laboratory tested 166 patients May 1, 2020 - April 28, 2021. Findings are: A. During interview on 04/22/2021 at 9:57 am, the Laboratory Manager stated the laboratory did not perform a validation study for the i-STAT Chemistry Analyzer. See D5421 B. The Laboratory Director was not available for interview during the survey.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) 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)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions/notices, and interview with the Laboratory Manager, the Laboratory Director failed to ensure laboratory personnel were following manufacturer's instructions for the Abbott i-STAT Chemistry Analyzer Chem 8+ cartridges used to perform Sodium, Potassium, Chloride, Total Carbon Dioxide, Ionized Calcium, Glucose, Blood Urea Nitrogen, Creatinine, and Hematocrit tests. The laboratory tested 166 patients May 1, 2020 - April 28, 2021. Findings are: A. During interview on 04/22/2021 at 11:00 am, the Laboratory Manager stated the laboratory collected whole blood samples in a plain syringe (no anticoagulant such as heparin added to prevent clotting) for use with the Chem 8+ cartridges. B. Review of the manufacturer's Chem 8+ (BLUE) Product Letter, dated February 2020, revealed "Samples must be collected in syringes with balanced heparin or tubes with lithium heparin anticoagulant. Use of a sample collected without an anticoagulant is not supported." See D5411
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 review of Centers for Medicare and Medicaid Services(CMS) CASPER (Certification and Survey Provider Enhanced Reporting) Report 155 (historical summary of proficiency testing (PT) scores), and interview with the General Supervisor, the Laboratory Director failed to ensure the laboratory was enrolled in Proficiency Testing for Sodium, Potassium, Chloride, Total Carbon Dioxide, Ionized Calcium, Glucose, Urea Nitrogen, Creatinine, Hematocrit. The laboratory tested 166 patients May 1, 2020 - April 28, 2021. Findings are: The laboratory failed to enroll in proficiency testing for Sodium, Potassium, Chloride, TCO2, Ionized Calcium, Glucose, Urea Nitrogen, Creatinine, Hematocrit tests using the i-STAT Chem 8+ Abbott Analyzer. See 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 the review of the Standard Operating Procedure for the i-STAT (Policy Clin#101), patient records, email from the Laboratory Manager dated 05/04/2021 at 3:51 pm, and interview with the Laboratory Manager, the Laboratory Director failed to ensure an approved, written quality control program was established and followed for testing using the i-STAT chemistry analyzer. Findings are: A. The laboratory failed to perform and document the two levels of Quality Control each day of patient testing for 158 of 166 patients tested from May 1, 2020 to April 28, 2021. See D5447 B. The laboratory failed to have an approved, written quality control policy. See D5401 C. Review of patient records provided via email on 05/04/2021 at 3:51 pm revealed the laboratory tested 166 patients May 1, 2020 - April 28, 2021.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) 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)(10) Employ a sufficient number of laboratory personnel with the appropriate education and either experience or training to provide appropriate consultation, properly supervise and accurately perform tests and report test results in accordance with the personnel responsibilities described in this subpart; This STANDARD is not met as evidenced by: Based on the review of personnel records and interview with the Laboratory Manager, the Laboratory Director failed to ensure the all testing personnel had the education or experience to perform moderate complexity testing. Findings are: The laboratory failed to have documentation of the highest level of education for 1 Testing Person (TP #3) of 4 (TP #1 - TP #4) testing personnel. See D6064
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 the review of laboratory policies and interview with the Laboratory Manager, the Laboratory Director failed to ensure the laboratory had documentation of training and competency for 4 (TP #1 - TP #4) of 4 (TP #1 - TP #4) testing personnel. Findings are: A. During interview on 04/22/2021 from 9:47 am to 10:29 am, the Laboratory Manager stated: 1. The laboratory training and competency

	policies were sent to the laboratory on 04/21/2021 by the corporate office; 2. Competencies of the Testing Personnel were not performed; 3. Training is provided to Testing Personnel on the first day of hire but is not documented. B. Review of the training and competency policies received by the laboratory on 04/21/2021 revealed: 1. The policies were created 04/02/2020. 2. There was no documentation the Laboratory Director had reviewed and approved the policies.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) 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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on the review of laboratory policies and interview with the Laboratory Manager, the Laboratory Director failed to ensure the laboratory established and followed approved policies for evaluating competency of Testing Personnel. Findings are: A. During interview on 04/22/2021 from 9:47 am to 10:29 am, the Laboratory Manager stated: 1. The laboratory's competency policies were sent to the laboratory on 04/21/2021 by the corporate office; 2. Competencies of the Testing Personnel were not performed. B. Review of the competency policies received by the laboratory on 04 /21/2021 revealed: 1. The policies were created 04/02/2020. 2. There was no documentation the Laboratory Director had reviewed and approved the policies.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on the review of laboratory policies and interview with the Laboratory Manager, the Laboratory Director failed to ensure the laboratory had approved policies /procedures prior to 04/21/2021. The laboratory used the Abbott i-STAT Chemistry Analyzer Chem 8+ cartridges to perform: Sodium, Potassium, Chloride, Total Carbon Dioxide, Ionized Calcium, Glucose, Blood Urea Nitrogen, Creatinine, and Hematocrit. Findings are: The laboratory did not have approved written policies for all aspects of laboratory testing using the i-STAT analyzer. See D5401

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 the review of the CMS (Centers for Medicare & Medicaid Services) Personnel Report Form 209, CMS CASPER Report 155 (historical summary of proficiency test [PT] scores), Standard Operating Procedure for the i-STAT (Policy Clin#101), patient records, email from the Laboratory Manager dated 05/04/2021 at 3: 51 pm, manufacturer's instructions/notices, and interview with the Laboratory Manager, the laboratory failed to have a qualified Technical Consultant that could provide technical oversight of the laboratory. Findings are: A. The laboratory failed to employ a qualified Technical Consultant to provide the technical oversight of the laboratory. See D6034 B. The Technical Consultant failed to ensure validation studies were performed for the Chem 8+ cartridge. See D6040 C. The Technical Consultant failed to ensure the laboratory was enrolled in Proficiency Testing for Sodium, Potassium, Chloride, Total Carbon Dioxide, Ionized Calcium, Glucose, Urea Nitrogen, Creatinine, and Hematocrit. See D6041 D. The Technical Consultant failed to establish and follow a written quality control program for testing using the i-STAT chemistry analyzer. See D6042 E. The Technical Consultant failed to perform and document competency evaluations for 4 of 4 Testing Personnel within the first six months after the transition to non-waived laboratory testing. See D6046
D6034	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411 The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section. This STANDARD is not met as evidenced by: Based on the review of the CMS (Centers for Medicare & Medicaid Services) Personnel Report Form 209 and interview with the Laboratory Manager, the laboratory failed to employ a qualified Technical Consultant to provide the technical oversight of the laboratory. Findings are: A. Review of the CMS Personnel Report Form 209 signed by the Laboratory Director on 04/21/2021 revealed no one was designated as the laboratory's Technical Consultant. B. During interview on 04/22 /2021 at 9:45 am, the Laboratory Manager stated that she was unaware of the function of the Technical Consultant and confirmed the Laboratory Director did not perform the responsibilities of the Technical Consultant. She further stated she used the i-STAT at her previous job but was not responsible for the technical oversight.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2)

	The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on interview with the Laboratory Manager, the Technical Consultant failed to ensure validation/verification studies were performed for the Chem 8+ cartridge. The laboratory tested 166 patients from May 1, 2020 - April 28, 2021. Findings are: During interview on 04/22/2021 at 9:57 am, the Laboratory Manager stated the laboratory did not perform a validation study after the Chem 8+ cartridge was reclassified from waived to moderate complexity in February 2020. See D5421
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b) The technical consultant is responsible for-- (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on review of Centers for Medicare and Medicaid Services(CMS), CASPER (Certification and Survey Provider Enhanced Reporting) Report 155 (historical summary of proficiency testing [PT] scores), and interview with the Laboratory Manager, the Technical Consultant failed to ensure the laboratory was enrolled in Proficiency Testing for Sodium, Potassium, Chloride, Total Carbon Dioxide, Ionized Calcium, Glucose, Urea Nitrogen, Creatinine, Hematocrit. The laboratory tested 166 patients from May 1, 2020 - April 28, 2021. Findings are: The laboratory failed to enroll in proficiency testing for Sodium, Potassium, Chloride, Total Carbon Dioxide, Ionized Calcium, Glucose, Urea Nitrogen, Creatinine, Hematocrit tests using the i-STAT Chem* Abbott Analyzer. See D2000
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 the review of the Standard Operating Procedure for the i-STAT (Policy Clin#101), patient records, email from the Laboratory Manager dated 05/04/2021 at 3: 51 pm, and interview with the Laboratory Manager, the Technical Consultant failed to establish and follow a written quality control program for testing using the i-STAT chemistry analyzer. Findings are: A. The laboratory failed to perform and document the two levels of Quality Control each day of patient testing for 158 of 166 patients tested from May 1, 2020 to April 28, 2021. See D5447 B. The laboratory failed to

	have an approved, written quality control policy. See D5401 C. Review of patient records provided via email on 05/04/2021 at 3:51 pm revealed the laboratory tested 166 patients from May 1, 2020 - April 28, 2021.
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 personnel records, the laboratory's application history and interview with the Laboratory Manager, the Technical Consultant failed to perform and document competency evaluations for 4 (TP#1 - TP#4) of 4 (TP#1 - TP#4) Testing Personnel within the first six months of testing. Findings are: A. Review of the laboratory's application (CMS 116) history revealed: 1. The laboratory applied for and received a Certificate of Waiver on 02/21/2019 for the i-STAT Chem 8+ cartridge, pregnancy tests, and fingerstick glucose testing. 2. On 04/24/2020, the laboratory submitted a request to change to a Certificate of Compliance for the I-STAT Chem 8+ cartridge. B. Review of the personnel records for TP#1 - TP#4 revealed no documentation of competency evaluations since the certificate type was changed on 04/24/2020. C.. During interview on 04/22/2021 at 9:57 am, the Laboratory Manager stated no competency evaluations were performed.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on the review of personnel records and interview with the Laboratory Manager, the laboratory failed to meet the Condtion for Testing Personnel. Findings are: The laboratory failed to have documentation of the highest level of education for 1 (TP #3) of 4 (TP #1 - TP #4) testing personnel. See D6064
D6064	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(a) Each individual performing moderte complexity testing must possess a current license issued by the State in which the laboratory is located, if such licensing is required. This STANDARD is not met as evidenced by: Based on the review of personnel records and interview with the Laboratory Manager, the laboratory failed to have documentation of the highest level of education for 1 (TP #3) of 4 (TP #1 - TP #4) testing personnel. Findings are: A. Review of personnel

	records revealed no documentation of the highest level of education for TP #3. B. During interview on 04/22/2021 at 10:29 am, the Laboratory Manager confirmed this finding.