Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1013919	03/26/2026
Name of Provider or Supplier	**Street Address, City, State**	
Doctors Hospital At Renaissance Laboratory	5501 South Mccoll Road, Edinburg, 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	A validation survey was completed on 03/26/2026. Immediate Jeopardy existed for the following condition level deficiencies: 42 C.F.R. 493.1250 Condition: Analytic systems 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director 42 C.F.R. 493.1447 Condition: Laboratories performing high complexity testing; technical supervisor 42 C.F.R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the hospital's policies, and staff interview, the laboratory failed to ensure that procedures for identification of transfusion reactions were defined and available to hospital personnel responsible for recognizing and reporting potential transfusion reactions, resulting in unclear criteria for identifying transfusion reactions for 14 of 14 signs and symptoms. The findings included: 1. The laboratory's policy titled "Transfusion Reaction Investigation" (Policy Number: Lab TS-8081) under the section titled "Nursing Investigation" stated: "Signs and Symptoms: Uticaria Dyspnea Fever* Hemoglobinuria Chills Shock Chest Pain Generalized Bleeding Hypotension Oliguria or Anuria Nausea Back pain Flushing Pain at infusion site * An increase of at least 2F over the pre-transfusion temperature" 2. The hospital policy titled "Blood And Blood Products System-Wide Policy" (Policy Number: PC5064) under the section titled "Monitoring and Reactions" used by staff responsible for monitoring patients during transfusion stated: Notification of the physician should take place for the following types of transfusion

	reactions: - Hemolytic - Allergic - Febrile - Bacterial The hospital's policy did not include signs and symptoms for identifying potential transfusion reactions. 3. In an interview on 3/26/2026 at 1635 hours, Technical Supervisor #5 stated she was unaware of what criteria nursing staff used to identify potential transfusion reactions.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of the laboratory's College of American Pathologists' proficiency testing records from 2025, staff interview, the laboratory failed to document evaluation activities following an unacceptable proficiency testing result, including assessment of the impact on patient results as required for testing for 1 of 1 analytes. The findings included: 1. The laboratory's policy titled "Performance Verification Program" (Policy Number: LAB GEN-70060, effective 01/2010) under the section titled "External Audit System" stated: "Ongoing Evaluation of PT and alternative assessment results, with appropriate corrective action taken for each unacceptable result (graded, ungraded or educational challenge) is documented on the Proficiency Testing Exemption Summary Report. The Proficiency Testing Exception Report will be reviewed by the Pathologist and Laboratory Designee to evaluate the impact on patient samples." 2. A review of the laboratory's College of American Pathologists' C-A 2025 General Chemistry/Therapeutic Drugs determined the laboratory received a 0% score for the analyte of Free T3 for the first event of 2025. The results were: a) CHM-01 Reported Value: 14.3 Acceptable Range: 10.0 - 13.6 b) CHM-02 Reported Value: 9.3 Acceptable Range: 6.0 - 8.9 c) CHM-03 Reported Value: 1.6 Acceptable Range: 0.1 - 1.5 d) CHM-04 Reported Value: 9.2 Acceptable Range: 5.6 - 8.8 e) CHM-05 Reported Value: 19.5 Acceptable Range: 15.6 - 19.1 3. A review of the laboratory's Proficiency Testing Exception Summary Report determined that the cause of the unacceptable results was a "Methodologic Problem". 4. A review of an email from the Field Engineering Specialist from the manufacturer dated June 5, 2025 stated the following steps were performed to correct the problems with the analyzer: - Performed the adjustment of the Magnet position. - Replaced the bead mixer paddle and verified/adjusted the mech adjustments. - Replaced the DU2 sipper probe and verified/adjusted the mech adjustments. - Verified gear pump pressure adjustment. - Verified/adjusted the rinse stations water volumes. - Performed FT3 reagent pack calibration. 5. The laboratory failed to have documentation of evaluating patient samples for potential impact as required by its policy. 6. Technical Supervisor number #7 (as listed on Form CMS 209) confirmed during an interview on 03/25/2026 at 1025 hours that there was no documentation available demonstrating evaluation of patient results following the unacceptable proficiency testing event.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen

acceptability and rejection. (a)(8) Specimen referral.

This STANDARD is not met as evidenced by:
I. Based off surveyor direct observation, review of laboratory policy, and confirmed in interview, the laboratory did not have a mechanism in place to ensure the integrity of patient specimens in transportation to the laboratory for 43 of 43 patient received into the laboratory for testing on March 23, 2026. The findings included: 1. During a tour of the laboratory on 3/23/2026 at 09:45 hours, surveyor requested to perform direct observation of a client specimen drop. The surveyor asked that the laboratory vice president ensure that the courier who was dropping off the specimens wait for the arrival of the surveyor before proceeding through their drop off routine. At 13:37 hours the specimen drop off occurred under the observation and included the courier with a large, soft shelled, cooler who placed two large bags filled with specimens into a large clear plastic container. This clear plastic container is where the specimens would stay until the laboratory specimen processors were able to receive the samples into the laboratory, and sort them to their respective departments for testing. At 13:40 hours, the surveyor observed the cooler bag did not have any cooler packs in the body of the bag and no evidence of temperature control. At 13:42 hours, the surveyor observed a second courier with a much smaller soft shelled cooler providing specimens to a laboratory specimen processor. 2. Surveyor asked at 13:48 hours, in the specimen processing area, if cooler validations were performed to ensure the temperature requirements were maintained through transport, the assistant vice president stated they did not know, but they would look into it. 3. A review of eight cooler validation sheets provided on 3/23/2026 included documentation for 16 coolers that had been validated for the transportation of specimens at a temperature of 2-8 (degrees)C. However, the documentation did not include identification of the individual coolers or a mechanism to link the validation results to the specific coolers used by couriers. 4. Review of the laboratory provided policy titled "Transport Container QC", section III "Procedure for Standard Coolers", included the following information: "Specimen Transport" A. Sandwich the thermometer between specimens and hold them together with a rubber band. Place it at the bottom of the container. B. Place one large or multiple small ice pack(s) on top of the specimens. C. Close the lid and place the container on the counter. D. Take the first temperature reading after 60 minutes and record on the Transport Container QC log. E. Continue to take 5 more readings an hour apart so that the final reading is 6 hours after placing the specimens inside the cooler. Record all temps on log. Record ambient temperature." Section IV "Interpretation:" "A temperature reading from 2(degrees) C through 8(degrees)C is acceptable at the given times for the standard transport coolers for specimens." 5. Review of the laboratory policy titled "Sample Transport" did not include step by step instructions on how to pack transport coolers with ice packs to ensure that acceptable temperature was maintained for the patient testing being performed. 6. Review of the 43 laboratory client requisitions from the two bags observed during the drop off on 3 /23/2026 at 13:37 included the following 20 patients and the laboratory testing ordered (for the complete list of patients please see patient alias list (PAL) 11: Patient MRN: Tests Performed RL159416: CMP, Ca, Lipid panel, Mg, Prolactin, Total T3, Free T4, Total T4 (thyroxine), PSA, Random Urine Protein/ Creatinine Ratio, CBC, Hemoglobin A1C. RL1172861: CMP, Lipid panel, Mg, Total T4 (thyroxine), TSH, Uric Acid, PSA, Vitamin D 25-Hydroxy Total, CBC w differential RL451949: CBC w differential RL190767: Urinalysis w/reflex to culture RL421391: CMP, Free T4, Lipid panel, TSH, PSA Total, Random Urine Protein/creatinine Ratio, CBC w /differential, Hemoglobin A1C RL254378: Urine Culture RL814878: Vitamin B12, CMP, Free T4, Insulin, Iron Panel, Lipid Panel, TSH, Folate, Urinalysis w/reflex to

	culture, Vitamin D 25-Hydroxy Total, CBC w/ differential, Hemoglobin A1C RL1354863: Free T4, total T3, Total T4 Thyroxine, TSH RL165368: CMP, Ca, Lipid panel, Mg, TSH, Urinalysis w/ reflex to culture, Vitamin D 25 Hydroxy Total, CBC w /Differential RL1187850: Vitamin B12, CMP, Lipid Panel, TSH, Folate, Hemoglobin A1C RL679140: CMP, Lipid Panel, TSH, Urinalysis w/reflex to culture, RL167534: Urine Culture RL186986: CMP, Lipid Panel, Mg, Total T4 (Thyroxine), TSH, Uric Acid, Hemoglobin A1C RL941638: Vitamin B12, CMP, Lipid Panel, Total T3, Free T3, Total T4 (Thyroxine), TSH, Folate, Liver Fibrosis Test-Acti Test Panel, Smooth Muscle Antibody Screen, Urine ALB/CREA Ratio, Vitamin D 25-Hydroxy Total, CBC w/differential, Hemoglobin A1C, RL1905386: Vitamin B12, CMP, Free T4, TSH, Folate, Testosterone Total and Free S, Vitamin D 25 Hydroxy Total, CBC w /differential RL1756589: CMP, PSA Total, CBC w/differential RL254378: CMP, Lipid Panel, Mg, Total T4 (Thyroxine), TSH, Uric Acid, PSA Total, Complete Urinalysis, Vitamin D 25 Hydroxy Total, CBC w/differential, Hemoglobin A1C RL1207798: Vitamin B12, CMP, Free T4, Iron Panel, Lipid Panel, Mg, Free T3, TSH, Folate, Complete Urinalysis, Vitamin D 25 Hydroxy Total, CBC w/ differential, Hemoglobin A1C RL1454284: CMP, Free T4, Lipid panel, TSH, PSA Total, Random Urine Protein/creatinine Ratio, CBC w/differential, Hemoglobin A1C RL902420: Vitamin B12, CMP, Iron Panel, Lipid Panel, Total T3, Free T3, Total T4 (Thyroxine), TSH, Folate, Urinalysis w/Reflex to Culture, Vitamin D 25 Hydroxy Total, CBC w /differential, Hemoglobin A1C 7. In an interview on 3/25/2026 at 12:04 hours, in the outreach supervisor's office, the outreach supervisor stated that there were 15 - 20 coolers in use by the couriers who picked up client specimens and confirmed they did not have a way to track which cooler had been validated as outlined by the above procedure, and that couriers were supposed to have ice packs in the coolers to maintain an acceptable temperature. II. Based on surveyor direct observation, review of laboratory policy, and confirmed in interview, the laboratory failed to maintain consistency between two microbiology processing policies two of two body fluid cultures inoculated into vitek blood culture bottles processed on 3/25/2026. The findings included: 1. During direct observation of microbiology specimen work ups on 3/26/2026 at 09:20 hours, in microbiology, testing personnel (TP) 6 could not locate the plates for sampled 26-083-0457 and 26-083-04577 for patient MRN 01375814 pleural body fluid culture. TP6 contacted the Technical Supervisor (TS) 3, and they found documentation the provider had requested the culture to be placed into blood culture bottles and placed on the Vitek Bact/Virturo blood culture system, and no direct plates were inoculated or streaked for culture. 2. Review of the laboratory microbiology policy titled "Body Fluid Cultures (Excluding Blood, Cerebrospinal Fluid, and Urine)", section "C. Specimen collection" included the following information: "4. Immediately place a portion of the joint fluid or peritoneal fluid collected from patients with peritonitis secondary to CAPD or SBP into aerobic and anaerobic blood culture bottles, retaining some (1.0 to 3.0 mL for Gram stain and direct plating." 3. Review of the laboratory policy titled "Setup Guide for Microbiology", section "Media Set-Up Chart" included the following microbiology media to be used when culturing a Body Fluid: SBA, CA, MAC, Thio 4. In an interview on 3/26/2026 at 10:55 hours, in the surveyor's designated office, Technical Supervisor 3 confirmed the microbiology setup policy did not include the instruction for direct plating as required by the laboratory's "Body Fluid Cultures" policy. Key: SBA: Sheep blood agar CAN: Colistin-nalidixic acid colmubia[sic] agar with defibrinated sheep blood, MAC: MacConkey Agar, Thio: Thioglycholate.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d)

	(d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policies and procedures, and interviews, the laboratory failed to ensure the laboratory client service manual provided to clients included information regarding specimen storage and preservation, and instructions for the conditions for specimen transport, as well as rejection criteria for the testing performed at the laboratory. The findings included: 1. In a tour of the laboratory on 3/24/2026 at 09:45 hours, the surveyors were introduced to the client services are where couriers would drop off samples in the afternoon from various clients in the region for patient testing. 2. Review of the client services manual, provided by the Laboratory Vice president, did not include information to the clients regarding the storage and preservation, transportation of specimens to the laboratory for testing, or rejection criteria. 3. In an interview on 3/25/2026 at 09:43 hours, in the hallway, the laboratory vice president confirmed that the provided client service manual used for client reference, did not include information for the conditions of specimen storage, transport, and rejection criteria.
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, the laboratory failed to ensure the overall quality of its analytic systems, including failure to establish, verify, and monitor test performance and quality control processes for non-waived testing. The findings included: 1. The laboratory failed to document reference range verification studies (refer to D5421). 2. The laboratory failed to have documentation of establishment studies for modified FDA-approved testing of body fluids (refer to D5423 I). 3. The laboratory failed to have documentation of establishment studies for modified FDA-approved testing on Accuchek Inform II glucometers (refer to D5423 II). 4. The laboratory failed to have documentation of written quality control procedures for body fluid testing (refer to D5441). 5. The laboratory failed to have documentation of performing quality control testing each day of patient testing for body fluid testing (refer to 5447).
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)

	(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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: I. Based on surveyor observation, review of laboratory policy, manufacturer instructions, GEM 5000 Blood Gas Analyzer verification studies, patient final reports and confirmed in interview, the laboratory failed to document reference range verification studies on venous blood samples tested on the GEM 5000 for two of four sample types tested from May 2024-January 2026. Findings included: 1. During a tour of the facility on 03/24/2026 at 09:40 AM, the surveyor observed the following GEM 5000 Blood Gas analyzers in patient testing areas: a. Serial Number: 23095445 b. Serial Number: 23095446 c. Serial Number: 23095455 d. Serial Number: 23095456 2. Review of laboratory policy, "GEM Premier 5000 Blood Gas Analyzer" (Approved by the laboratory director on 05/2024) revealed the following: " ...VI. SPECIMEN COLLECTION AND HANDLING CRITERIA ACCEPTABLE SAMPLE TYPES Heparinized whole blood samples from the following sources are acceptable for patient testing on the GEM Premier 5000: arterial, capillary, mixed venous, venous." 3. Review of manufacturer's instructions, "GEM Premier 5000" (Version 1) revealed the following: " ...Results interpretation: In arterial mode, on the analyzer screen, abnormal results will be flagged using a color coded system, on the printout these are denoted by flags and the reference ranges will also appear on the printout. There are no established reference ranges for any other blood gas sample types." 4. Review of laboratory verification studies performed in May 2024, revealed the laboratory failed to document verification of venous and mixed venous sample type reference ranges prior to testing and reporting patient results. 5. Random review of patient final reports revealed the laboratory performed 15 venous blood gas patient tests in January 2026. Refer to Patient Alias List 9. 6. In an interview on 03/25/2026 at 10:11 AM in the laboratory office, the point of care lead confirmed the laboratory failed to document reference range verification studies on venous blood samples tested on the GEM 5000 for two of four sample types tested from May 2024-January 2026. II. Based on laboratory policy, Prothrombin Time (PT) RecombiPlasTin reagent lot rollover studies, random review of patient final reports, and confirmed in interview, the laboratory failed to document complete PT reference range verification prior to patient analysis for one of one RecombiPlasTin reagent lot rollover performed in 2025. Findings included: 1. Review of laboratory policy, "Prothrombin Time (PT) ACL TOP" (Approved by the laboratory director on 08/2024) revealed the following: " ...IV. GEOMEAN DETERMINATION PROCEDURE: 1. Obtain 20 normal patients. 2. Perform PT on all specimens ..." 2. Review of laboratory EP Evaluator, "Verification Studies" procedure performed in June 2025 revealed the following: " ... Use samples from normal (healthy) patients (i.e., individuals without disease or interfering medications" Review of Prothrombin Time (PT) RecombiPlasTin (Lot Number: NO158883) reagent lot rollover study performed in June 2025, revealed the laboratory failed to document patient demographics for the 20 normal patients referenced in the laboratory policy. The laboratory was asked to provide the above patient demographics on 03/26/2026 at 11:10 AM, and no documentation was provided. 3. Random review of patient final reports, revealed the following PT patient specimens analyzed in December 2025: a. Refer to Patient Alias List 10. PT Patient Reference Range: 10.4-12.8 seconds 4. In an interview on 03/26/2026 at 11:10 AM in the laboratory office, Technical Supervisor 3 (TS-3) confirmed the laboratory failed to document complete PT reference range verification prior to patient analysis for one of one RecombiPlasTin reagent lot rollover performed in 2025.

D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) (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: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: I. Based on review of survey forms, manufacturer's instructions, laboratory policy, establishment studies, patient final reports, and confirmed in interview, the laboratory failed to perform complete establishment studies, when modifying an FDA approved test, in body fluid testing for three of six analytes performed from January 2024-February 2026. Findings included: 1. Review of survey forms submitted at time of survey, 03/24/2026, revealed the laboratory performed cholesterol, lactate dehydrogenase, and albumin on body fluid sample types (pleural and peritoneal). 2. Review of manufacturer's instructions, "Roche Cholesterol CHOL2" (Version 3.0; 09-2023), revealed the following: "Specimen collection and preparation For specimen collection and preparation only use suitable tubes or collection containers. Only the specimens listed below were tested and found acceptable. Serum. Plasma" Review of manufacturer's instructions, "Roche Lactate Dehydrogenase LDHI2" (Version 3.0; 03-2023), revealed the following: For specimen collection and preparation only use suitable tubes or collection containers. Only the specimens listed below were tested and found acceptable. Serum. Plasma" Review of manufacturer's instructions, "Roche Albumin ALB" (Version 10.0; 08-2015), revealed the following: "Specimen collection and preparation For specimen collection and preparation only use suitable tubes or collection containers. Only the specimens listed below were tested and found acceptable. Urine Serum (not for cobas c 311 analyzer) Plasma: Li-heparin and K2 EDTA plasma (not for cobas c 311 analyzer) CSF (not for cobas c 311 analyzer)" The manufacturer did not include pleural and peritoneal body fluids as acceptable sample types for any of the above analytes. 3. Review of laboratory policy, "Routine Body Fluids" (Approved by the Laboratory Director on 08/2024) revealed the following: " ... B. Routine Body Fluids This procedure includes all body fluids except synovial fluid. Examination of the fluid should be done in a timely manner. Routine analysis- unless otherwise specified will be: A. Tube #1 is for protein, glucose, and fluid electrophoreses, if requested. B. Tube #2 is for culture. C. Tube #3 is for cell count and differential." The laboratory policy failed to include cholesterol, LDH, and albumin body fluid analysis. No additional policy to include the above analytes was provided upon request on 03/26/2026 at 10:17 AM. 4. Review of laboratory body fluid establishment studies performed in 2023, revealed the laboratory failed to document performance specifications of analytic sensitivity, analytic specificity to include interfering substances, reportable range and reference ranges for cholesterol, LDH, and albumin body fluid analysis. 5. Review of annual patient volumes in 2024 and 2025, revealed the laboratory performed the following body fluid analysis (pleural and peritoneal): 2024 (Refer to Patient Alias List 4) a. Cholesterol Total patient volume: 690 b. LDH Total patient volume: 332 c. Albumin Total patient volume: 350

2025 (Refer to Patient Alias List 5) e. Cholesterol Total patient volume: 770 f. LDH Total patient volume: 299 g. Albumin Total patient volume: 270 Note: The following was stated on all patient reports for the above specimen types, "Albumin, Fluid, Cholesterol, Fluid, LDH, Fluid This specimen type is considered clinically unique. The reference ranges have not been established for this body fluid. The test result must be integrated into the clinical context for interpretation." Reference ranges were not listed on the test reports. Refer to D5807. 6. In an interview on 03/26/2026 at 02: 55 PM in the laboratory office, the assistant vice president of laboratory services confirmed the laboratory failed to perform complete establishment studies in body fluid testing for three of six analytes performed from January 2024-February 2026. II. Based on surveyor observation, manufacturer's instructions, laboratory policy, laboratory establishment studies, RALS middleware system, patient final reports, and confirmed in interview, the laboratory failed to perform complete establishment studies, when modifying an FDA approved test, in glucose testing for one of one glucometer test systems in 2025. Findings included: 1. During a tour of the facility on 03/24/2026 at 10:10 AM, the surveyor observed multiple Accu-Chek Inform II Glucometers located in the Intensive Care Unit (ICU) (Serial Number: UU14628055 and UU14614394) and Trauma Emergency Room area (ER) (Serial Numbers: UU14443096 and UU14587094). 2. Review of manufacturer's instructions, "Roche Accu-Chek Inform II Blood Glucose Monitoring System" (Version 08424705001; 04 /2017) revealed the following: " ...12. General Product Information Specification ... The performance of this system has not been evaluated on the critically ill." 3. Review of laboratory policy, "Accu-Chek Inform II Glucometer" (Policy was not approved by the laboratory director.) revealed the following: " ...Specimen Requirements and Interferences The performance of the Accu-Chek Inform II glucometer system has not been evaluated in the critically ill; therefore testing 'critically ill' patients with the glucometer system is strictly prohibited. For the specific use of glucose meters, critically ill at DHR Health will be defined as "a patient on mechanical ventilation with a mean arterial pressure less than 60 mmHg despite the use if pressors. Glucose testing on these patients must be performed on a venous or arterial blood sample sent to the central laboratory." Review of laboratory policy, "DHR Laboratory Validation Studies" (Reviewed by the Laboratory Director on 08/2025) revealed the following: "Policy Doctors Hospital at Renaissance Laboratory will perform validation studies for all new methods to include but not limited to Laboratory Developed or Laboratory Modified test, prior to implementing new instruments, changing reagent (s) and/or implementation of a new method. The purpose of validating methods is to ensure the procurement of high quality results. ...The laboratory director ensures that the performance specifications for new tests, instruments, and methods introduced to the laboratory have been properly validated or verified prior to being used for patient testing." 4. Review of Accu-Chek Inform II laboratory documentation revealed the laboratory failed to document performance of complete establishment studies when modifying an FDA approved test system. 5. Random review of laboratory RALS middleware system, revealed the following ICU patients tested using the Accu-Chek Inform II Glucometer in 2025: March 4th, 2025 a. Refer to Patient Alias List 6 November 11th, 2025 b. Refer to Patient Alias List 7 December 16th, 2025 c. Refer to Patient Alias List 8 6. In an interview on 03/25/2026 at 09:45 AM in the ICU, the on shift certified nursing assistant (CNA) confirmed they would use the Accu-Chek on critically ill patients with a pressure of less than 60 mmHg. The CNA was asked to demonstrate access to the current Accu-Chek Inform II policy defining critically ill patients as "a patient on mechanical ventilation with a mean arterial pressure less than 60 mmHg despite the use if pressors.". The CNA did not have access to the above policy. In an interview on 03/25/2026 at 09:58 AM in the ER, the on shift registered nursing (RN) lead confirmed they would use the Accu-Chek on critically ill patients

	with a pressure of less than 60 mmHg. In an interview on 03/25/2026 at 10:06 AM in the laboratory office, the point of care lead confirmed the laboratory failed to perform complete establishment studies, when modifying an FDA approved test, in glucose testing for one of one glucometer test systems in 2025. Word Key FDA- Food and Drug Administration mmHg- millimeters of mercury
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. This STANDARD is not met as evidenced by: Based on review of laboratory survey documentation, laboratory policy, establishment studies, quality control records, patient annual volumes, and confirmed in interview, the laboratory failed to establish control procedures to include the number, type and frequency, for three of six laboratory developed body fluid tests in 2023. Findings included: 1. Review of survey forms submitted at time of survey, 03/24/2026, revealed the laboratory performed cholesterol, lactate dehydrogenase, and albumin on body fluid sample types (pleural and peritoneal). 2. Review of laboratory policy, "Routine Body Fluids" (Approved by the laboratory director on 08/2024) revealed the laboratory failed to establish a quality control procedure for Albumin, Cholesterol, and LDH body fluid analysis. The laboratory was asked to provide a quality control policy for the above sample types on 03/26/2026 at 10:17 AM, and no documentation was provided. 3. Review of laboratory establishment studies in 2023 for the above body fluid sample types, revealed the laboratory failed to document establishment of quality control procedures to include the number, type and frequency of quality control performance. The laboratory was asked to provide the above establishment study documentation, and none was provided. Refer to D5423 I. 4. Review of albumin, cholesterol and LDH body fluid quality control records in 2024 and 2025, revealed the laboratory failed to perform quality control every day of patient testing for all patients tested in 2024 and 2025. Refer to D5447 and Patient Alias lists 4 and 5. 5. In an interview on 03/26/2026 at 02:55 PM in the laboratory office, the assistant vice president of laboratory services confirmed the laboratory failed to establish control procedures to include the number, type and frequency, for three of six laboratory developed body fluid tests in 2023.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) (d) 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. (d)(3) At least once each day patient specimens are assayed or examined perform the following for: This STANDARD is not met as evidenced by: Based on review of testing, laboratory policy, laboratory Individualized Quality Control Plans (IQCP), quality control (QC) records, patient testing, and confirmed in interview, the laboratory failed to perform quality control testing every day of patient testing for gram-negative (GN) and gram-positive (GP) bacterial identification performed for 866 of 912 patients with testing on the Vitek 2 systems for records reviewed from August to September 2025. The findings included: 1. Review of laboratory testing included the Vitek 2 used in GN and GP bacterial identification from patient cultures. 2. Review of the laboratory policy titled "Vitek 2 Identification Procedure", section IV "Quality Control" included the following information: "A. Perform Quality Control The comprehensive quality control organisms listed below. Appropriate positive and negative control organisms are tested and resulted with each new lot and shipment of reagent used for bacterial ID. The QC organisms should be processed according to the procedure for test isolates." 3. Review of the laboratory IQCP's for microbiology did not include documentation for the Vitek 2 GN and GP identification cards. At 10:56 hours on 3/26/2026, surveyor asked Technical Supervisor (TS) 3 for the Vitek 2 GN and GP identification cards IQCP, to support the laboratory's reduction in quality control from everyday of patient testing, to each new lot and shipment, and none was provided. 4. Review of microbiology Vitek 2 GN and GP laboratory quality control records and patient bacterial identification testing included the 866 patients tested on days where QC was not performed for records reviewed in August and September 2025. In August 2025, 401 patients had testing performed on the Vitek 2, for bacterial identification, on days without quality control to include the following 10 random patients (for the total patient list, please see patient alias list (PAL) 12): Laboratory ID: ID Card Used 2521501387 - GNID 2521502550 - GPID 2521607814 - GPID 2521608144 - GNID 2521706859 - GNID 2521708584 - GPID 2521905504 - GPID 2521805395 - GNID 2521803712 - GPID 2522303484 - GNID In September 2025, 465 patients had testing performed on the Vitek 2, for bacterial identification, on days without quality control, to include the following 10 random patients (for the total patient list, please see the PAL 13): Laboratory ID: ID Card Used 2524401113 - GPID 2524403110 - GNID 2524502559 - GNID 2524502559 - GPID 2524606485 - GNID 2524609774 - GPID 2525106862 - GNID 2526108016 - GPID 2526504834 - GPID 2526606761 - GNID 5. In an interview at 11:20 hours on 3/26/2026, in the surveyors designated office, TS3 confirmed quality control was not performed each day of patient testing on the Vitek 2 for the GN and GP identification cards for August and September 2025.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on review of laboratory survey documentation, laboratory policy, quality control records, patient annual volumes, and confirmed in interview, the laboratory

	failed to document quality control every day of patient testing for two of two years (2024 and 2025). Findings included: 1. Review of survey forms submitted at time of survey, 03/24/2026, revealed the laboratory performed cholesterol, lactate dehydrogenase, and albumin on body fluid sample types (pleural and peritoneal). 2. Review of laboratory policy, "Routine Body Fluids" (Approved by the laboratory director on 08/2024) revealed the laboratory failed to establish a quality control procedure for Albumin, Cholesterol, and LDH body fluid analysis. 3. Review of albumin, cholesterol and LDH body fluid quality control records in 2024 and 2025, revealed the laboratory failed to perform quality control every day of patient testing for all patients tested in 2024 and 2025. 4. Review of patient final reports revealed the following patients tested for the above body fluid analytes in 2024 and 2025: 2024 (Refer to Patient Alias List 4) a. Cholesterol Total patient volume: 690 b. LDH Total patient volume: 332 c. Albumin Total patient volume: 350 2025 (Refer to Patient Alias List 5) e. Cholesterol Total patient volume: 770 f. LDH Total patient volume: 299 g. Albumin Total patient volume: 270 5. In an interview on 03/26/2026 at 02:50 PM in the laboratory technical supervisor 5 (TS-5) confirmed the laboratory failed to document quality control every day of patient testing for two of two years (2024 and 2025).
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control records for testing on the Phadia 250 analyzers from September 2025 and October 2025, review of patient test records from August 2025, September 2025 and October 2025, and staff interview, the laboratory failed to have documentation of evaluating patient samples tested prior to quality control failure on 3 of 3 dates. The findings included: 1. A review of the laboratory's Phadia 250 quality control records from September 2025 and October 2025 identified 3 days where the Curve Control for IgG failed and the instrument was recalibrated: a) Phadia serial number N20761 Date: 09/02/2025 Result: 40 Expected value: 20 Date: 09/24/2025 Result: 23 Expected value: 20 b) Phadia serial number N20047 Date: 10/02/2025 Result: 28 Expected value: 20 2. Because calibration was performed following failed quality control results, evaluation of patient results tested since the last acceptable quality control run was required. No documentation was available to demonstrate this evaluation was performed. 3. The review of patient test records from August 2025, September 2025, and October 2025 identified .patients tested prior to correction of quality control failures who required evaluation, including: the following 691 patient results requiring evaluation: a) Phadia serial number N20761 Test date: 8/29/2025 216 patients tested (see patient alias list 1) b) Phadia serial number N20761 Test date: 9/24/2025 305 patients tested (see patient alias list 2) c) Phadia serial number N20047 Test date: 10/06/2025 170 patients tested (see patient alias list 3) 4. In an interview on 03/25/2026 at 1045 hours, Technical Supervisor #5 (as listed on Form CMS 209) confirmed evaluation of patient results following the quality control failures had not been performed or documented.

D5787	TEST RECORDS CFR(s): 493.1283(a) (a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of laboratory policy, RALS middleware system, and confirmed in interview, the laboratory failed to document TEG Hemostasis Analyzer operator test performance for one of four operators in 2026. Findings included: 1. Review of laboratory policy, "TEG 6s Hemostasis Analyzer- Individual Quality Control Plan (IQCP)" (Effective: 01/2025) revealed the following: " ...Operator Access ...Operator IDs gives traceability to patient test results" 2. Review of point of care RALS middleware system revealed the following one of four TEG operator ID's were not registered to a testing person: User ID- 21375 Testing documented in: January 2026 February 2026 Documentation identifying the individual associated with this User ID in the RALS middleware system was requested on 03/25/2026 at 03:15 PM, and no documentation was provided. 3. In an interview on 03/25/2026 at 03:15 PM in the laboratory office, the point of care lead confirmed that operator identification for TEG Hemostasis Analyzer was not documented for one of four operators in 2026. Word Key ID's- Identification
D5807	TEST REPORT CFR(s): 493.1291(d) (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 laboratory policy, establishment studies, patient final reports, and confirmed in interview, the laboratory failed to document reference intervals for body fluid testing on patient final reports, for 18 of 18 patients randomly reviewed in March 2025. Findings included: 1. Review of survey forms submitted at time of survey, 03/24 /2026, revealed the laboratory performed cholesterol, lactate dehydrogenase, and albumin on body fluid sample types (pleural and peritoneal). 2. Review of manufacturer's instructions, "Roche Cholesterol CHOL2" (Version 3.0; 09-2023), revealed the following: "Specimen collection and preparation For specimen collection and preparation only use suitable tubes or collection containers. Only the specimens listed below were tested and found acceptable. Serum. Plasma" Review of manufacturer's instructions, "Roche Lactate Dehydrogenase LDHI2" (Version 3.0; 03-2023), revealed the following: For specimen collection and preparation only use suitable tubes or collection containers. Only the specimens listed below were tested and found acceptable. Serum. Plasma" Review of manufacturer's instructions, "Roche Albumin ALB" (Version 10.0; 08-2015), revealed the following: "Specimen collection and preparation For specimen collection and preparation only use suitable tubes or collection containers. Only the specimens listed below were tested and found

	acceptable. Urine Serum (not for cobas c 311 analyzer) Plasma: Li-heparin and K2 EDTA plasma (not for cobas c 311 analyzer) CSF (not for cobas c 311 analyzer)" The manufacturer did not include pleural and peritoneal body fluids as acceptable sample types for any of the above analytes. 3. Review of laboratory body fluid establishment studies performed in 2023, revealed the laboratory failed to document reference range performance specifications for cholesterol, LDH, and albumin body fluid analysis. Documentation was requested for reference range specifications for body fluid analysis on 03/26/2026 at 10:15 A.M. and none was provided. 4. Random review of patient final reports in March of 2025, revealed the laboratory failed to include reference ranges for albumin, cholesterol and LDH body fluid analysis, for 18 of 18 patients randomly reviewed in March 2025. Refer to Patient Alias List 5. The following statement was documented at the conclusion of each patient body fluid report, ""Albumin, Fluid, Cholesterol, Fluid, LDH, Fluid This specimen type is considered clinically unique. The reference ranges have not been established for this body fluid. The test result must be integrated into the clinical context for interpretation." 5. In an interview on 03/26/2026 at 02:55 PM in the laboratory office, the assistant vice president of laboratory services confirmed the laboratory failed to document reference intervals for body fluid testing on patient final reports, for 18 of 18 patients randomly reviewed in March 2025.
D6028	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(10) (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 review of the laboratory's user list for the GEM 5000 blood gas analyzers, review of the laboratory's personnel records, and staff interview, the laboratory director failed to ensure 4 of 24 testing personnel who performed testing on the GEM 5000 blood gas analyzers had the appropriate education to perform moderate complexity testing. The findings included: 1. A review of the laboratory's user list for the GEM 5000 blood gas analyzers identified 24 testing personnel performed testing. 2. A review of the laboratory's personnel records identified the laboratory failed tomet the education requirements to qualify 4 of the 24 personnel to perform testing. Individuals were (as listed on Form CMS 209): a) Testing personnel # 66 b) Testing personnel # 87 c) Testing personnel # 75 d) Testing personnel # 92 3. In an interview conducted on 03/26/2026 at 15:48 hours, Technical Consultant #1 (as listed on Form CMS 209) stated that education records for the identified personnel could not be located.
D6055	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's instrumentation, review of the laboratory's policies, review of employee records, and staff interview, the technical consultant failed to ensure competency assessments were performed prior to patient testing for 18 of 18 personnel when new instrumentation was installed. The findings included: 1. A review of the laboratory's instrumentation identified the laboratory placed 4 GEM 5000 blood gas analyzers into use in May 2024. They were: a) serial number: 23095445 b) serial number: 23095446 c) serial number: 23095455 d) serial number: 23095456 2. The laboratory's policy titled "Quality Management in the Blood Gas Lab" (Policy Number: POC-5501) under the section titled "Competency" stated: "Prior to starting patient testing and prior to reporting patient results for new methods or instruments, each individual must have documented initial training and be evaluated for proper test performance on all instruments/methods applicable to their designated job." 3. A review of the laboratory's personnel records identified the following 18 of 18 testing personnel who were trained on the new instruments in 2024 and did not have documentation of competency assessments being performed prior to reporting patient results. They were (as listed on Form CMS 209): a) Testing personnel number 80 trained: April 2024 competency: May 2025 b) Testing personnel number 95 trained: May 2024 competency: May 2025 c) Testing personnel number 67 trained: April 2024 competency: May 2025 d) Testing personnel number 86 trained: April 2024 competency: May 2025 e) Testing personnel number 88 trained: April 2024 competency: June 2025 f) Testing personnel number 62 trained: April 2024 competency: May 2025 g) Testing personnel number 82 trained: April 2024 competency: June 2025 h) Testing personnel number 64 trained: April 2024 competency: none i) Testing personnel number 93 trained: May 2024 competency: June 2025 j) Testing personnel number 96 trained: May 2024 competency: June 2025 k) Testing personnel number 71 trained: April 2024 competency: none l) Testing personnel number 78 trained: April 2024 competency: June 2025 m) Testing personnel number 97 trained: April 2024 competency: June 2025 n) Testing personnel number 74 trained: April 2024 competency: May 2025 o) Testing personnel number 69 trained: April 2024 competency: May 2025 p) Testing personnel number 81 trained: April 2024 competency: June 2025 q) Testing personnel number 68 trained: May 2024 competency: May 2025 r) Testing personnel number 85 trained: April 2024 competency: May 2025 s) Testing personnel number 72 trained: April 2024 competency: May 2025 t) Testing personnel number 84 trained: April 2024 competency: none 4. Technical consultant #1 (as listed on Form CMS 209) confirmed the findings in an interview conducted on 03/26/2026 at 1548 hours in the office.
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 records and staff interview, the laboratory director failed to provide oversight for the laboratory to ensure accurate and reliable results. The findings included: 1. The laboratory director failed to ensure control procedures were established (refer to D6093 I). 2. The laboratory director failed to ensure quality control testing was performed each day of patient testing (refer to D6093 II). 3. The laboratory director failed to ensure establishment studies were performed for modified FDA-approved testing on body fluids (refer to D6095 I). 4. The laboratory director

	failed to ensure establishment studies were performed for the modified FDA-approved testing on the Accu-Chek Inform II glucometers (refer to D6095 II). 5. The laboratory director failed to ensure reference intervals were documented for body fluid testing results (refer to D6098). 6. The laboratory director failed to ensure documentation of training (refer to D6101).
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: I. Based on review of laboratory survey documentation, laboratory policy, establishment studies, quality control records, patient annual testing volumes, and confirmed in interview, the laboratory director failed to ensure control procedures were established to include the number, type and frequency, for three of six laboratory developed body fluid tests in 2023. Refer to D5441. II. Based on review of laboratory survey documentation, laboratory policy, quality control records, patient annual volumes, and confirmed in interview, the laboratory director failed to ensure quality control performance each day of patient testing for two of two years (2024 and 2025). Refer to D5447.
D6095	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(6) (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: I. Based on review of survey forms, manufacturer's instructions, laboratory policy, establishment studies, patient final reports, and confirmed in interview, the laboratory director failed to ensure complete establishment studies were performed, when modifying an FDA-approved test, in body fluid testing for three of six analytes performed from January 2024-February 2026. Refer to D5423 I. II. Based on surveyor observation, manufacturer's instructions, laboratory policy, laboratory establishment studies, RALS middleware system, patient final test reports, and confirmed in interview, the laboratory director failed to ensure complete establishment studies were performed, when modifying an FDA-approved test, in glucose testing for one of one glucometer test systems in 2025. Refer to D5423 II.
D6098	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(8) (e)(8) Ensure that reports of test results include pertinent information required for interpretation; This STANDARD is not met as evidenced by: Based on review of laboratory policy, establishment studies, patient final test reports,

	and confirmed in interview, the laboratory director failed to ensure reference intervals were documented for body fluid testing on patient final reports, for 18 of 18 patients randomly reviewed in 2025. Refer to D5807.
D6101	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(11) (e)(11) 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 review of patient test records and lack of response from the laboratory, the facility failed to provide documentation of training for 7 of 7 personnel who performed testing on the FDA-modified Accu-Chek Inform II glucometers. The findings included: 1. A random sampling of ICU personnel performing testing on the Accu-Chek Inform II glucometers from March 4, 2025, November 12, 2025 and December 16, 2025 identified 7 personnel performed testing (See ICU testing list). 2. Documentation of training was requested via email to the Point-of-Care supervisor on 03/31/2026 at 3:02 pm, with a deadline of 04/01/2026 at 5:00 pm. 3. As of 04/01/2026 at 5:26 pm no documentation has been received.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's records, and staff interview, the technical supervisor failed to provide technical oversight for the laboratory. The findings included: 1. The technical supervisor failed to ensure control procedures were established (refer to D6117 I). 2. The technical supervisor failed to ensure quality control testing was performed each day of patient testing (refer to D6117 II). 3. The technical supervisor failed to ensure establishment studies were performed for modified FDA- approved testing on body fluids (refer to D6115 I). 4. The technical supervisor director failed to ensure establishment studies were performed for the modified FDA-approved testing on the Accu-Chek Inform II glucometers (refer to D6115 II). 5. The technical supervisor failed to ensure competency assessments were performed (refer to D6120).
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) (b)(2) Verification of the test procedures performed and establishment of the laboratorys test performance characteristics, including the precision and accuracy of each test and test system;

	This STANDARD is not met as evidenced by: I. Based on review of survey forms, manufacturer's instructions, laboratory policy, establishment studies, patient final test reports, and confirmed in interview, the technical consultant (TS-5) failed to ensure complete establishment studies were performed, when modifying an FDA-approved test, in body fluid testing for three of six analytes performed from January 2024-February 2026. Refer to D5423 I. II. Based on surveyor observation, manufacturer's instructions, laboratory policy, laboratory establishment studies, RALS middleware system, patient final test reports, and confirmed in interview, the technical consultant (TC-1) failed to ensure complete establishment studies were performed, when modifying an FDA-approved test, in glucose testing for one of one glucometer test systems in 2025. Refer to D5423 II.
D6117	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(4) (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: I. Based on review of laboratory survey documentation, laboratory policy, establishment studies, quality control records, patient annual testing volumes, and confirmed in interview, the technical consultant (TC-5) failed to ensure control procedures were established to include the number, type and frequency, for three of six laboratory developed body fluid tests in 2023. Refer to D5441. II. Based on review of laboratory survey documentation, laboratory policy, quality control records, patient annual volumes, and confirmed in interview, the technical consultant (TC-5) failed to ensure quality control performance each day of patient testing for two of two years (2024 and 2025). Refer to D5447.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (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 patient test records and lack of response from the laboratory, the facility failed to provide documentation of competency assessments for 7 of 7 personnel performing testing on the FDA-modified AccuChek Inform II glucometers. The findings included: 1. A random sampling of ICU personnel performing testing on the Accu-Chek Inform II glucometers from March 4, 2025, November 12, 2025 and December 16, 2025 identified 7 personnel performed testing (See ICU testing list). 2. Documentation of competency assessments was requested via email from the Point-of-Care supervisor on 03/31/2026 at 3:02 pm, with a deadline of 04/01/2026 at 5:00 pm. 3. As of 04/01/2026 at 5:26 pm no documentation has been received.

D6139	CLINICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1457(c) (c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and This STANDARD is not met as evidenced by: Based on review of laboratory policy, establishment studies, patient final reports, and confirmed in interview, the clinical consultant (CC-1) failed to ensure reference intervals were documented for body fluid testing on patient final reports, for 18 of 18 patients randomly reviewed in March 2025. Refer to D5807.
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 patient test records and lack of response from the laboratory, the facility failed to provide documentation of education to qualify 7 of 7 personnel (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 (b)(2)(i) Have earned a doctoral, master's, or bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (b)(2)(ii) Be qualified under the requirements of 493.1443(b)(3) or 493.1449(c)(4) or (5); or (b)(3)(i) Have earned an associate degree in a laboratory science or medical laboratory technology from an accredited institution or (b)(3)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes (b)(3)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either (b)(3)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(3)(ii)(A)(2) 24 semester hours of science courses that include (b)(3)(ii)(A)(2)(i) 6 semester hours of chemistry; (b)(3)(ii)(A)(2)(ii) 6 semester hours of biology; and (b)(3)(ii)(A)(2)(iii) 12 semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(3)(ii)(B) Have laboratory training that includes: (b)(3)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES or the CAAHEP (this training may be included in the 60 semester hours listed in paragraph (b)(3)(ii)(A) of this section); or (b)(3)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing; or (b)(4) Successful completion of an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and having held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(5) Notwithstanding any other provision of this section, an individual is considered

	qualified as a high complexity testing personnel under this section if they were qualified and serving as a high complexity testing personnel in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. (b)(6) For blood gas analysis (b)(6)(i) Be qualified under paragraph (b)(1), (2), (3), (4), or (5) of this section; or (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. (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (f) to perform tissue examinations. This STANDARD is not met as evidenced by: Based on review of patient test records and lack of response from the laboratory, the facility failed to provide documentation of education to qualify 7 of 7 personnel performing testing on the FDA-modified AccuChek Inform II glucometers. The findings included: 1. A random sampling of ICU personnel performing testing on the Accu-Chek Inform II glucometers on March 4, 2025, November 12, 2025 and December 16, 2025 identified 7 personnel performed testing (See ICU testing list). 2. Documentation of education for the testing personnel to ensure qualification to perform high complexity testing was requested via email to the Point-of-Care supervisor on 03/31/2026 at 3:02 pm, with a deadline of 04/01/2026 at 5:00 pm. 3. As of 04/01/2026 at 5:26 pm no documentation has been received.