Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0503473	04/16/2026
Name of Provider or Supplier	**Street Address, City, State**	
Valley Baptist Medical Center-Brownsville	1040 West Jefferson, Brownsville, TX	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The laboratory was found to be out of compliance with 42 CFR Part 493, Requirements for Laboratories following a survey completed on 04/16/2026 resulting in a finding of IMMEDIATE JEOPARDY. The following condition(s) were not met: D2000 - 42 C.F.R. 493.801 Condition: Enrollment and Testing of Samples [Proficiency Testing] D2016 - 42 C.F.R. 493.803 (a)(b)(c) Condition: Successful Participation [Proficiency Testing] D5300 - 42 C.F.R. 493.1240 Condition: Preanalytic systems; D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6000 - 42 C.F.R. 493.1290 Condition: Postanalytic systems; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director; D6168 - 42 C.F.R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel;
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on surveyor observation, review of laboratory policy, proficiency testing (PT) records, and confirmed in interview, the laboratory failed to enroll in a Centers for Medicare and Medicaid Services (CMS) approved PT program for chemistry analysis on the i-STAT EG7+ cartridge for seven of seven analytes in the subspecialty of Routine Chemistry from the years of 2024, 2025, and 2026. Refer to D2001.

D2001	ENROLLMENT CFR(s): 493.801(a)(1)(2)(i) The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; and This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policy, proficiency testing (PT) records, patient annual testing volumes, and confirmed in interview, the laboratory failed to enroll in a CMS approved PT program for seven of seven analytes in the subspecialty of Routine Chemistry from the years of 2024, 2025, and 2026. Findings included: 1. During a tour of the facility respiratory therapy testing areas on 04/14 /2026 at 09:40 AM, the surveyor observed multiple i-STAT testing devices (Serial Numbers: 372601 and 368434) available for patient testing. Also available for use in all respiratory testing areas were i-STAT EG7+ cartridges (Lot Number: 101944417). In the intensive care unit at 09:45 AM, the respiratory therapy technical consultant (TC-3) confirmed EG7+ cartridges were the only i-STAT testing cartridges used for patient blood gas analysis by respiratory therapists. TC-3 further confirmed all regulated analytes tested on the EG7+ cartridge were reported to patient physicians. 2. Review of laboratory policy, "Individualized Quality Control Plan (IQCP) for i-STAT I" (reviewed by the laboratory director on 02/17/2025) revealed the following: " ...I. Policy: The Quality Control Plan (IQCP) is for the i-STAT testing performed in the following areas: EG7+ in ER EG7+ in MICU EG7+ in SICU EG7+ in NICU" Review of laboratory policy, "Ancillary Testing Program" (approved by the laboratory director on 10/2019) revealed the following: " ...2. Proficiency test samples will be utilized on a regular basis. Results of the evaluations received will be reviewed and corrective actions taken if necessary." 3. Review of laboratory American Proficiency Institute (API) PT records from 2024-2026, revealed the laboratory failed to enroll in PT for the following regulated analytes performed on the i-STAT EG7+ cartridge: a. Sodium b. Potassium c. Hematocrit d. Hemoglobin e. pH f. pCO2 g. pO2 On 04/14 /2026 at 09:57 AM the laboratory manager was asked to provide documentation of enrollment in an approved CMS PT agency for the above regulated analytes tested on the i-STAT EG7+ cartridge in 2024 and 2025. No documentation was provided. 4. Review of patient annual testing volumes in 2024 and 2025 performed on the i-STAT EG7+ cartridge for the above regulated analytes, revealed the following: 2024 Patient annual testing volume: 9,530 2025 Patient annual testing volume: 9,506 5. In an interview on 04/14/2026 at 10:20 AM in the laboratory conference room, TC-3 stated the laboratory began i-STAT EG7+ cartridge patient testing in 2015. TC-3 further confirmed the laboratory failed to designate enrollment in a CMS approved PT program to determine compliance for seven of seven regulated analytes performed on the i-STAT EG7+ testing cartridge from 2015-2026. Word Key CMS- Centers for Medicare and Medicaid Services pCO2- partial pressure of carbon dioxide pO2- partial pressure of oxygen pH- potential of hydrogen ER- Emergency Room MICU- Medical Intensive Care Unit SICU- Surgical Intensive Care Unit NICU- Newborn Intensive Care Unit
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)

	(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: "Based on review of the American Proficiency Institute's (API) proficiency testing (PT) records, and staff interview, the laboratory failed to achieve satisfactory performance in two of three testing events for the analyte of Hemoglobin A1C in 2025 (refer to D2096), and Gram Stain testing in 2024 (refer to D2028) resulting in an initial unsuccessful performance.
D2028	BACTERIOLOGY CFR(s): 493.823(e) (e) Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2024 and staff interview, the laboratory failed to achieve satisfactory performance for two of three events for gram stain testing. The findings included: 1. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2024 included the following scores for gram stain testing, resulting in an unsatisfactory performance, for two of three events: 2024 Event 1 60% 2025 Event 3 60% 2. In an interview on 4/15/2026 at 14:48 hours, in the conference room, General Supervisor (GS) 2 confirmed the gram stain proficiency testing failures in 2024.
D2096	ROUTINE CHEMISTRY CFR(s): 493.841(f) (f) Failure to achieve satisfactory performance for the same analyte or test in two consecutive testing events or two out of three consecutive testing events is unsuccessful performance. This STANDARD is not met as evidenced by:

	Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2025, and staff interview, the laboratory failed to achieve satisfactory performance for two of three events for the analyte of hemoglobin A1C. The findings included: 1. A review of the laboratory's American Proficiency Institute's proficiency testing records from 2025 determined the laboratory received the following unsatisfactory performances for hemoglobin A1C on two of three events: 2025 Event 1 60% 2025 Event 3 60% 2. In an interview conducted on 04/14/2026 at 11:00 am in the conference room, technical consultant number 3 (as listed on Form CMS 209) confirmed the findings.
D3021	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(c)(1) Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's logs and graphs, and staff interview, the laboratory failed to follow its policies for performing the quarterly alarm checks on the blood bank refrigerator, freezer, and platelet incubator for 4 of 4 checks done in 2025. Findings include: 1. A review of the laboratory's policy titled 'Refrigerator/Freezer Alarm Checks' revealed the following: "To assure that blood and blood products are maintained at the required temperature Transfusion Services will perform quarterly alarm testing on each refrigerator/freezers used to store blood and frozen blood products. Procedure Refrigerators Low Activation Test: - Place the three refrigerator thermocouples in the cup of ice water at a temperature of 2-4C. - Add a few cubes of ice at a time to slowly decrease temperature until alarm goes off (1.5C); continue until the Reese Monitor alarm goes off. Make sure the graph has recorded this drop in temperature. - Record this temperature as the low activation temperature in log. Record low alarm check next to the dip on graph and also on the Reese Monitor tape. High Activation Test: - Place the three refrigerator thermocouples in the cup of ice water at a temperature of 2-4C. - Add a few drops of warm water at a time to slowly increase temperature until alarm goes off (5.5C); continue until the Reese Monitor alarm goes off. Make sure the graph has recorded this increase in temperature. - Record this temperature as the high activation temperature in log. Record high alarm check next to the increase on graph and also on the Reese Monitor tape. Procedure Freezer - Open freezer door and place the three thermocouples in the antifreeze container located on top shelf. - Place room temperature antifreeze solution by drops slowly allowing the temperature of the antifreeze to warm. - Record the temperature at which the alarm sounds on log (-20.0C). Continue until the Reese monitor alarm goes off. Make sure the graph has recorded this increase in temperature and record high alarm check. Record this temperature as the high activation temperature in log. Record "high alarm check" next to dip on graph and also on the Reese Monitor tape." 2. A review of the laboratory's policy titled 'Platelet Incubator Alarm Test' revealed the following: "A quarterly check of the high and low temperature of activation will be performed. Low activation: - Prepare a cup of water at room temperature of 22C to 23C and place inside the incubator. - Slide the four thermocouples out of the holding clip located in the chamber's right side and upper back side. Place in the room temperature cup of water. - Add a few cubes of ice at a time to slowly decrease temperature until alarm goes off (20C); continue until the

	Reese Monitor alarm goes off. Make sure the graph has recorded this drop in temperature. - Record this temperature as the low activation temperature in log. Record low alarm check next to the dip on graph and also on the Reese Monitor tape. High activation: - Prepare a cup of water at room temperature of 22C to 23C and place inside the incubator. - Slide the four thermocouples out of the holding clip located in the chamber's right side and upper back side. Place in the room temperature cup of water. - Add a few drops of warm water at a time to slowly increase temperature until alarm goes off (23.5C); continue until the Reese Monitor alarm goes off. Make sure the graph has recorded this drop in temperature. - Record this temperature as the high activation temperature in log. Record high alarm check next to the dip on graph and also on the Reese Monitor tape." 3. A review of the laboratory's Refrigeration/Freezer/Platelet Incubator Alarm Testing logs revealed the quarterly alarm checks were performed on the following dates: 3/20/25 6/30/25 9/28/25 12/20 /25 4. A review of the refrigerator, freezer and platelet incubator graphs, for those dates listed above, revealed no dips or documentation of the alarm checks being performed. 5. In an interview on 4/15/26 at 9:40 a.m. in the laboratory, technical supervisor #1 (as indicated on the CMS 209 form) revealed the laboratory only tests the alarms via the digital display and does not follow the procedures in the Refrigerator/Freezer Alarm Checks and Platelet Incubator Alarm Test policies when performing the quarterly alarm checks. Key: C = Degrees Celsius
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 a review of the laboratory's policies, the hospital's policies, and staff interview, the laboratory failed to ensure that one of one procedure for identification of transfusion reactions was defined for the personnel responsible for recognizing and reporting the signs and symptoms of potential transfusion reactions. Findings include: 1. A review of the laboratory's policy titled 'Transfusion Reaction Investigation' revealed the following: "Transfusion Reaction "signs and symptoms": Urticaria Dyspnea Fever* Chills Hemoglobinuria Shock Chest Pains Generalized Bleeding Hypotension Oliguria or Anuria Nausea Back pain Flushing Infusion site pain * An increase of at least 2F over the pre-transfusion temperature." 2. A review of the hospital's policy titled 'Transfusion of Blood and Blood Products' revealed the following: "For all reactions (including urticaria, hives, fever & chills): 1. Stop the transfusion(s) but keep vein open with normal saline ..." *The hospital's policy failed to define all signs and symptoms of potential transfusion reactions. 3. In an interview on 4/16/26 at 10:00 a.m. in the conference room, after review of the records, technical supervisor #1 (as indicated on the CMS 209 form) confirmed the above findings.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition,

	retain the following: This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory quality control documentation, and interview, the laboratory failed to retain hematology quality control data for the DxH hematology analyzer for 29 of 245 days reviewed from May 2025 to December 2025. The findings include: 1. Review of the laboratory policy titled "Performance Verification (Quality Management)", section III "Analytical", subsection "Internal Audit System" included the following information: " ... Quality control records will be maintained in each department and reviewed monthly by the department Team Leader and their supervisors, or in his/her absence, a Team Leader" 2. Review of the hematology "QC Summary Report" from May 2025 to December 2025 for the DxH1 hematology analyzer did not include the following QC dates for the monthly review: May 12, 2025, through June 7, 2025 (27 days) November 3, 2025, and November 4, 2025 (2 days) Surveyor asked Testing Personnel (TP) 3, on 4/15/2026 at 16:00 hours, in the conference room, for QC records for the above date, and none were provided. 3. In an interview on 4/16/2026 at 9:00 hours, in the conference room, TP 3 confirmed the laboratory did not retain QC records for the above dates.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2024 and staff interview, the laboratory failed to have documentation of evaluating proficiency testing results returned as 'not graded' by the proficiency testing agency on 1 of 3 events. The findings included: 1. A review of the laboratory's American Proficiency Institute's Core Chemistry proficiency testing records from 2024 (events 1, 2 and 3) identified the following proficiency testing results returned as 'not graded' by the proficiency testing agency: a) 2024 event 1 Bilirubin, Total sample: CH-02 sample: CH-03 sample: CH-05 2. Further review of the laboratory's proficiency testing records determined the laboratory failed to have documentation of evaluating these non graded results. 3. In an interview conducted on 04/14/2026 at 11:00 am in the conference room, technical consultant number 3 confirmed the results had not been evaluated.
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 American Proficiency Institute's proficiency testing records from 2024, review of the laboratory's Corrective Action Checklist from 2024, and staff interview, the laboratory failed to have documentation of the remediation of patients as required by its policy for 1 of 3 events. The findings

	included: 1. A review of the laboratory's American Proficiency Institute's Core Chemistry proficiency testing records from 2024 (events 1, 2, and 3) identified the following failed results: a) Event 3 Analyte: Bilirubin, Direct (Neonatal) Score: 40% 2. A review of the laboratory's Corrective Action Checklists for the Neonatal Direct Bilirubin failures from event 3 determined the laboratory failed to had documentation of the potential effect on patient results as required by the form. 3. In an interview conducted on 04/14/2026 at 11:00 am in the conference room, technical consultant number 3 (as listed on Form CMS 209) confirmed the findings.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of manufacturer's instructions, review of patient records, and staff interview, the laboratory failed to meet the meet the requirements for preanalytic systems. The findings included: 1. The laboratory failed to ensure lactate samples were centrifuged within 15 minutes of collection as required by the manufacturer (refer to D5311 I). 2. The laboratory failed to ensure ammonia samples were centrifuged in a cold centrifuge as required by the manufacturer (refer to D5311 II).
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 on review of the manufacturer's instructions for the Beckman Coulter Lactate assay, review of patient test records from October 2025 - December 2026, and staff interview, the laboratory failed to ensure plasma was separated from the cells within 15 minutes for 68 of 260 samples. The finding included: 1. The manufacturer's instructions for the Beckman Coulter Lactate assay (BAOSR693 13, September 2025) under the section titled "Specimen Storage and Stability" stated: "Keep the sample on ice and separate plasma from cells within 15 minutes of collection." 2. A review of patient test records from October 2025 - December 2026 identified 68 of 260 results where the time from collection to receipt in the laboratory exceeded 15 minutes. Examples with elevated results were: a) Date: 10/6/2025 Accession number: 003172025279000838 Medical Record #: 4158957 Collection: 19:11 Received: 21:01 Elapsed time: 110 minutes Result: 5.1 normal range: 0.5 - 2.2 b) Date: 11/26/2025 Accession number: 003172025330000226 Medical Record #: 503048 Collection: 05:

	01 Received: 06:28 Elapsed time: 87 minutes Result: 3.2 normal range: 0.5 - 2.2 c) Date: 12/27/2025 Accession number: 003172025361000500 Medical Record #: 584172 Collection: 09:32 Received: 11:05 Elapsed time: 93 minutes Result: 3.3 normal range: 0.5 -2.2 d) Date: 12/27/2025 Accession number: Medical Record #: 4077146 Collection: 12:40 Received: 13.10 Elapsed time: 30 minutes Result: 2.6 normal range: 0.5 - 2.2 e) Date: 12/27/2025 Accession number: 003172025361000684 Medical Record #: 606457 Collection: 14:00 Received: 14:25 Elapsed time: 25 minutes Result: 7.0 normal range: 0.5 - 2.2 f) Date: 12/30/2025 Accession number: 003172025364000421 Medical Record #: 657627 Collection: 10:30 Received: 11:08 Elapsed time: 38 minutes Result: 2.4 normal range: 0.5 - 2.2 3. In an interview conducted on 04/14/2026 at 03:50 pm in the conference room, technical consultant number 4 (as listed on Form CMS 209) confirmed the manufacturer's 15 minute requirement had been exceeded. II. Based on review of the manufacturer's instructions for the Beckman Coulter Ammonia assay, surveyor observation of laboratory equipment in the laboratory, review of patient test records from November 2025 and December 2025, and staff interview, the laboratory failed to ensure 440 of 440 samples for ammonia testing were centrifuge at a cold temperature as required by the manufacturer. The findings included: 1. The manufacturer's instructions for the Beckman Coulter Ammonia assay (JL840872 R4, 2021-10-28) under the section titled "Specimen Collection and Handling" stated: "The collection tube should be completely filled with blood and immediately placed on ice. Centrifuge (cold) the sample to separate the plasma and store on ice until analysis." 2. Surveyor observation of laboratory equipment on 04/15/2026 at 9:30 am identified the laboratory had a single centrifuge in use for centrifuging samples. It was: ThermoScientific Sorval ST Plus centrifuge Serial number: Temperature adjustment of the centrifuge was not possible. All samples were centrifuged at room temperature. 3. A review of ammonia test records from November 2025 and December 2025 determined the laboratory performed testing on 440 samples. 4. Examples of elevated patient results potentially caused by not centrifuging a cold temperatures were: a) Date: 12/10/2025 Accession number: 3172025344000260 Result: 259 normal range: 16 - 53 b) Date: 12/14/2026 Accession number: 3172025349000100 Result: 106 normal range: 16 - 53 c) Date: 12 /16/2025 Accession number: 3172025350000180 Result: 136 normal range: 16 - 53 d) Date: 12/21/2025 Accession number: 3172025356000120 Result: 98 normal range: 16 - 53 e) Date: 12/28/2025 Accession number: 3172025362000620 Result: 88 normal range: 16 - 53 f) Date: 12/30/2025 Accession number: 3172025364000460 Result: 124 normal range: 16 - 53 5. In an interview conducted on 04/15/2026 at 10:00 am, the quality director confirmed the findings after her review of the records.
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 the laboratory's records and staff interview, the laboratory failed to meet the requirements for analytic systems. The findings included: 1. The laboratory failed to failed to follow their own testing procedure in glucose patient

	analysis (refer to D5403). 2. The laboratory failed to document complete PT reference range verification prior to patient analysis (refer to D5421). 3. The laboratory failed to perform complete establishment studies when modifying an FDA approved test (refer to D5423).
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policy, patient final testing reports in 2025, and confirmed in interview, the laboratory failed to follow their own testing procedure in glucose patient analysis for two of four patients randomly reviewed in 2025. Findings included: 1. During a tour of the facility on 04/14/2026 at 11:10 AM, the surveyor observed multiple Accu-Chek Inform II Glucometers located in the Surgical Intensive Care Unit (MICU) (Serial Numbers: UU144443292 and UU14622370) and Trauma Emergency Room area (ER) (Serial Numbers: UU14447549). 2. Review of laboratory policy, "Point of Care - Glucometer Inform II Procedure" (approved by the laboratory director on 03/03/2025) revealed the following: " ...Interpretation of results: ...Results less than 40 mg/dL or greater than 300 mg/dL must be verified by repeating the test with a fresh strip. If result repeats low (less than 54 mg/dL) treat patient for hypoglycemia and notify the attending physician if the patient is not on a sliding scale or glucose protocol. If the glucose repeats greater than 400 mg/dL notify the physician if the patient is not on a sliding scale or glucose protocol." 3. Random review of patient testing reports in 2025 revealed the following patient point of care Accu-Chek glucose results greater than 300 mg/dL documented: 01/10/2025 1. Patient ID: Refer to Patient Alias List 4 a. Performed at: 4:42 PM Result: 410 (H) mg/dL The laboratory quality manager was asked to provide documentation of repeating the above patient test with a fresh testing strip, or laboratory serum glucose confirmation. The documentation below was provided: b. Performed at: 9:05 PM (Time elapsed since last Accu-Chek reading: four hours and twenty-three minutes.) Result: 318 (H) mg/dL No repeat of the above patient test result was documented by Accu-Check glucose testing or laboratory serum glucose confirmation. 11/12/2025 2. Refer to Patient Alias List 6 c. Performed at: 2:14

	PM Result: 395 (H) mg/dL The laboratory quality manager was asked to provide documentation of repeating the above patient test with a fresh testing strip, or laboratory serum glucose confirmation. The documentation below was provided: d. Performed at: 5:50 PM Result: 268 mg/dL (Time elapsed since last Accu-Chek reading: three hours and thirty-six minutes.) 4. In an interview on 04/15/2026 at 11:14 AM in the laboratory conference room, the laboratory quality manager confirmed the laboratory failed to follow their own testing procedure in glucose patient analysis for two of four patients randomly reviewed in 2025. Word Key (H)- High
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (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 a review of the RPR Test Card for Syphilis Instructions for Use, surveyor observation, patient test reports, and staff interview, the laboratory failed to ensure the patient's results for Rapid Plasma Reagin (RPR) testing were read under a high-intensity light source for 2 of 2 patient tests observed on April 15, 2026. Findings include: 1. A review of the RPR Test Card for Syphilis Instructions for Use revealed the following: "Immediately read results macroscopically in the "wet" state under a high-intensity light source." 2. Surveyor observation on 4/15/26 at 9:45 a.m. in the laboratory revealed testing person #6 performing RPR testing. When it was time to read the patient's results, testing person #6 failed to read the results under a high-intensity light source, per the manufacturer's requirements. 3. A review of the patient's test reports revealed the following 2 patients were run by testing person #6 on 4/15/26 at 9:45 a.m.: - Patient ID: 110513033 - Patient ID: 110513017 4. In an interview on 4 /16/26 at 10:30 a.m. in the conference room, after review of the records, technical supervisor #1 (as indicated on the CMS 209 form) confirmed the above findings.
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: Based on laboratory policy, Prothrombin Time (PT) Innovin 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 Innovin reagent lot rollover performed in 2025. Findings included: 1. Review of laboratory policy, "Prothrombin Time on the CS-2500" (approved by the laboratory director on 03/10/2023) revealed the following: " ...

	XII. Limitations of Procedure 1. Many commonly administered drugs may affect the results obtained in Prothrombin time testing." Review of laboratory policy, "Method Validation" (approved by the laboratory director on 08/2020) revealed the following: " ...VI Reference Range Verification: ...B. Procedure 1. The samples are selected from the usual and typical population to which the reference range will be applied. The samples must be from known clinically healthy members of the population. 2. A minimum of 20 representative samples must be run to verify manufacturer's reference range." 2. Review of Prothrombin Time (PT) Innovin (Lot Number: 564668) reagent lot rollover study performed in February 2026, revealed the laboratory failed to document patient demographics for the 20 normal patients referenced in the laboratory policy. 3. Random review of patient final reports, revealed the following PT patient specimens analyzed in December 2025: a. Refer to Patient Alias List 7 PT Patient "Normal" Range: 9.3-11.7 seconds 4. In an interview on 04/15/2026 at 10:29 AM in the laboratory conference room, the coagulation lead technologist confirmed the laboratory failed to document complete PT reference range verification prior to patient analysis for one of one Innovin 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: Based on surveyor observation, manufacturer's instructions, laboratory policy, establishment studies, UniPOC 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 system in 2025. Findings included: 1. During a tour of the facility on 04/14/2026 at 11:10 AM, the surveyor observed multiple Accu-Chek Inform II Glucometers located in the Surgical Intensive Care Unit (MICU) (Serial Numbers: UU144443292 and UU14622370) and Trauma Emergency Room area (ER) (Serial Numbers: UU14447549). 2. Review of Roche manufacturer instructions letter, "TP-01030" (Delivered on 08/12/2020), revealed the following: " ...Roche conducted critically ill studies focused on hospitalized patients receiving intensive critical care, or intensive medical intervention and therapy. After much consideration and analysis of the results from these studies, we have made the difficult decision to not re-submit the 501(k) application and to no longer pursue a critically ill claim for Accu-Chek Inform II. ...What This Means You can continue using the Accu-Chek Inform II system according to the label. The system has not received FDA clearance for use with patients receiving intensive medical intervention or therapy." 3. Review of laboratory policy, "Glucose Testing in Critically Ill Patients" (approved by the laboratory director on 10/15/15) revealed the following: "Valley Baptist Medical Center Laboratory Medical Director with consensus from the Emergency Room

	Medical Director and the Intensive Care Unit Medical Director, and approval from the Critical Care Committee, has initiated the following policy to provide safe, effective, and timely care for hospital patients in an acute care setting who are critically ill. ...I. Procedure A. The following patients who exhibit any of the following are considered critically ill: Lactic Acidosis Septic Shock Vasopressor Dependent B. Glucose bedside testing must not be used exclusively in these patient populations. A venous glucose specimen must be performed at intervals so as to confirm patient glucose measurements." Review of laboratory policy, "Chemistry: Method Validation" (approved by the laboratory director in 08/2020) revealed the following: "1. Purpose To verify or establish performance specifications for each new method for the following performance characteristics---accuracy, precision, reference range verification, interferences, and reportable range verification for each analytic procedure before implementation." 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 UniPOC middleware system, revealed the following MICU, ER and MRI patients tested using the Accu-Chek Inform II glucometer in 2025: January 10th, 2025- 3T MRI a. Refer to Patient Alias List 4 March 4th, 2025- MICU b. Refer to Patient Alias List 5 November 12th, 2025- ER c. Refer to Patient Alias List 6 6. In an interview on 04/14/2026 at 02:20 PM in the MICU, the on shift charge nurse and one registered nurse (RN) both confirmed they would use the Accu-Chek Inform II on critically ill patients with lactic acidosis, septic shock or who were vasopressor dependent. In an interview on 04/14/2026 at 02:25 PM in the ER, the on shift RN confirmed she would use the Accu-Chek Inform II on critically ill patients with lactic acidosis, septic shock or who were vasopressor dependent. In an interview on 04/14 /2026 at 02:31 PM in the hospital hallway, 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 system in 2025. Word Key MICU- Medical Intensive Care Unit ER- Emergency Room MRI- Magnetic Resonance Imaging
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (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 laboratory's test menu, review of the laboratory's calibration verification records from 2024 and 2025, and staff interview, the laboratory failed to have documentation of performing calibration verifications on 4 of 39 analytes on the Beckman DxC700 analyzer, 3 of 37 analytes on the Beckman AU480 analyzer and 2 of 2 analytes on the Advanced Instruments Osmometer. The findings included: 1. A review of the laboratory's test menu identified the following tests were performed: a) Beckman Coulter DxC700 analyzer Albumin, blood urea nitrogen, calcium, cholesterol, chloride, creatine, glucose, potassium, lactate, magnesium, sodium, phosphate, total protein, triglycerides, carbon dioxide, iron, ethanol, ammonia, uric acid, alkaline phosphatase, alanine aminotransferase, amylase, aspartate aminotransferase, creatine kinase, lactate dehydrogenase, lipase, total bilirubin, direct bilirubin, high density lipoprotein, low density lipoprotein, urine ethanol, urine potassium, urine sodium, urine uric acid, urine total protein, urine urea nitrogen, cerebral spinal fluid glucose, cerebral spinal fluid total protein, and cerebral spinal fluid lactate. b) Beckman AU480 analyzer Alkaline phosphatase, alanine aminotransferase, amylase, aspartate aminotransferase, creatine kinase, lipase, total bilirubin, direct bilirubin, high density lipoprotein, carbon dioxide, iron, ethanol, ammonia, uric acid, urine uric acid, urine total protein, urine urea nitrogen, urine ethanol, potassium, sodium, albumin, blood urea nitrogen, calcium, cholesterol, calcium, creatine, glucose, lactate, magnesium, sodium, phosphate, total protein, triglycerides, potassium, cerebral spinal fluid glucose, cerebral spinal fluid total protein, and cerebral spinal fluid lactate . c) Advanced Instruments Osmometer serum osmolality, urine osmolality 2. Each of the listed tests utilized 2 calibrators and 2 levels of quality control and thus required calibration verification every 6 months. 3. A review of the laboratory's calibration verification records from 2024 and 2025 determined the laboratory failed to perform calibration verification on the following analytes: a) Beckman Coulter DxC700 - June 2024 cerebral spinal fluid glucose cerebral spinal fluid total protein cerebral spinal fluid lactate - January 2025 urine uric acid cerebral spinal fluid glucose cerebral spinal fluid total protein cerebral spinal fluid lactate - June 2025 cerebral spinal fluid glucose cerebral spinal fluid total protein cerebral spinal fluid lactate - December 2025 cerebral spinal fluid glucose cerebral spinal fluid total protein cerebral spinal fluid lactate b) Beckman 480 - June 2024 cerebral spinal fluid glucose cerebral spinal fluid total protein cerebral spinal fluid lactate - December 2024 cerebral spinal fluid glucose cerebral spinal fluid total protein cerebral spinal fluid lactate urine uric acid magnesium - June 2025 cerebral spinal fluid glucose cerebral spinal fluid total protein cerebral spinal fluid lactate potassium December 2025 cerebral spinal fluid glucose cerebral spinal fluid total protein cerebral spinal fluid lactate 4. In an interview conducted on 04/15/2026 at 2:50 pm in the conference room, the quality director confirmed the findings after she reviewed the records.
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 a review of the laboratory's policies, test records, quality control records, and staff interview, the laboratory failed to ensure quality control materials were run in each test run for Rapid Plasma Reagin (RPR) testing for 12 of 12 months from January to December 2025. Findings include: 1. A review of the laboratory's policy titled 'RPR Card Test' revealed the following: "Controls with graded reactivity should be included in each test run to confirm optimal reactivity of the antigen." 2. A review of the laboratory's test records revealed RPRs are run on each of the three shifts (day, evening and night). 3. A review of the laboratory's quality control records for all 12 months from January to December 2025 revealed that 3 levels of quality control material (non-reactive, weak reactive, and reactive) were only run on one shift each day of patient testing, not each run as required per the laboratory's policy. 4. Further review of the laboratory's test records revealed the laboratory estimated performing 2884 RPR tests annually. 5. In an interview on 4/15/26 at 11:15 a.m. in the conference room, after review of the records, technical supervisor #1 (as indicated on the CMS 209 form) confirmed the above findings.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on review of the laboratory's Individual Quality Control Plan (IQCP) for Ruptured of Membrane, review of the laboratory's quality control records from January 2025 to January 2026, review of patient test records from May 2025 to December 2025, and staff interview, the laboratory failed to follow its IQCP for modifying the frequency of quality control testing 4 of 17 days when quality control was performed. The findings included: 1. The laboratory's Individual Quality Control Plan (IQCP) for Ruptured of Membrane (effective 10/2024) stated the laboratory modified the frequency of quality control testing for Ruptured of Membrane testing to every 30 days or new shipment of reagent. 2. A review of the laboratory's Ruptured of Membrane quality control records from January 2025 to January 2026 identified the laboratory performed quality control testing on 17 days. The days performed were: 1/2 /2025 1/20/2025 (18 days later) 2/9/2025 (20 days later) 3/5/2025 (23 days later) 3/24 /2025 (19 days later) 4/1/2025 (8 days later) 5/7/2025 (36 days later) 6/19/2025 (43 days later) 7/1/2025 (12 days later) 8/4/2025 (34 days later) 9/1/2025 (28 days later) 9 /19/2025 (18 days later) 10/1/2025 (12 days later) 10/4/2025 (3 days later) 10/20/2025 (16 days later) 11/1/2025 (12 days later) 12/1/2025 (31 days later) 1/2/2026 (32 days later) 3. A review of patient test records from May 2025 to December 2025 identified the following 7 patients tested on days when more than 30 days had passed since the previous quality control testing was performed: a) May 1, 2025 to May 6, 2025 Medical Record number: 4159500 tested: 05/05/2025 Medical Record number: 4159462 tested: 05/04/2025 Medical Record number: 4013686 tested: 05/04/2025 Medical Record number: 4125436 tested: 05/02/2025 b) June 6, 2025 to June 18, 2025 Medical Record number: 410606 tested: 06/18/2025 Medical Record number: 416123 tested: 06/17/2025 Medical Record number: 588128 tested: 06/08/2025 c) August 1, 2025 to August 3, 2025 no patients tested d) January 1, 2025 no patients tested 4. In an interview conducted on 04/15/2026 at 9:30 am in the conference room, the quality director confirmed the findings after her review of the records.

D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g) (d)(3)(iii) Test procedures producing graded or titered results, include a negative control material and a control material with graded or titered reactivity, respectively; This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's records, and staff interview, the laboratory failed to have documentation of testing a control material with titered reactivity on 7 of 7 days patient's Rapid Plasma Reagin (RPR) and Rheumatoid Factor (RF) titers were performed from October to December 2025. Findings include: 1. A review of the laboratory's policy titled 'RPR Card Test' revealed the following: "Controls with graded reactivity should be included in each test run to confirm optimal reactivity of the antigen. All REACTIVE RPRs need to be titered and sent out for confirmation." 2. A review of the laboratory's policy titled 'Sure Vue RF Latex' revealed the following: "Prior to each set of determination, the latex reagent should be tested with each run using the positive and negative controls provided in the kit. Both controls should be used following steps 4 through 8 of the Qualitative procedure." *There was no mention in the laboratory's policies of testing control material with titered reactivity when performing RPR and RF titers on patient samples. 3. A review of the laboratory's records from October to December 2025 revealed the following 7 days when RPR or RF titers were performed on patients and there was no documentation of titered control material being run: Date: 10/31/25 Patient ID: 110084951 RPR Titer: 1:2 Date: 11/12/25 Patient ID: 110111390 RPR Titer: 1:16 Date: 12/2/25 Patient ID: 110165362 RPR Titer 1:4 Date: 12/12/25 Patient ID: 110195419 RPR Titer 1:64 Date: 12/21/25 Patient ID: 110207982 RPR Titer 1:16 Date: 12/21/25 Patient ID: 110214392 RF Titer 1:32 Date: 12/29/25 Patient ID: 110226958 RF Titer 1:128 4. In an interview on 4/15/26 at 11:15 a.m. in the conference room, after review of the records, technical supervisor #1 (as indicated on the CMS 209 form) confirmed the above findings.
D5463	CONTROL PROCEDURES CFR(s): 493.1256(d)(7)(g) (d)(7) Over time, rotate control material testing among all operators who perform the test. This STANDARD is not met as evidenced by: Based on review of survey documentation, laboratory policy, quality control (QC) records, and confirmed in interview, the laboratory failed to rotate QC performance among all operators who perform Hemochron Elite coagulation testing for two of two instruments in 2024 and 2025. Findings included: 1. Review of survey documentation submitted at time of survey, 04/14/2026, revealed the laboratory performed ACT coagulation testing on the Hemochron Signature Elite (Serial Numbers: 16928 and 16929) in the hospital Cath Lab. 2. Review of laboratory policy, "Individual Quality Control Plan (IQCP) for Hemochron Signature Elite" (approved by the laboratory director on 02/17/2025) revealed the following: " ...b. On new shipments or every 30 days, perform acceptability testing by analyzing two levels of Direct check liquid QC." 3. Review of Hemochron Signature Elite ACT QC results in 2024 and 2025 revealed the following: 2024 a. Serial Number: 16928 January-December: 12 months QC performed Performed by Testing Person (TP): TP-69 b. Serial Number: 16929

	January-December: 12 months QC performed Performed by Testing Person (TP): TP-69 2025 c. Serial Number: 16928 January-December: 12 months QC performed Performed by Testing Person (TP): TP-69 d. Serial Number: 16929 January-December: 12 months QC performed Performed by Testing Person (TP): TP-69 On 04 /15/2026 at 11:18 AM in the laboratory conference room, the point of care (POC) lead was asked if multiple TP performed ACT patient testing on the above Hemochron Signature Elite devices. The POC lead stated all nursing staff assigned to the Cath Lab performed ACT patient testing during active procedures. 4. In an interview on 04/15 /2026 at 11:18 AM in in the laboratory conference room, the POC lead confirmed the laboratory failed to rotate QC performance among all operators who perform Hemochron Elite coagulation patient testing for two of two instruments in 2024 and 2025. Word Key ACT- Activated clotting time
D5631	CYTOLOGY CFR(s): 493.1274(c)(6) (c)(6) An evaluation of the case reviews of each individual examining slides against the laboratorys overall statistical values, documentation of any discrepancies, including reasons for the deviation, and, if appropriate, corrective actions taken. (d) Workload limits. The laboratory must establish and follow written policies and procedures that ensure the following: This STANDARD is not met as evidenced by: Based on review of laboratory personnel, laboratory cytology statistics, laboratory policy, and confirmed in interview, the laboratory failed to ensure individual statistics were performed for each personnel reviewing cytology slides, against the laboratory's overall statistical values, for two of two personnel reviewing and reporting cytology slides in 2024 and 2025. The findings include: 1. Review of laboratory personnel performing cytology slide examination and reporting included the following two testing personnel (TP): TP 18 TP 22 2. Review of the laboratory annual cytology statistics for 2024 and 2025 did not include the statistics of the two testing personnel as compared to the overall laboratory statistics. 3. Review of the laboratory policy titled "Non-Gyn Cytopathology Quality Assurance and Quality Control Surveillance" and "Cytology Specimen Assessment", did not include the instructions for the statistical comparison of individuals performing cytology slide examination and reporting to the overall laboratory statistics. 4. In an interview on 4/15/2026 at 13:40 hours, in the conference room, general supervisor (GS) 3 confirmed the annual cytology statistics did not include a comparison of individuals performing cytology slide examination and reporting to the overall laboratory statistics.
D5641	CYTOLOGY CFR(s): 493.1274(d)(2)(ii) (d)(2)(ii) For the purposes of establishing workload limits for individuals examining slides in less than an 8-hour workday (includes full-time employees with duties other than slide examination and part-time employees), a period of 8 hours is used to prorate the number of slides that may be examined. The formula-- Number of hours examining slides X 100 / 8 is used to determine maximum slide volume to be examined; This STANDARD is not met as evidenced by:

Based on review of laboratory policies and procedures, workload records, and interview, the laboratory failed to establish written policies and procedures to ensure the prorated workload limits for personnel performing primary slide nongynecological (non-gyn) examination would not be exceeded when examining slides in less than eight hours for 329 out of 394 days for records reviewed from January 2024 to December 2025. The findings include: 1. Review of the laboratory policy titled "Quality Assurance and Quality Control Surveillance", section "XII. Cytology - Daily Slide Count" did not include a procedure on prorating the workload limit when examining slides in less than an eight- hour day. 2. Review of the laboratory "Pathologist Workload Log Sheet" for 2024 and 2025 included the following 329 days where the total number of half slides examined (maximum workload limit - 24 slides per hour) exceeded the prorated workload limit: Date, Total half slides Examined, Time Screened (minutes), [Prorated Slides Allowed] January 2024: 13 out of 19 days 01/04/2024 8 12 [5] 01/08/2024 10 12 [5] 01/10/2024 10 15 [6.3] 01/11/2024 4 8 [3.3] 01/15/2024 8 15 [6.3] 01/16/2024 14 22 [9.2] 01/17/2024 4 7 [2.9] 01/18/2024 8 15 [6.3] 01/19/2024 4 6 [2.5] 01/23/2024 6 12 [5] 01/29/2024 7 15 [6.3] 01/30/2024 13 30 [12.5] 01/31/2024 4 6 [2.5] February 2024: 8 out of 15 days 02/05/2024 6 8 [3.3] 02/06/2024 4 6 [2.5] 02/07/2024 4 6 [2.5] 02/08/2024 4 6 [2.5] 02/09/2024 4 6 [2.5] 02/20/2024 12 18 [7.5] 02/22/2024 6 10 [4.2] 02/27/2024 8 12 [5] March 2024: 12 out of 13 days 03/05/2024 6 10 [4.2] 03/08/2024 4 8 [3.3] 03/11/2024 6 12 [5] 03/12/2024 12 22 [9.2] 03/13/2024 8 12 [5] 03/14/2024 4 8 [3.3] 03/20/2024 6 10 [4.2] 03/22/2024 6 10 [4.2] 03/25/2024 6 10 [4.2] 03/26/2024 8 12 [5] 03/27/2024 20 45 [18.5] 03/28/2024 6 10 [4.2] April 2024: 21 out of 21 days 04/02/2024 12 15 [6.3] 04/03/2024 6 10 [4.2] 04/04/2024 4 6 [2.5] 04/05/2024 10 18 [7.5] 04/08/2024 6 10 [4.2] 04/09/2024 2 3 [1.3] 04/10/2024 6 10 [4.2] 04/11/2024 6 10 [4.2] 04/12/2024 8 18 [7.5] 04/13/2024 2 3 [1.3] 04/16/2024 8 15 [6.3] 04/17/2024 6 10 [4.2] 04/18/2024 10 19 [7.9] 04/19/2024 8 15 [6.3] 04/20/2024 4 7 [2.9] 04/23/2024 2 3 [1.3] 04/25/2024 2 3 [1.3] 04/26/2024 4 6 [2.5] 04/29/2024 8 16 [6.7] 04/30/2024 2 3 [1.3] May 2024: 16 out of 18 days 05/02/2024 8 18 [7.5] 05/07/2024 8 18 [7.5] 05/08/2024 6 12 [5] 05/09/2024 10 20 [8.3] 05/10/2024 2 3 [1.3] 05/13/2024 4 5 [2.1] 05/14/2024 4 5 [2.1] 05/15/2024 2 3 [1.3] 05/16/2024 10 17 [7.1] 05/21/2024 6 10 [4.2] 05/22/2024 8 17 [7.1] 05/23/2024 10 20 [8.3] 05/28/2024 6 12 [5] 05/29/2024 4 5 [2.1] 05/30/2024 2 3 [1.3] 05/31/2024 2 3 [1.3] June 2024: 15 out of 16 days 06/04/2024 6 8 [3.3] 06/05/2024 2 3 [1.3] 06/07/2024 14 20 [8] 06/10/2024 4 8 [3.3] 06/11/2024 6 8 [3.3] 06/12/2024 4 8 [3.3] 06/14/2024 2 3 [1.3] 06/18/2024 4 7 [2.9] 06/19/2024 10 20 [8.3] 06/21/2024 8 10 [4.3] 06/24/2024 4 6 [2.5] 06/25/2024 6 8 [3.3] 06/26/2024 8 10 [4.2] 06/27/2024 2 3 [1.3] 06/28/2024 6 8 [3.3] July 2024: 17 out of 19 days 07/02/2024 8 16 [6.7] 07/03/2024 22 40 [16.7] 07/05/2024 10 20 [8.3] 07/08/2024 4 6 [2.5] 07/10/2024 4 6 [2.5] 07/12/2024 4 6 [2.5] 07/17/2024 2 3 [1.3] 07/18/2024 2 3 [1.3] 07/19/2024 2 3 [1.3] 07/22/2024 2 3 [1.3] 07/23/2024 2 3 [1.3] 07/24/2024 8 16 [6.7] 07/25/2024 4 6 [2.5] 07/26/2024 2 3 [1.3] 07/29/2024 4 6 [2.5] 07/30/2024 2 3 [1.3] 07/31/2024 8 16 [6.7] August 2024: 19 out of 19 days 08/02/2024 2 4 [1.7] 08/05/2024 4 6 [2.5] 08/07/2024 6 7 [2.9] 08/08/2024 6 7 [2.9] 08/09/2024 6 7 [2.9] 08/12/2024 4 6 [2.5] 08/13/2024 6 7 [2.9] 08/14/2024 6 7 [2.9] 08/15/2024 8 9 [3.8] 08/16/2024 8 9 [3.8] 08/19/2024 4 5 [2.5] 08/20/2024 4 5 [2.5] 08/21/2024 2 4 [1.7] 08/22/2024 6 7 [2.9] 08/23/2024 4 7 [2.9] 08/26/2024 6 7 [2.9] 08/28/2024 6 7 [2.9] 08/29/2024 6 7 [2.9] 08/30/2024 2 4 [1.7] September 2024: 14 out of 18 days 09/02/2024 6 7 [2.9] 09/04/2024 8 10 [4.2] 09/05/2024 4 5 [2.1] 09/06/2024 6 7 [2.9] 09/09/2024 12 15 [6.3] 09/12/2024 4 5 [2.1] 09/16/2024 12 16 [6.7] 09/18/2024 8 10 [4.2] 09/19/2024 4 6 [2.5] 09/20/2024 2 3 [1.3] 09/24/2024 4 7 [2.9] 09/26/2024 6 8 [3.3] 09/27/2024 2 4 [1.7] 09/30/2024 4 6 [2.5] October 2024: 16 out of 17 days 10/01/2024 4 5 [2.1] 10/03/2024 12 20 [8.3] 10/04/2024 4 5 [2.1] 10/07/2024 4 5 [2.1] 10/08/2024 4 5 [2.1] 10/09/2024 2 3 [1.3] 10/10/2024 2 3 [1.3] 10/11/2024 12 20 [8.3] 10/14/2024 6 12 [5] 10/16/2024 6 12 [5] 10/17

/2024 2 3 [1.3] 10/22/2024 4 5 [2.1] 10/23/2024 12 20 [8.3] 10/28/2024 8 16 [6.7] 10/29/2024 10 20 [8.3] 10/30/2024 12 20 [8.3] November 2024: 11 out of 15 days 11/05/2024 4 6 [2.5] 11/07/2024 2 4 [1.7] 11/11/2024 6 7 [2.9] 11/12/2024 4 6 [2.5] 11/13/2024 6 7 [2.9] 11/18/2024 4 7 [2.9] 11/20/2024 6 8 [3.3] 11/21/2024 6 8 [3.3] 11/26/2024 20 25 [10.4] 11/27/2024 4 7 [2.9] 11/29/2024 4 8 [3.3] December 2024: 12 out of 16 days 12/04/2024 6 8 [3.3] 12/05/2024 4 6 [2.5] 12/10/2024 8 10 [4.2] 12/12/2024 4 6 [2.5] 12/18/2024 2 4 [1.7] 12/19/2024 6 9 [3.8] 12/20/2024 6 9 [3.8] 12/23/2024 6 10 [4.2] 12/24/2024 4 7 [2.9] 12/26/2024 8 10 [4.2] 12/27/2024 4 8 [3.3] 12/31/2024 10 12 [5] January 2025: 20 out of 20 days 01/02/2025 4 5 [2.1] 01/06/2025 4 5 [2.1] 01/07/2025 2 3 [1.3] 01/08/2025 18 20 [8.3] 01/09/2025 2 3 [1.3] 01/10/2025 4 5 [2.1] 01/13/2025 2 3 [1.3] 01/14/2025 2 3 [1.3] 01/15/2025 6 7 [2.9] 01/16/2025 2 3 [1.3] 01/17/2025 8 10 [4.2] 01/20/2025 8 10 [4.2] 01/21/2025 4 5 [2.1] 01/22/2025 2 3 [1.3] 01/23/2025 8 11 [4.6] 01/24/2025 6 7 [2.9] 01/27/2025 2 3 [1.3] 01/28/2025 10 9 [3.8] 01/30/2025 10 10 [4.2] 01/31/2025 6 6 [2.5] February 2025: 13 out of 18 days 02/06/2025 6 7 [2.9] 02/07/2025 6 7 [2.9] 02/10/2025 8 7 [2.9] 02/11/2025 6 7 [2.9] 02/12/2025 6 7 [2.9] 02/14/2025 6 7 [2.9] 02/17/2025 2 3 [1.3] 02/18/2025 2 3 [1.3] 02/19/2025 6 8 [3.3] 02/20/2025 6 7 [2.9] 02/21/2025 4 5 [2.1] 02/24/2025 6 7 [2.9] 02/26/2025 4 6 [2.5] March 2025: 16 out of 18 days 03/03/2025 4 6 [2.5] 03/04/2025 14 19 [7.9] 03/07/2025 16 25 [10.4] 03/10/2025 10 22 [9.2] 03/11/2025 12 18 [7.5] 03/12/2025 4 6 [2.5] 03/13/2025 4 5 [2.1] 03/14/2025 2 3 [1.3] 03/18/2025 2 3 [1.3] 03/19/2025 4 5 [2.1] 03/21/2025 6 7 [2.9] 03/24/2025 2 3 [1.3] 03/25/2025 2 3 [1.3] 03/26/2025 8 12 [5] 03/27/2025 4 6 [2.5] 03/28/2025 2 3 [1.3] April 2025: 10 out of 12 days 04/01/2025 10 15 [6.3] 04/04/2025 2 3 [1.3] 04/07/2025 4 5 [2.1] 04/08/2025 8 12 [5] 04/09/2025 16 25 [10.4] 04/14/2025 6 10 [4.2] 04/15/2025 2 3 [1.3] 04/16/2025 4 5 [2.1] 04/17/2025 2 3 [1.3] 04/29/2025 2 5 [2.1] May 2025: 14 out of 15 days 05/01/2025 2 3 [1.3] 05/05/2025 4 6 [2.5] 05/06/2025 4 6 [2.5] 05/07/2025 6 8 [3.3] 05/09/2025 2 3 [1.3] 05/12/2025 2 3 [1.3] 05/13/2025 4 6 [2.5] 05/14/2025 4 6 [2.5] 05/16/2025 4 6 [2.5] 05/19/2025 4 6 [2.5] 05/20/2025 2 3 [1.3] 05/27/2025 4 6 [2.5] 05/28/2025 10 18 [7.5] 05/29/2025 2 3 [1.3] June 2025: 7 out of 17 days 06/03/2025 8 10 [4.2] 06/10/2025 8 11 [4.6] 06/11/2025 4 7 [2.9] 06/12/2025 6 8 [3.3] 06/16/2025 4 6 [2.5] 06/24/2025 10 15 [6.3] 06/25/2025 4 6 [2.5] July 2025: 14 out of 15 days 07/01/2025 2 3 [1.3] 07/02/2025 6 7 [2.9] 07/03/2025 4 5 [2.1] 07/07/2025 8 15 [6.3] 07/08/2025 4 5 [2.1] 07/09/2025 2 3 [1.3] 07/10/2025 10 15 [6.3] 07/15/2025 10 22 [9.2] 07/16/2025 2 3 [1.3] 07/17/2025 4 5 [2.1] 07/18/2025 8 15 [6.3] 07/21/2025 2 3 [1.3] 07/23/2025 6 7 [2.9] 07/31/2025 8 15 [6.3] August 2025: 12 out of 12 days 08/01/2025 4 6 [2.5] 08/07/2025 2 3 [1.3] 08/12/2025 4 6 [2.5] 08/14/2025 8 15 [6.3] 08/18/2025 12 18 [7.5] 08/19/2025 2 3 [1.3] 08/20/2025 4 6 [2.5] 08/22/2025 4 6 [2.5] 08/25/2025 2 3 [1.3] 08/26/2025 2 3 [1.3] 08/27/2025 2 3 [1.3] 08/29/2025 2 3 [1.3] September 2025: 17 out of 17 days 09/02/2025 4 5 [2.1] 09/03/2025 4 5 [2.1] 09/04/2025 8 12 [5] 09/05/2025 4 5 [2.1] 09/08/2025 8 12 [5] 09/09/2025 12 18 [7.5] 09/10/2025 6 10 [4.2] 09/11/2025 6 10 [4.2] 09/15/2025 8 12 [5] 09/16/2025 4 5 [2.1] 09/17/2025 2 3 [1.3] 09/18/2025 8 12 [5] 09/19/2025 2 3 [1.3] 09/23/2025 4 5 [2.1] 09/24/2025 6 10 [4.2] 09/25/2025 8 12 [5] 09/30/2025 4 5 [2.1] October 2025: 14 out of 19 days 10/03/2025 10 18 [7.5] 10/08/2025 6 8 [3.3] 10/13/2025 2 3 [1.3] 10/15/2025 4 6 [2.5] 10/16/2025 4 6 [2.5] 10/17/2025 2 3 [1.3] 10/20/2025 14 24 [10] 10/21/2025 14 8 [3.3] 10/23/2025 12 20 [8.3] 10/24/2025 2 3 [1.3] 10/27/2025 4 6 [2.5] 10/29/2025 6 9 [3.8] 10/30/2025 2 3 [1.3] 10/31/2025 6 12 [5] November 2025: 9 out of 12 days 11/03/2025 4 6 [2.5] 11/04/2025 12 19 [7.9] 11/05/2025 4 6 [2.5] 11/06/2025 2 3 [1.3] 11/10/2025 2 3 [1.3] 11/11/2025 8 12 [5] 11/12/2025 6 12 [5] 11/24/2025 4 7 [2.9] 11/25/2025 4 6 [2.5] December 2025: 10 out of 13 days 12/01/2025 8 12 [5] 12/03/2025 6 10 [4.2] 12/08/2025 4 8 [3.3] 12/11/2025 6 10 [4.2] 12/16/2025 4 7 [2.9] 12/17/2025 4 7 [2.9] 12/23/2025 8 12 [4] 12/24/2025 6 10 [4.2] 12/29/2025 6 10 [4.2] 12/31/2025 4 7 [2.9] 3. In an interview on 4/14/2026 at 13:37 hours, in the conference room, general

	supervisor (GS) 3 confirmed the laboratory did not ensure the total number of half slide examined would not exceed the prorated workload limit.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. This STANDARD is not met as evidenced by: Based on review of the laboratory's test menu, review of the laboratory's method comparison studies from 2024 and 2025, and staff interview, the laboratory failed to have documentation of performing comparison studies for 27 of 51 analytes. The findings included: 1. A review of the laboratory's test menu identified the following 51 tests which were performed on the Beckman DxC700 and the Beckman AU480 chemistry analyzers: Blood urea nitrogen, calcium, cholesterol, creatine, direct bilirubin, glucose, iron, lipase, magnesium, phosphate, c-reactive protein, total bilirubin, triglycerides, total protein, uric acid, vancomycin, high density lipoprotein, albumin, alkaline phosphatase, alanine transferase, ammonia, amylase, aspartate transaminase, sodium, potassium, chloride, urine sodium, urine potassium, urine protein, urine phosphate, urine amylase, urine calcium, urine urea, urine uric acid, BNP, human chorionic gonadotropin, creatine kinase, carbon dioxide, gentamicin, salicytic acid, lactate, acetaminophen, thyroid stimulating hormone, free T4, troponin, procalcitonin, high density lipoprotein, transferrin, cerebral spinal fluid glucose, cerebral spinal fluid total protein, and cerebral spinal fluid lactate. 2. A review of the laboratory's method comparison studies from 2024 and 2025 determined the laboratory failed to have documentation performing method comparisons for 27 of 51 tests. The missing comparisons were: a) June 2024 direct bilirubin c-reactive protein urine sodium urine potassium urine phosphate urine amylase urine calcium urine urea urine uric acid gentamicin acetaminophen troponin procalcitonin high density lipoprotein cerebral spinal fluid glucose cerebral spinal fluid total protein cerebral spinal fluid lactate b) December 2024 vancomycin ammonia urine sodium urine potassium urine phosphate urine amylase urine calcium urine urea urine uric acid BNP human chorionic gonadotropin gentamicin salicytic acid lactate acetaminophen thyroid stimulating hormone free T4 procalcitonin high density lipoprotein cerebral spinal fluid glucose cerebral spinal fluid total protein cerebral spinal fluid lactate c) June 2025 vancomycin urine sodium urine potassium urine phosphate urine amylase urine calcium urine urea urine uric acid gentamicin salicytic acid acetaminophen cerebral spinal fluid glucose cerebral spinal fluid total protein cerebral spinal fluid lactate d) December 2025 high density lipoprotein transferrin cerebral spinal fluid glucose cerebral spinal fluid total protein cerebral spinal fluid lactate 3. In an interview conducted on 04/15/2026 at 1100 hours in the conference room, the quality director confirmed the findings after her review of the records. 44278 II. Based on surveyor observation, review of laboratory comparison studies, and confirmed in interview, the laboratory failed to perform twice annual comparisons for two instruments performing the same tests for two of two years in 2024 and 2025. Findings included: 1. During a tour of the facility respiratory therapy testing areas on 04/14/2026 at 09:40 AM, the surveyor observed multiple i-STAT testing devices (Serial Numbers: 372601 and 368434) available for patient testing. Also available for use in all respiratory testing areas were i-STAT EG7+ cartridges (Lot Number:

	101944417). In the intensive care unit at 09:45 AM, the respiratory therapy technical consultant (TC-3) confirmed the following chemistry (non-blood gas) analytes were reported on the EG7+ cartridge for patient testing: a. Sodium b. Potassium During a tour of the facility on 04/14/2026 at 09:20 AM, the surveyor observed one Beckman DXC700 chemistry analyzer available for patient testing. Review of chemistry posted analyte list on the DXC analyzer revealed the above analytes were also performed on the DXC700. 2. Review of laboratory chemistry comparison studies in 2024 and 2025, revealed the laboratory failed to document twice annual comparisons in sodium and potassium for the i-STAT EG7+ cartridge and the DXC chemistry analyzer. On 04 /14/2026 at 3:18 PM, the point of care lead was asked to provide documentation of the above twice annual comparisons in 2024 and 2025. No documentation was provided. 3. In an interview on 04/14/2026 at 3:18 PM, the point of care lead confirmed the laboratory failed to perform twice annual comparisons for two instruments performing the same tests for two of two years in 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 chemistry quality control records from October 2025 and November 2025, review of patient test records, and staff interview, the laboratory failed to have documentation of evaluating patient results tested prior to quality control failure for 4 of 4 days. The findings included: 1. A review of the laboratory's chemistry control records from October 2025 and November 2025 identified the following days were quality control for an analyte failed and calibration was required to obtain acceptable quality control results on th Beckman DxC700 chemistry analyzer: a) Date: 10/02/2025 Analyte: Carbon Dioxide b) Date: 10/18 /2025 Analyte: Iron c) Date: 11/03/2025 Analyte: Creatine f) Date: 11/04/2025 Analyte: Calcium 2. A review of patient test records from October 2025 and November 2025 identified the following patient results requiring evaluation due to failed quality control results: a) Date: 10/01/2025 Analyte: Carbon dioxide 136 patients (see patient alias list 1) b) Date: 10/17/2025 Analyte: Iron 1 patient Sample ID: 31729100224A c) Date: 11/02/2025 Analyte: Creatine 68 patients (see patient alias list 2) d) Date: 11/03/2025 Analyte: Calcium 102 patients (see patient alias list 3) 3. In an interview conducted on 04/16/2026 at 9:10 am in the conference room, technical supervisor number 4 confirmed the findings after her review of the records.
D5801	TEST REPORT CFR(s): 493.1291(a) (a) The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to

	network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of laboratory reports, review of the laboratory's calculation verification records from 2024 and 2025, and staff interview, the laboratory failed to have documentation of verifying 4 of 14 calculations in 2024 and 2025. The findings included: 1. The laboratory's policy titled "Calculations" (effective date: 05/2023) stated: "Computer calculation will be reviewed every two (2) years or when a system changes is made that may affect the calculations." 2. A review of laboratory reported identified 14 results which were calculations: Urine Calcium 24 hour Urine Amylase 24 hour Urea Nitrogen 24 hour Urine Protein 24 hour Urine Sodium 24 hour Urine Potassium 24 hour Urine Uric Acid 24 hour Urine Phosphate 24 hour Iron Saturation Creatine Clearance eGlomerular Filtration Rate Cholesterol/Triglyceride Ratio LDL (calculated) LDL /HDL Ratio 3. A review of the laboratory's calculation verification records from 2024 and 2025 identified the laboratory failed to have documentation of verifying the following 4 calculations: eGlomerular Filtration Rate Cholesterol/Triglyceride Ratio LDL (calculated) LDL/HDL Ratio 4. In an interview on 04/15/2026 at 2:50 pm in the conference room, the quality director confirmed the findings after her review of the records. Key LDL - low density lipoprotein HDL - high density lipoprotein
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's records and staff interviews, the laboratory director failed to provide overall management and direction of the laboratory services. The findings included: 1. The laboratory director failed to ensure enrollment in a CMS approved PT program (refer to D6015). 2. The laboratory director failed to ensure successful participation in a HHS approved proficiency testing program (refer to D6016). 3. The laboratory director failed to ensure the laboratory's proficiency testing action plan was followed (refer to D6019). 4. The laboratory director failed to ensure a quality control plan was developed and followed (refer to D6020).
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) (e)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed and that-- This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policy, proficiency testing (PT) records, and confirmed in interview, the laboratory failed to enroll in a Centers for Medicare and Medicaid Services (CMS) approved PT program for chemistry analysis

	on the i-STAT EG7+ cartridge for seven of seven analytes in the subspecialty of Routine Chemistry from the years of 2024, 2025, and 2026. Refer to D2000.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part; This STANDARD is not met as evidenced by: I. Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2025, and staff interview, the laboratory director failed to ensure successful participation in a HHS approved proficiency testing program for the analyte of hemoglobin A1C for two of three events in 2025, resulting in an initial unsuccessful performance (refer to D2096). II. Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2024 and staff interview, the laboratory failed to achieve satisfactory performance in two of three testing events for Gram Stain testing resulting in an initial unsuccessful performance (refer to D2028).
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) (e)(4)(iv) An approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory; This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2024 and 2025, and staff interview, the laboratory director failed to ensure the laboratory's proficiency testing action plan was followed. The findings included: 1. The laboratory director failed to ensure the laboratory evaluated results reported as 'not graded' by the proficiency testing agency (refer to D5213). 2. The laboratory director failed to ensure the laboratory assessed patient impact after failed proficiency results (refer to D5221).
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(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: Based on review of the laboratory's quality control records and staff interview, the laboratory director failed to ensure a quality control plan was developed and followed. The findings included: 1. The laboratory failed to ensure quality control materials were run in each test run for Rapid Plasma Reagin (RPR) testing (refer to D5441). 2. The laboratory failed to follow its IQCP for modifying the frequency of quality

	control testing (refer to D5449). 3. The laboratory failed to have documentation of testing a control material with titered reactivity (refer to D5451). 4. The laboratory failed to rotate QC performance among all operators (refer to D5463).
D6041	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(3) (b)(3) Enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered; This STANDARD is not met as evidenced by: Based on review of laboratory policy, proficiency testing (PT) records, patient annual testing volumes, and confirmed in interview, the technical consultant failed to ensure enrollment in a CMS approved PT program to determine compliance for seven of seven regulated analytes performed on the i-STAT EG7+ testing cartridge from 2015-2026. Refer to D2001.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) (b)(9) Thereafter, evaluations must be performed at least annually This STANDARD is not met as evidenced by: Based on a review of the laboratory's submitted CMS 209 form (respiratory department), personnel files, and staff interview, the laboratory failed to have documentation of the technical consultant performing a competency assessment on 12 of 37 testing personnel in 2024 and 2025 for blood gas testing on the Abbott i-STAT analyzer. Findings include: 1. A review of the laboratory's submitted CMS 209 form (respiratory department) revealed the laboratory identified 37 testing personnel performing blood gas testing on the Abbott i-STAT analyzer. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation of the technical consultant performing a competency assessment for the following 12 testing personnel: - Testing Person #12 - missing a competency assessment in 2024 and 2025 - Testing Person #13 - missing a competency assessment in 2025 - Testing Person #18 - missing a competency assessment in 2025 - Testing Person #22 - missing a competency assessment in 2024 and 2025 - Testing Person #23 - missing a competency assessment in 2025 - Testing Person #24 - missing a competency assessment in 2025 - Testing Person #26 - missing a competency assessment in 2024 and 2025 - Testing Person #29 - missing a competency assessment in 2024 and 2025 - Testing Person #30 - missing a competency assessment in 2025 - Testing Person #31 - missing a competency assessment in 2025 - Testing Person #35 - missing a competency assessment in 2025 - Testing Person #36 - missing a competency assessment in 2024 3. Further review of the personnel records revealed competency assessments were performed on all of the above testing personnel for 2024 and 2025, however, the personnel performing the assessments did not qualify to be a technical consultant for moderate complexity testing. 4. In an interview on 4/16/26 at 10:55 a. m. in the conference room, after review of the records, testing person #12 (as indicated on the CMS 209 form- respiratory department) confirmed the above findings.
D6061	CLINICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1419(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 manufacturer's instructions, patient final reports, and interview, the clinical consultant failed to ensure that pertinent information on the limitation for the identification Escherichia coli (E.coli) results on the Verigene Gram-Negative Blood Culture Nucleic Acid Test (BC-GN) was included on the patient test results for nine of nine patients, with E.coli detected, reviewed in December 2025. The findings include: 1. Review of the Luminex "Verigene Gram-Negative Blood Culture Nucleic Acid Test (BC-GN) Package Insert" included the following foot note for Escherichia coli as one of the Bacterial Genera and Species the BC-GN detects and identifies: "BC-GN will not distinguish Escherichia coli from Shigella spp. (S. dysenteria, S. flexneri, S. boydii, and S. sonnei)." 2. Review of patient final reports in December 2025 did not include the statement for the following nine patients where E. coli was identified on the Luminex Verigene: MRN Date Tested 4108726 12/08/2025 4077590 12/09/2025 4156635 12/10/2025 4167750 12/11/2025 363120 12/14/2025 4168278 12 /24/2025 4093465 12/26/2025 580909 12/27/2025 4165125 12/31/2025 3. In an interview on 4/15/2026 at 15:00, in the conference room, General Supervisor (GS) 2 confirmed that the patient final reports did not include the Verigene limitation statement for the identification of E. coli in patient samples.
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. The findings were: 1. The laboratory director failed to ensure establishment studies were performed for modified FDA-approved test systems (refer to D6095). 2. The laboratory director failed to ensure the competency for 5 of 361 testing personnel was assessed for testing on the FDA-modified Accu-Chek Inform II glucometers in 2024 and 2025. Refer to D6103.
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: Based on surveyor observation, manufacturer's instructions, laboratory policy, establishment studies, UniPOC middleware system, 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 glucose testing for one of one glucometer test systems in 2025. Refer to D5423.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on a review of the Point of Care policies, the submitted CMS 209 form (Nursing), a random sampling of personnel records, and staff interview, the laboratory director failed to ensure the competency for 5 of 361 testing personnel was assessed for testing on the FDA-modified Accu-Chek Inform II glucometers in 2024 and 2025. Findings include: 1. A review of the Point of Care policy titled 'Ancillary Testing Program' revealed the following: "Competency Assessment (waived) A. Competency assessment must be verified upon orientation at least annually thereafter." 2. A review of the submitted CMS 209 form (Nursing) revealed the laboratory identified 361 personnel performing testing on the Accu-Chek Inform II glucometers. 3. A random sampling of personnel performing testing on the Accu-Chek Inform II glucometers revealed the following 5 personnel records failed to have documentation of a competency assessment: - Testing person #22- missing competency assessment in 2024 and 2025 - Testing person #166- missing competency assessment in 2024 - Testing person #253- missing competency assessment in 2025 - Testing person #279- missing competency assessment in 2024 - Testing person #327- missing competency assessment in 2025 4. In an interview on 4/15/26 at 1:20 p.m. in the conference room, after review of the records, the quality officer confirmed the above findings.
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: Based on surveyor observation, manufacturer's instructions, laboratory policy, establishment studies, UniPOC middleware system, patient final reports, and confirmed in interview, the technical supervisor 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.
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 a review of the laboratory's submitted CMS 209 form (Nursing), a random sampling of personnel records, and staff interview, the laboratory failed to ensure 27 of 361 testing personnel met the educational requirements to perform high complexity testing on the Accu-Chek Inform II glucometers. (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 a review of the submitted CMS 209 form (Nursing), a random sampling of personnel records, and staff interview, the laboratory failed to ensure that 27 of 361 testing personnel performing high complexity testing on the Accu-Chek Inform II glucometers met the educational requirements prior to testing. Findings include: 1. A

	review of the submitted CMS 209 form (Nursing) revealed the laboratory identified 361 personnel performing testing on the Accu-Chek Inform II glucometers. 2. A random sampling of the personnel performing testing on the Accu-Chek Inform II glucometers revealed the following 27 personnel records failed to include educational documentation demonstrating compliance with the requirements at 493.1487 for: - Testing person #12 - Testing person #22 - Testing person #57 - Testing person #68 - Testing person #80 - Testing person #90 - Testing person #92 - Testing person #100 - Testing person #118 - Testing person #131 - Testing person #137 - Testing person #138 - Testing person #157 - Testing person #166 - Testing person #174 - Testing person #190 - Testing person #192 - Testing person #199 - Testing person #203 - Testing person #218 - Testing person #232 - Testing person #252 - Testing person #265 - Testing person #276 - Testing person #285 - Testing person #327 - Testing person #328 3. In an interview on 4/15/26 at 3:30 p.m. in the conference room, after review of the records, the quality officer confirmed the above findings.