Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2113612	09/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Eminent Medical Center, Llc	1351 West President George Bush Hwy, Richardson, 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	Noted deficiencies and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiency, and no such evidence was provided prior to survey exit. Based upon the onsite survey conducted 09/24/2018-09/26/2018, this facility was found NOT to be in compliance with the CLIA regulations found at 42 CFR 493.1250 Analytic Systems 493.1421 Testing personnel, (moderate complexity) 493.1441 Laboratory Director, (high complexity) 493.1487 Testing Personnel (high complexity) The laboratory's failure to be in compliance with these regulations was found to pose IMMEDIATE JEOPARDY to the patients served by the laboratory. NOTE: The laboratory was asked to cease glucose testing using the Accu-ChekBlood Glucose Monitoring System on patients without a known history of diabetes. The laboratory voluntarily ceased glucose testing on patients without a history of diabetes. See letter dated 09/26/2018 and signed by the laboratory director. The laboratory was asked to cease testing using the ACL Elite coagulation analyzer until all verification studies have been completed. The laboratory voluntarily ceased coagulation testing and will evaluated the possibility of using a different testing device. See letter dated 09/26/2018 and signed by the laboratory director.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Alere iCup DX Drug Screen Cup, review of patient test records, and staff interview, it was revealed the

	laboratory failed to follow the manufacturer's instructions for reporting out preliminary positive results. The findings were: 1. A review of the manufacturer's instructions for the Alere iCup DX Drug Screen Cup (422141-IC-W, Revision 1, August 2010) under the section titled "Reading the Results" revealed: "Preliminary Positive: Important: No colored line next to the test region (1, 2, or T) indicates a preliminary positive result for that drug. Clinical consideration and professional judgment should be applied to any drug of abuse result, particularly when preliminary positive results are indicated. Understanding the Results: A preliminary positive test result does no always mean a person took illegal drugs. What is meant by a Preliminary Positive Result? The iCup DX Drug Screen Cup is considered a 'screening test'. It is the first step in a two-step process. Screening tests are not as accurate as laboratory tests, and it is possible to get a preliminary positive result when the person did not take drugs. 2. A review of patient test results from January 2018 to August 2018 revealed the laboratory reported out 'positive' results for 4 of 4 patients with preliminary positive results: Date ID Drug 01/29 657 Opiates 03/01 1114 THC 07 /17 1116 THC 08/06 1025 THC 3. The laboratory was asked to provide documentation of reporting out the results as 'preliminary positive' as required by the manufacturer. No documentation was provided. 4. An interview with the laboratory director on 09/25/2018 at 1000 hours in the laboratory revealed the facility reported out 'positive' results without performing additional confirmatory testing. She stated she was unaware the results were to be reported as 'preliminary positive'. This confirmed the findings. KEY THC - tetrahydrocannabinol 39812 Based on review of the Accu-Chek Performa Test Strip manufacturer's instructions, laboratory records, and confirmed in interview, it was revealed the laboratory failed to document room temperature and humidity for the areas where Accu-Chek Performa test strips were in-use according to manufacturer's requirements for storage. Findings included: 1. The Accu-Chek Performa Test Strip manufacturer's instructions (07299761004-0316) stated, "Use the test strips at temperatures between 61-95?F (16-35?C). Use the test strips between 10-80% relative humidity." 2. Review of laboratory records revealed the following Accu-Chek Performa devices were in use and test strips were stored in these areas of the facility: a. Serial Number 55012536047; In-use in the Pre-Operative (Pre-Op) area b. Serial Number 55012544246; In-use in the Emergency Department area c. Serial Number 55012544333; In-use in the Post Surgery Unit (PSU) area 3. In an interview on 09/26/2018 at 1013 hours in the breakroom, the laboratory director was asked to provide documentation of daily temperature and humidity reading for each of the areas where Accu-Chek Performa test strips were stored. No documentation was provided. This confirmed the above findings.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's chemistry proficiency testing records from 2017, and staff interview, it was revealed the laboratory failed to have documentation of the laboratory director signing 2 of 3 attestation statements. The findings were: 1. A review of the laboratory's American Proficiency Institute's chemistry proficiency testing records from 2017 (Core Chemistry events 1, 2, and 3) revealed the laboratory failed to have documentation of

	the laboratory director signing 2 of 3 attestation statements. They were: 2017 Core Chemistry Event 2 2017 Core Chemistry Event 3 2. The laboratory was asked to provide documentation of the laboratory director signing the identified attestation statements. No documentation was provided. 3. An interview with the laboratory director on 09/24/2018 at 1311 hours in the doctor's lounge - after her review of the records- confirmed the findings.
D3033	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)(i) In addition, the laboratory must retain records of test system performance specifications that the laboratory establishes or verifies under 493.1253 for the period of time the laboratory uses the test system but no less than 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's verifications studies performed on the Alere Triage Cardiac Test in October 2016, and staff interview, it was revealed the laboratory failed to retain instrument printouts for testing performed as part of the studies. The findings were: 1. A review of the laboratory's verification studies performed on the Alere Triage Cardiac Test in October 2016 revealed the laboratory failed to retain the instrument printouts for accuracy, precision, and linearity for the analyte of Troponin. Troponin was the only analyte evaluated. 2. The laboratory was asked to provide documentation of the instrument printouts. No documentation was provided. 3 An interview with the laboratory director on 09/25/2018 at 1530 hours in the doctor's lounge revealed the laboratory was unable to locate the instrument printouts. This confirmed the findings.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of performing competency assessments for 1 of 1 clinical consultants and 2 of 2 technical consultants. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 09/13 /2018) revealed the laboratory identified 1 clinical consultant and 2 technical consultants. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of performing competency assessments for each of the consultants. 3. The laboratory was asked to provide documentation of performing the required competency assessments. No documentation was provided. 4. An interview with the laboratory director on 09/25/2018 at 1300 hours in the doctor's lounge revealed competency assessments had not been performed. This confirmed the findings.
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 review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for urine microscopic testing in 2017. The findings were: 1. A review of the laboratory's records revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for urine microscopic testing in 2017. 2. The laboratory was asked to provide documentation of being enrolled in proficiency testing or having some other method to assess the accuracy of urine microscopic testing. No documentation was provided. 3. An interview with the laboratory director on 09/24/2018 at 1030 hours in the doctor's lounge revealed the laboratory did not perform twice annual accuracy assessments for urine microscopic testing in 2017. This confirmed the 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 review of laboratory records, and staff interview, it was revealed the laboratory failed to provide overall quality in analytic systems. The findings were: 1. The laboratory failed to ensure procedures were approved by the current laboratory director (refer to D5407). 2. The laboratory failed to follow the manufacturer's instructions for studies to be performed on the Sysmex XP-300 hematology analyzer and the Beckman ACL coagulation analyzer (refer to D5411). 3. The laboratory failed to ensure reagents did not exceed stability (refer to D5417). 4. The laboratory failed to ensure verification studies were complete (refer to D5421). 5. The laboratory failed to have documentation of performing establishment studies for its modifiction of the Accu-Chek Performa Blood Glucose Monitoring system (refer to D5423). 6. The laboratory failed to have documentation of performing calibration verifications on the Alere Epoc Blood Gas System (refer to D5439). 7. The laboratory failed to have documentation of monitoring quality control values over time for Troponin and Blood Gas testing (refer to D5441). 8. The laboratory failed to have documentation of complete Individualized Quality Control Plans (refer to D5445).
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS Form 116, review of the laboratory's procedures, and staff interview, it was revealed current laboratory procedures were not approved by the new laboratory director. The findings were: 1. A review of the laboratory's CMS Form 116 revealed the laboratory acquired a new laboratory director effective 11/01/2017. 2. A random review of the laboratory's procedures revealed the current laboratory director did not document approval of the procedures. The following are a random sampling of laboratory procedures all signed on 11/11 /2016 by the previous laboratory director: a. Procedure Title: Prothrombin Time b. Procedure Title: INR Calculation c. Procedure Title: Activated Partial Thromboplastin Time d. Procedure Title: Instrument Maintenance 3. An interview with the current laboratory director on 09/24/2018 at 1310 hours in the doctor's lounge confirmed the above findings.
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 the manufacturer's instructions for the Sysmex XP-300 hematology analyzer, review of the laboratory's verification studies, and staff interview, it was revealed the laboratory failed to follow the manufacturer's instructions for the type of samples to use as part of its verification studies. The findings were: 1. A review of the manufacturer's instructions "Resource and Validation Manual: Sysmex XP-300 Hematology Analyzer (document number: 1050-LSS, Rev. 1, July 2013)" under the section titled "Sample Selection" revealed: "The CLSI Method Comparison and Bias Estimation Using Patient Samples, (EPA09-A2-IR) , suggests at least 40 specimens, 20 normal and 20 abnormal. The abnormal samples should challenge the reportable range for each parameter as well as contain a wide array of abnormal flags." 2. A review of the laboratory's verification studies performed on the Sysmex XP-300 hematology analyzer (serial number A9430) performed in October 2016 revealed the laboratory failed to include 20 abnormal samples as part of its comparison studies as required by the manufacturer. 3. The laboratory was asked to provide documentation of including 20 abnormal samples. No documentation was provided. 4. An interview with the laboratory director on 09/24 /2018 at 1330 hours in the doctor's lounge - after her review of the records- confirmed the findings. 39812 A. Based on review of Beckman ACL Elite coagulation analyzer manufacturer's instructions, reference interval study for PT (prothrombin time) and staff interview, the laboratory failed to follow manufacturer's instructions for establishing the reference interval (patient normal range) for PT reagent (RecombiPlasTin 2G) upon installation of the ACL Elite analyzer. Findings included: 1. The laboratory's procedure manual did not include a procedure for establishing a reference interval of PT upon installation of the ACL Elite analyzer. 2. Review of records for Beckman ACL Elite coagulation analyzer revealed it was installed 10 /2016. The current MNPT (mean normal prothrombin time) was based on the PT reagent, RecombiPlasTin 2G, Lot #N0361728 with 30 George King plasma samples (Batch Number 792, 15 females and 15 males). 3. Further review of records for Beckman ACL Elite coagulation analyzer revealed the current MNPT (mean normal

prothrombin time) was also based on the PT reagent, RecombiPlasTin 2G, Lot #N0361728 with 21 individuals (13 Female; 5 Male; 3 of unknown gender). The following is a list of questions on the "Laboratory Normal Patient Questionnaire": Date of Birth Sex Male or Female 1. Do you consider yourself to be healthy? 2. Do you exercise regularly? If yes, how often? 3. What is the degree of activity? 0 1 2 3 4 5 6 7 8 9 10 4. Do you eat a special diet? If yes, please describe: 5. Have you been sick recently? If yes, when? Please describe illness: 6. Are you currently taking any prescribed medication? If yes, what? 7. Do you have any exposure to hazardous chemicals? 8. Do you use tobacco? If yes, what form? How often? 9. Do your drink alcoholic beverages? If yes, what form? How often? 10. Have you been hospitalized recently? If yes, why? When? 11. Are there any inherited health disorders in your family? If yes, describe. 12. Have you taken any ASPIRIN or other pain relievers recently? If yes, what? When? 13. Are you taking any blood-thinning (Plavix, Coumadin, etc) medications? If yes, what? When? 14. Are you taking diet pills? For Women Specifically: 15. Are you currently menstruating? If yes, when was your last period? If NO, are you on hormone replacement therapy? 16. Are you breast feeding? 17. Are you pregnant? If yes, what is your due date? 18. Are you using ORAL or IMPLANT contraceptives? NOTE: This form references CLSI document C28-A3C. 4. Review of the questionnaires completed by the 21 individuals revealed the following 11 of 21 subjects who should NOT have been accepted for the study: a. Patient N1; no documentation of completed questionnaire b. Patient N3; Answered yes to taking birth control (question #6) c. Patient N4; Answered yes to taking prescribed medicines but did not specify what (question #8) Answered yes to taking aspirin (question #12); Answered yes to taking blood-thinning medication (question #13) d. Patient N6; Answered yes to taking Aspirin (question #12) e. Patient N8; Answered yes to taking Aspirin (question #12) f. Patient N10; ONLY answered yes to taking Aspirin (question #12); All other questions not answered. g. Patient N11; Answered yes to taking Aspirin (question #12) h. Patient N16; Did not answer any questions i. Patient N19; Answered yes to taking Aspirin (question #12) j. Patient N20; Answered yes to taking Aspirin (question #12) k. Patient N21; Answered yes to taking ORAL or IMPLANT contraceptives (question #18) 5. The laboratory did not establish the mean of the normal patient range with the 120 normal individuals as required by the manufacturer which refers to a CLSI document (C28-A3). The laboratory did not include donors from their own population with documentation for ensuring individuals were normal and did not include an even distribution of females /males. 6. During an interview on 09/24/2018 at 1100 hours in the doctor's lounge, the laboratory director confirmed the laboratory did not establish a normal patient range with 120 individuals. B. Based on review of manufacturer's instructions, the laboratory's Hemastasis Performance Verification Manual, and staff interview, the laboratory failed to follow manufacturer's instructions for calculation of the mean normal Prothrombin Time reference interval on the Beckman ACL Elite coagulation analyzer for 2 of 2 crossover studies. Findings included: 1. The manufacturer's instructions for RecombiPlasTin 2G under the section titled "Composition" stated, "Enter the ISI value from the insert and establish the mean of the PT Normal Range with each new lot." 2. The laboratory's Hemostasis Performance Verification Manual in the section titled "Establishing a Reference Interval" stated, "Reference Interval should be established whenever there is a change in the lot number of reagent ... reference intervals should be established over several days, at different times of day, including such variables as age of reagent, different vials of reagent, different operators ....the number of samples used can vary (120 or 20 normal donors)." 3. A review of the facility roll-over studies revealed the facility did not establish a new mean normal PT for any new RecombiPlasTin 2G reagent lot numbers since the initial validation in 10/2016 (Lot number N0361728). The following lot numbers have been

	utilized since 10/2016: Lot number N0177148; Expiration 01/31/2019 Lot number N0184979; Expiration 01/31/2020 4. The laboratory was asked to provide documentation of performing a mean normal PT study on a minimum of 20 normal samples using the new lot of reagent. No documentation was provided. 5. In an interview on 09/24/2018 at 1330 hours in the doctor's lounge, the laboratory director was asked what is the procedure for new lot roll over for RecombiPlasTin 2G reagent. The laboratory director stated, "I run quality control material with the new lot and compare to the old lot." The laboratory director was asked if 20 normal samples are tested to establish a new mean normal PT. The laboratory director stated, "No". This confirmed the above findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on surveyor observation, review of manufacturer's instructions, interview with manufacturer technical service and staff interview, the laboratory failed to ensure that RecombiPlasTin 2G and SynthAsil reagents used on the Beckman ACL Elite Coagulation analyzer had not exceeded the on-board expiration date. Findings included: 1. A tour of the laboratory on 09/25/2018 at 1000 hours revealed a Beckman ACL Elite coagulation analyzer (Serial Number 16051888). The following reagents were observed on-board the instrument: a. RecombiPlasTin 2G; Lot number N0184979, expiration date 01/2020; open date 09/07/2018; new expiration date 10/07 /2018; Position on-board analyzer R1 b. SynthAsil; Lot number N0185006, expiration date 02/2020; open date 09/05/2018; new expiration date 10/05/2018; Position on-board analyzer R2 (Note: ACL Elite analyzer tests the analytes: Prothrombin Time - PT and Activated Partial Thromboplastin Time - APTT) 2. The manufacturer's instructions for RecombiPlasTin 2G (Revision 11/2014) stated the following under the section titled "Reagent storage and stability: "Unopened reagents are stable until the expiration date shown on the vial, when stored at 2-8?C Stability after reconstitution: Please note revised on-board stability 10 days at 2-8?C, 5 days at 15-25?C in the original vial, 4 days on the ACL Elite" 3. The manufacturer's instructions for SynthAsil (Revision 11/2014) stated the following under the section titled "Reagent storage and stability": "Unopened reagents are stable until the expiration date shown on the vial, when stored at 2-8?C APTT reagent: Opened reagent is stable for 30 days at 2-8?C in the original vial, 3 days at 15?C on the ACL system" 4. Review of the operator's manual for the Beckman ACL Elite coagulation analyzer (Rev 1 April 2010) in the section titled "Section 1.4.4 Reagent Area" stated the following: "Positions R1 to R4 and R9 to R12: 10-16?C Positions R5 to R8 are room temperature" 5. During an interview with the laboratory director on 09/25/2018 at 1015 hours in the laboratory, the laboratory director explained that after the reagents were opened, they were stored in the refrigerator, then placed on board the instrument for quality control and patient testing, and then placed back into the refrigerator to extend the expiration date. 6. In a phone interview with the manufacturer of the RecombiPlasTin 2G and SynthAsil reagent (Instrumentation Laboratory), the technical service representative stated, "We stand by the package insert. There are no guidelines for putting reagents in the refrigerator, then on-board the instrument, and then back in the refrigerator." 7. The laboratory began coagulation testing in October

	2016. The coagulation test annual volume for 2018 was 21 patients. 8. The laboratory was asked to provide documentation of studies for the RecombiPlasTin 2G and SynthAsil that ensure the reagents remain stable for a month with the change of temperature from refrigerator to on-board the instrument and back to the refrigerator. No documentation was provided. The laboratory was also asked to provide documentation of dates when the reagents were opened and loaded on board the instrument. No documentation was provided. This confirms 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 review of the laboratory's verification studies, review of patient normal ranges, and staff interview, it was revealed the laboratory failed to have documentation of complete studies for the Sysmex XP-300 hematology analyzer, the Alere Epoc Blood Gas analyzer, and the Alere Triage Cardiac analyzer. The findings were: 1. A review of the laboratory's verifications studies performed on the Sysmex XP-300 hematology analyzer (serial number A9430) in October 2016 revealed the laboratory failed to have documentation of verifying patient reference ranges. 2. A review of patient hematology test results revealed the laboratory utilized the following reference ranges for all patients regardless of age or sex: WBC 3.0 - 15.0 RBC 2.5 - 5.50 HGB 8.0 - 17.0 HCT 26.0 - 50.0 MCV 86.0 - 110.0 MCH 26.0 - 38.0 MCHC 31.0 - 37.0 PLT 50 - 400 LYM% 5.0 -55.0 MXD% 1.0 -20.0 NEUT% 45.0 - 95.0 RDW-SD 37.0 - 54.0 RDW-CV 11.0 - 16.0 MPV 9.0 - 13.0 3. A review of the laboratory's verification studies performed on the Alere Epoc Blood Gas analyzer in October 2016 revealed the laboratory failed to have documentation of verifying patient reference ranges. 4. A review of patient blood gas test results revealed the laboratory utilized the following reference ranges: a) arterial pH 7.35 - 7.45 pCO2 35 - 48 pO2 83 - 108 Na+ 138 - 146 K+ 3.5 - 4.5 Ca+ 4.6 - 5.3 Cl- 98 - 107 Glucose 74 - 100 Lactate 0.56 - 1.39 Creatinine 0.51 - 1.19 Hemoglobin 12 - 17 Hematocrit 38 - 51 b) venous pH 7.32 - 7.43 pCO2 42 - 51 pO2 83 - 108 Na+ 138 - 146 K+ 3.5 - 4.5 Ca+ 4.6 - 5.3 Cl- 98 - 107 Glucose 74 - 100 Lactate 0.56 - 1.39 Creatinine 0.51 - 1.19 Hemoglobin 12 - 17 Hematocrit 38 - 51 4. A review of the laboratory's verification studies performed on the Alere Triage Cardiac Test in October 2016 revealed the study summary stated the studies were performed at a different facility. The identified second facility was across the parking lot from the facility being inspected. The study documents failed to have any way to identify that the study was indeed performed at the correct facility. 5. The laboratory was asked to provide documentation to address each of the issues identified in its studies. No documentation was provided. 6. An interview with the laboratory director on 09/25/2018 at 1530 hours in the doctor's lounge - after her review of the records - confirmed the findings. Key WBC white blood cell RBC red blood cell HGB hemoglobin HCT hematocrit MCV mean corpuscular volume MCH mean corpuscular hemoglobin MCHC mean corpuscular hemoglobin concentration PLT platelet LYM% percent lymphocytes MXD% percent

	mixed cells NEUT% percent neutrophils MPV mean platelet volume pCO2 partial pressure of CO2 pO2 partial pressure of O2 Na+ sodium K+ potassium Ca+ calcium Cl- chloride
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Accu-Chek Performa Blood Glucose Monitoring System, random review of patient history and test records from 06/2017, 07/2017, 08/2018 and 09/05/2018, review of laboratory records and staff interview, it was revealed the laboratory failed to have documentation of performing establishment studies for a laboratory-modified test system. Findings included: 1. The manufacturer's instructions (05959594004-0416) for the Accu-Chek Performa Blood Glucose Monitoring System stated "The Accu-Chek Performa Blood Glucose Monitoring System should not be used for the diagnosis of or screening for diabetes." 2. A random review of patient history and testing records from 06/2017, 07/2017, 08/2018 and 09/05/2018 revealed the laboratory used the Accu-Chek Performa Blood Glucose Monitoring System for glucose testing on the following patient who did NOT have a history of diabetes: a. Date: 06/12/2017; Patient#305; Glucose=105 b. Date: 07/12/2017; Patient#296; Glucose=113 c. Date: 08/10/2018; Patient#602; Glucose=130 d. Date: 09/05/2018; Patient#1319; Glucose=150 e. Date: 09/05/2018; Patient#1292; Glucose=80 3. Since the laboratory had modified the instrument system approved by the Food and Drug Administration (FDA) as waived, the test system becomes high complexity and the test system performance specifications for sensitivity, specificity, accuracy, and precision could be affected. Establishment studies must be performed by the laboratory. 4. Review of laboratory records revealed the laboratory failed to have documentation of performance specifications for sensitivity, specificity, accuracy, and precision for the Accu-Chek Performa Blood Glucose Monitoring System. 5. During an interview on 09/26/2018 at 1030 hours in the facility breakroom, the laboratory director was asked to provide documentation of performing establishment studies for the Accu-Chek Performa Blood Glucose Monitoring System. No documentation was provided. This 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 review of the manufacturer's instructions for the Alere Epoc blood gas analyzer, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing calibration verification every six months from November 2016 to August 2018. The findings were: 1. A review of the manufacturer's instructions for the Alere Epoc blood gas analyzer (510000636 Rev:09) under the section titled "9.3.1 Calibration Verification" revealed: "Follow Calibration Verification procedure to verify accuracy of Test Results over extended measurement range of a Test. Performance of this procedure at defined intervals may be required by regulatory or accreditation bodies." 2. A review of the laboratory's record revealed the facility utilized two calibrators and two levels of controls for daily operation of the Alere Epoc blood gas analyzer, thus calibration verification was required every two months. 3. The laboratory was asked to provide documentation of calibration verification being performed from November 2016 (installation) to August 2018 (the time of the inspection). No documentation was provided. 4. An interview with the laboratory director on 09/26/2018 at 1100 hours in the doctor's lounge revealed the laboratory had never performed calibration verification as required. This confirmed the findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records, and staff interview it was

	revealed the facility failed to have documentation of monitoring quality control values over time to detect shifts and trends for Troponin testing performed on the Alere Triage Cardiac Test and for Blood gas testing on the Alere Epoc blood gas analyzer. The findings were: 1. A review of the laboratory's quality control records from January 2017 to July 2018 revealed the laboratory failed to have documentation of monitoring quality control values over time to detect shifts and trends of the following tests: Alere Triage Troponin Alere Epoc Blood Gas 2. The laboratory was asked to provide documentation of monitoring the control values over time. No documentation was provided. 3. An interview with the laboratory director on 09/26/2018 at 1230 hours in the laboratory revealed the facility did not have a mechanism in place to monitor quality control values over time for the identified tests. This confirmed the 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 review of the laboratory's Individualized Quality Control Plans for the Alere Triage Cardiac Test and the Alere Epoc Blood Gas analyzer, and staff interview, revealed the laboratory failed to have documentation of performing complete plans. The findings were: 1. A review of the laboratory's Individual Quality Control Plans for the Alere Triage Cardiac Test and the Alere Epoc Blood Gas Analyzer revealed both of the plans failed to have documentation of the following: a) Risk Assessment b) Quality Control plan c) Quality Assurance plan d) Laboratory director approval 2. Review of the laboratory's quality control records revealed the laboratory modified the frequency of quality control testing for each test from each day of patient testing to every 30 days. 3. The laboratory was asked to provide documentation of the missing components of the Individualized Quality control plans. No documentation was provided. 4. An interview with the laboratory director on 09/26/2018 at 1015 hours in the laboratory revealed she did not know where the completed Individualized Quality Control Plans were or if they had been performed. This confirmed the findings.
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 review of a sampling of coagulation test results from November 2016 to August 2018, and staff interview, it was revealed the laboratory failed to provide the address of the facility on 15 of 15 test reports. The findings were: 1. A review of a sampling of coagulation test results from November 2016 to August 2018 revealed 15 of 15 reports failed to have the address's of the performing laboratory on them. They were: Date ID 11/21/16 23 11/22/16 27 02/10/17 115 03/12/17 165 03/27/17 none provided 03/30/17 206 06/23/17 325 07/28/17 350 11/20/17 546 12/18/17 566 03/27 /18 751 04/02/18 751 04/03/18 751 06/19/18 1020 08/28/18 1270 2. The laboratory was asked to provide documentation of providing the address on the test report. No documentation was provided. 3. An interview with the laboratory director on 09/26 /2018 at 0930 hours in the laboratory - after her review of the records - confirmed the 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 review of a sampling of patient troponin test reports from March 2018 to August 2018, and staff interview, it was revealed the laboratory provided two different normal values on each report for troponin testing on 9 of 9 reports. The findings were: 1. A review of a sampling of patient troponin test reports from March 2018 to July 2018 revealed the laboratory provided two different normal ranges on 9 of 9 patient reports. The laboratory attached the instrument printout to a report form. The instrument printout had a defined normal range of 0.00 - 0.05. The report form had a different normal range of 0.00 - 0.40. The reports were: Date ID 03/01/18 709 03 /03/18 715 05/30/18 791 07/17/18 1116 07/20/18 1138 07/23/18 1143 2. An interview with the laboratory director on 09/26/2018 at 0930 hours in the laboratory revealed the correct normal range for Troponin was 0.00 - 0.05. She stated she was not aware of, or why, the different normal range of 0.00 - 0.40 was also on the report. This confirmed the findings.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

	This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS 209, review of personnel records, and staff interview, it was revealed the laboratory director failed to have documentation of specifying the duties of each of the laboratory's clinical and technical consultants. The findings were: 1. A review of the laboratory's submitted Form CMS 209 (signed by the laboratory director on 09/13/2018) revealed the laboratory identified 1 clinical consultant and 2 technical consultants. 2. A review of the laboratory's personnel records revealed the laboratory director failed to have documentation of specifying the duties of each of the consultants. 3. The laboratory was asked to provide documentation of the consultants duties as defined by the laboratory director. No documentation was provided. 4. An interview with the laboratory director on 09/24/2018 at 1300 hours in the doctor's lounge confirmed the duties were not written.
D6053	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 at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records, the laboratory's training records for Siemens EPOC blood analysis system and Alere Triage Meter Pro blood analysis system, and staff interview, it was revealed the technical consultant failed to performed competency assessments twice within the first year on 36 of 40 testing personnel performing testing for at least a year. The findings were: 1. A review of the laboratory's personnel records and the laboratory's training records for Siemens EPOC blood analysis system and Alere Triage Meter Pro blood analysis system revealed the technical consultant failed to perform competency assessments twice within the first year of testing for 36 of 40 testing personnel. They were (as listed on Form CMS 209): a. Testing personnel #5 b. Testing personnel #6 c. Testing personnel #7 d. Testing personnel #8 e. Testing personnel #9 f. Testing personnel #10 g. Testing personnel #11 h. Testing personnel #12 i. Testing personnel #13 j. Testing personnel #14 k. Testing personnel #15 l. Testing personnel #16 m. Testing personnel #17 n. Testing personnel #18 o. Testing personnel #19 p. Testing personnel #20 q. Testing personnel #21 r. Testing personnel #22 s. Testing personnel #23 t. Testing personnel #24 u. Testing personnel #25 v. Testing personnel #26 w. Testing personnel #27 x. Testing personnel #28 y. Testing personnel #29 z. Testing personnel #30 aa. Testing personnel #31 bb. Testing personnel #32 cc. Testing personnel #33 dd. Testing personnel #34 ee. Testing personnel #35 ff. Testing personnel #36 gg. Testing personnel #37 hh. Testing personnel #38 ii. Testing personnel #39 jj. Testing personnel #40 2. The laboratory was asked to provide documentation of a semi-annual and annual competency for each testing person performed within the first year of testing. No documentation was provided. 3. An interview with the laboratory director on 09/26/2018 at 1030 hours in the breakroom revealed she had not performed a semi-annual or annual competency on the testing personnel.
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 review of the CMS-209 form and personnel records, the laboratory failed to have documentation that 36 of 40 testing persons met the qualifications required to perform moderate complexity testing. (Refer to D6065)
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on review of the CMS-209 form and personnel records, the laboratory failed to have documentation that 36 of 40 testing persons met the qualifications required to perform moderate complexity testing. Findings included: 1. Review of the CMS-209 form included Testing Person #1 through Testing Person #40 listed to perform testing on the Siemens EPOC blood analysis system and the Alere Triage Meter Pro blood analysis system. 2. Review of personnel records revealed the laboratory did not have documentation to ensure the following testing persons were qualified to perform moderate complexity testing: a. Testing person #5; No education documents provided b. Testing person #6; No education documents provided c. Testing person #7; No education documents provided d. Testing person #8; Records did not include an evaluation of education to determine equivalent foreign to United States education e. Testing person #9; No education documents provided f. Testing person #10; No education documents provided g. Testing person #11; No education documents provided h. Testing person #12; No education documents provided i. Testing person #13; No education documents provided j. Testing person #14; No education documents provided k. Testing person #16; No education documents provided l. Testing person #17; No education documents provided m. Testing person #19; No education documents provided n. Testing person #20; No education documents provided o. Testing person #22; No education documents provided p. Testing person #23; No education documents provided q. Testing person #24; No education documents provided r. Testing person #25; No education documents provided s. Testing person #26; No education documents provided t. Testing person #27; No education documents provided u. Testing person #28; No education documents provided v. Testing person #31; No education documents provided w. Testing person #32; No education documents provided x. Testing person #33; No education documents provided y. Testing person #35; No education documents provided z.

	Testing person #36; No education documents provided aa. Testing person #37; No education documents provided bb. Testing person #38; No education documents provided cc. Testing person #39; No education documents provided dd. Testing person #40; No education documents provided 3. The above findings were confirmed by the laboratory director in an interview on 09/26/2018 at 1030 hours in the breakroom.
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 training records for Alere Triage Meter Pro blood analysis system and staff interview, it was revealed the laboratory failed to ensure that 7 of 40 testing personnel had documentation of training prior to performing testing. The findings were: 1. Based on review of the laboratory's training records for the Alere Triage Meter Pro it was revealed the laboratory failed to have documentation of the training for 7 of 40 testing personnel. They were (as listed on Form CMS 209): Testing personnel #5 Testing personnel #9 Testing personnel #12 Testing personnel #19 Testing personnel #24 Testing personnel #34 Testing personnel #36 Testing personnel #38 2. An interview with the laboratory director on 09/26/2018 at 1030 hours in the breakroom confirmed the findings.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's modified Accu-Chek Performa blood glucose monitoring test system, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory director failed to have documentation to qualify as a laboratory director overseeing high complexity testing (refer to D6078) and failed to provide oversight for high complexity testing (refer to D6086).
D6078	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1443 The laboratory director must be qualified to manage and direct the laboratory personnel and performance of high complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and (b) The laboratory director must-- (b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess

	qualifications that are equivalent to those required for such certification; or (b)(2) Be a doctor of medicine, a doctor of osteopathy or doctor of podiatric medicine licensed to practice medicine, osteopathy or podiatry in the State in which the laboratory is located; and (b)(2)(i) Have at least one year of laboratory training during medical residency (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or (b)(2)(ii) Have at least 2 years of experience directing or supervising high complexity testing; or (b)(3) Hold an earned doctoral degree in a chemical, physical, biological or clinical laboratory science from an accredited institution and-- (b)(3)(i) Be certified and continue to be certified by a board approved by HHS; or (b)(3)(ii) Before February 24, 2003, must have served or be serving as director of a laboratory performing high complexity testing and must have at least-- (b)(3)(ii)(A) Two years of laboratory training or experience, or both; and (b)(3)(ii)(B) Two years of laboratory experience directing or supervising high complexity testing. (b)(4) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under regulations at 42 CFR 493.1415, published March 14, 1990 at 55 FR 9538, on or before February 28, 1992; or (b)(5) On or before February 28, 1992, be qualified under State law to direct a laboratory in the State in which the laboratory is located; or (b)(6) For the subspecialty of oral pathology, be certified by the American Board of Oral Pathology, American Board of Pathology, the American Osteopathic Board of Pathology, or possess qualifications that are equivalent to those required for certification. This STANDARD is not met as evidenced by: Based on review of the laboratory's blood glucose monitoring system, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory director failed to have documentation to qualify as a laboratory director overseeing high complexity testing. The findings were: 1. A review of the laboratory's glucose monitoring system revealed the laboratory had modified an FDA-approved test by utilizing the Accu-Chek Performa Glucose Monitoring system to test patients with no history of diabetes. 2. A review of the laboratory's personnel records revealed the laboratory director was NOT a licensed physician in the state of Texas or a PhD in chemical, physical, biological, or clinical laboratory science. 3. In interview on 09/26 /2018 at 1030 hours in facility breakroom, the laboratory director confirmed the above findings.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that 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 review of the manufacturer's instructions for the Accu-Chek Performa Glucose Monitoring system, review of patient test records from 12/2017 through 08 /2018, and staff interview, it was revealed the laboratory director failed to ensure establishment studies were performed prior to testing patient samples for a laboratory-modified test system (refer to D5423).
D6168	TESTING PERSONNEL

	CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the CMS-209 form and personnel records, it was revealed the laboratory failed to have documentation that 36 of 40 testing persons met the qualifications required to perform high complexity testing. (Refer to D6171)
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent

	stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of the CMS-209 form, review of the laboratory's Accu-Chek Performa Blood Glucose Monitoring System, and review of the laboratory's personnel records revealed the laboratory failed to have documentation that 36 of 40 testing persons met the qualifications required to perform high complexity testing. Findings included: 1. Review of the CMS-209 form included Testing Person #1 through Testing Person #40 listed to perform testing on the Accu-Chek Performa blood glucose monitoring system. 2. A review of the laboratory's glucose monitoring system revealed the laboratory had modified an FDA-approved test by utilizing the Accu-Chek Performa Blood Glucose Monitoring system to test patients with no history of diabetes. 3. Review of personnel records revealed the laboratory did not have documentation to ensure the following testing persons were qualified to perform high complexity testing: a. Testing person #5; No education documents provided b. Testing person #6; No education documents provided c. Testing person #7; No education documents provided d. Testing person #8; Records did not include an evaluation of education to determine equivalent foreign to United States education e. Testing person #9; No education documents provided f. Testing person #10; No education documents provided g. Testing person #11; No education documents provided h. Testing person #12; No education documents provided i. Testing person #13; No education documents provided j. Testing person #14; No education documents provided k. Testing person #16; No education documents provided l. Testing person #17; No education documents provided m. Testing person #19; No education documents provided n. Testing person #20; No education documents provided o. Testing person #22; No education documents provided p. Testing person #23; No education documents provided q. Testing person #24; No education documents provided r. Testing person #25; No education documents provided s. Testing person #26; No education documents provided t. Testing person #27; No education documents provided u. Testing person #28; No education documents provided v. Testing person #31; No education documents provided w. Testing person #32; No education documents provided x. Testing person #33; No education documents provided y. Testing person #35; No education documents provided z. Testing person #36; No education documents provided aa. Testing person #37; No education documents provided bb. Testing person #38; No education documents provided cc. Testing person #39; No education documents provided dd. Testing person #40; No education documents provided 4. The above findings were confirmed by the laboratory director in an interview on 09/26/2018 at 1030 hours in the breakroom.