Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0487422	07/03/2024
Name of Provider or Supplier	**Street Address, City, State**	
North Texas Medical Center	1900 Hospital Blvd, Gainesville, 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	An announced onsite recertification survey was completed on July 3rd, 2024, and the laboratory was found to NOT be in compliance with the following CLIA conditions for specialties/subspecialties surveyed for 42 CFR: 493.1250 Analytic Systems 493.1403 Laboratory Director, (moderate complexity). 493.1409 Technical Consultant
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by: Based on review of laboratory policy, American Proficiency Institute (API) Proficiency Testing (PT) records in 2024, and confirmed in interview, the laboratory failed to test Chemistry PT samples in the same manner as patient specimens for two of five chemistry PT specimens in 2024 (1st Event). Findings Included: 1. Review of laboratory policy, "Proficiency Testing" (Approved by the laboratory director on 03 /2022) revealed the following: "Policy: ...5. Proficiency samples will be examined in the same manner as patient samples. ...c. Samples will be tested the same number of times as patient samples." 2. Review of API Chemistry Core 1st Event PT results in 2024, revealed the following: API PT Chemistry Core 1st Event 2024 Samples: CM-01; CM-02; CM-03; CM-04; CM-05 Further review of the above API PT results in 2024 revealed the following included in the sample raw data: a. Sample ID: CM02

	Testing person comment written on PT sample instrument printout, "Repeated testing because results are identical. :)" b. Sample ID: CM04 Testing person comment written on PT sample instrument printout, "Repeated testing because results are identical. :)" The surveyor requested documentation of repeating patient specimens due to the above comment on 06/24/2024 at 01:15 PM, and none was provided. 3. In an interview on 06/24/2024 at 01:16 PM, the laboratory supervisor confirmed the laboratory failed to test Chemistry PT samples in the same manner as patient specimens for two of five chemistry PT specimens in 2024 (1st Event).
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of laboratory policy, American Proficiency Institute (API) Proficiency Testing (PT) Immunology/Immunohematology records in 2023, and confirmed in interview, the laboratory failed to have documentation of testing personnel attesting to the routine integration of PT samples into the patient workload for one of six testing persons (TP) in 2023. Findings Included: 1. Review of laboratory policy, "Proficiency Testing" (Approved by the laboratory director on 03 /2022) revealed the following: "Policy: ...5. Proficiency samples will be examined in the same manner as patient samples. ...ii. All testing personnel will sign the attestation form prior to submitting results for final review." 2. Review of API PT Immunohematology results for 2023 (1st Event) revealed the following samples with no TP attestation page signature documentation: API PT Immunology /Immunohematology 1st Event 2023 Samples: a. RED-01 b. RED-02 c. SER-01 d. SER-02 The surveyor requested documentation of testing personnel attesting to the routine integration of the above PT samples into the patient workload on 06/24/2024 at 01:18 PM, and none was provided. 3. In an interview on 06/24/2024 at 01:18 PM, the laboratory supervisor confirmed the laboratory failed to have documentation of testing personnel attesting to the routine integration of PT samples into the patient workload for one of six testing persons (TP) in 2023.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of 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 laboratory American Proficiency Institute (API) Proficiency Testing (PT) records in 2023, and confirmed in interview, the laboratory failed to have documentation of verifying the accuracy of analytes not scored by the PT program for two of three Immunology/Immunohematology PT events in 2023 (1st and 3rd Events). Findings Included: 1. Review of API PT Immunology /Immunohematology results in 2023 (1st and 3rd Events) revealed the following statement signed by the laboratory director for both events: "Laboratories are

	responsible for documenting and performing corrective action for failures and must perform a self-evaluation using statistics presented in the Participant Data Summary for samples that have not been graded." Further review of laboratory American Proficiency Institute API PT records in 2023, revealed the following analytes receiving a not graded result by the PT program: API PT Immunology /Immunohematology 1st Event 2023 a. Analyte: Crossmatch Type Samples: SER-01; Ser-02; SER-03; SER-04; SER-05 Performance: Not Graded b. Analyte: Crossmatch Reaction Strength (Tube Test) Samples: SER-01; Ser-02; SER-03; SER-04; SER-05 Performance: Not Graded API PT Immunology/Immunohematology 3rd Event 2023 c. Analyte: Compatibility Samples: SER-12 Performance: Not Graded d. Analyte: DAT- Polyspecific Samples: DAT-06 Performance: Not Graded The surveyor requested documentation of a self-evaluation for the above analytes not graded by the PT program in 2023 on 06/24/2024 at 01:20 PM, and none was provided. 2. In an interview on 06/24/2024 at 01:18 PM, the laboratory supervisor confirmed the laboratory failed to have documentation of verifying the accuracy of analytes not scored by the PT program for two of three Immunology/Immunohematology PT events in 2023 (1st and 3rd Events). Word Key: DAT- Direct Antibody Test
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 surveyor observation, review of laboratory policy, manufacturer's instructions, quality control (QC) records, patient final reports, and staff interview, it was revealed the laboratory failed to meet analytic systems requirements for three of five specialties reviewed in 2024, as evidenced by: 1. The laboratory failed to have a policy for performing lot rollovers for one of one Innovin reagent tested on the Sysmex CS-2500 analyzer. Refer to D5403 I. 2. The laboratory failed to establish QC lot rollover policies for one of one D-Dimer analyte tested on the Sysmex CS-2500 analyzer. Refer to D5403 II. 3. The laboratory failed to ensure the MNPT (mean normal prothrombin time) was calculated correctly for one of one lot of Innovin reagent in December 2023. Refer to D5411. 4. The laboratory failed to ensure verification studies were completed for three of three analytes (PT, aPTT and D-Dimer) tested on the Sysmex CS-2500 analyzer prior to testing and reporting patients. Refer to D5421 I. 5. The laboratory failed to verify the reference range for ten of ten randomly selected analytes in 2024. Refer to D5421 II. 6. The laboratory failed to have a QC system in place to detect immediate errors for three of three QC lots randomly reviewed in 2024. Refer to D5441 I. 7. The laboratory failed to have a QC system in place to detect immediate errors for two of four QC lots randomly reviewed in 2024. Refer to D5441 II. 8. The laboratory failed to document negative and positive control material at least once per day patient samples were tested for the Respiratory Panel 2.1 on the BioFire Torch analyzer for nine of nine days in 2023 (November-December) 19 of 19 days in 2024 (January-May). Refer to D5449 I. 9. The laboratory failed to document negative and positive control material at least once per day patient samples were tested for the Blood Culture Identification 2 (BCID2) Panel on the

	BioFire Torch analyzer for 12 of 12 days in 2023 (November-December) 22 of 22 days in 2024 (January-May). Refer to D5449 II. 10. The laboratory failed to document negative and positive control material at least once per day patient samples were tested for the Blood Culture Identification 2 (BCID2) Panel on the BioFire Torch analyzer for 12 of 12 days in 2023 (November-December) 22 of 22 days in 2024 (January-May). Refer to D5449 III. 11. The laboratory failed document for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for peripheral blood smears for 12 of 12 months in 2023 and six of six months in 2024 (January through June). Refer to D5473. 12. The laboratory failed to perform quality control checks on each batch of media to include its ability to support growth, and as appropriate, select or inhibit specific organisms or produce a biochemical response, for 10 of 10 batches of Columbia NaladixicAcid Agar (CNA) media received in 2024. Refer to D5477.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: I. Based on review of laboratory policy, American Proficiency Institute (API) Proficiency Testing (PT) records in 2023, and confirmed in interview, the laboratory failed to follow their own policy for PT result remedial action for one of three Chemistry PT events in 2023 (1st Event) and one of three Hematology PT events in 2023 (3rd Event). Findings Included: 1. Review of laboratory policy, "Proficiency Testing" (Approved by the laboratory director on 03/2022) revealed the following: "Policy: ...9. Remedial action will be taken and documented on any analyte with an unacceptable score, non-consensus, nonparticipation or late return of results." 2. Review of Hematology and Chemistry Core API PT results in 2023 revealed the following analytes scored as unacceptable by the PT agency: API Chemistry Core 1st Event 2023 a. Analyte: Thyroid Stimulating Hormone (TSH) Specimen: THY-04 Performance: Unacceptable b. Analyte: Total Iron Specimen: CH-02 Performance: Unacceptable API Hematology 3rd Event 2023 c. Analyte: Nucleated Red Blood Cell's Specimen: COU-12 Performance: Unacceptable d. Analyte: White Cell Count Specimen: COU-12 Performance: Unacceptable The surveyor requested documentation of remedial action for the above unacceptable PT results on 06/24 /2024 at 01:15 PM, and none was provided. 3. In an interview on 06/24/2024 at 01:16 PM, the laboratory supervisor confirmed the laboratory failed to follow their own policy for PT result remedial action for one of three Chemistry PT events in 2023 (1st Event) and one of three Hematology PT events in 2023 (3rd Event). II. Based on review of laboratory policy, patient 2024 transfusion records, and confirmed in interview, the laboratory failed to follow their own policy for possible transfusion reaction investigations for 3 of 20 patients randomly reviewed in 2024. Findings Included: 1. Review of laboratory policy, "Blood Products Administration and Transfusion Reaction Policy" (Approved by the laboratory director on 03/2024) revealed the following: "During Transfusion: ...3. Assess for vital signs: 1. Prior to transfusion; 2. 15 minutes after start of transfusion; 3. 15 minutes after increasing flow rate to desired speed; 4. Every hour during the transfusion; 5. At completion of transfusion ... 6. Assess vital signs and signs or symptoms of adverse effects upon

	completion of transfusion. Should any signs or symptoms of adverse effects be apparent, follow directions as delineated below. Transfusion Reaction Protocol 1. STOP BLOOD 2. Call provider 3. Notify lab personnel 4. Monitor patient 5. Notify House Supervisor/Lab Director 6. Return unused blood to blood bank 7. Order the "Transfusion Reaction Work-Up" in the EMR (Electronic Medical Record) 8. Complete the transfusion reactions documentation. ...Hypotension (Systolic BP suddenly or unexpectedly declines by greater than 30 mm Hg ..." 2. Random review of patient transfusion records in 2024 revealed the following three patients with a documented greater than 30 decline in blood pressure while receiving a transfusion: a. Patient 1 (See Patient Alias Chart 1) Transfusion Began: 01/05/2024 at 12:30 AM Transfusion Ended: 01/05/2024 at 02:55 AM Baseline Vitals recorded at 12:30 AM: Blood Pressure: 153/84 mmHg Vitals recorded at 01:45 AM: Blood Pressure: 117/56 mmHg Decrease in systolic pressure: 36 mmHg b. Patient 2 Transfusion Began: 01/28 /2024 at 23:40 PM Transfusion Ended: 01/29/2024 at 03:10 AM Vitals recorded on 01 /29/2024 at 00:55 AM: Blood Pressure: 150/78 mmHg Vitals recorded on 01/29/2024 at 01:55 AM: Blood Pressure: 114/66 mmHg Decrease in systolic pressure: 36 mmHg c. Patient 3 Transfusion Began: 01/31/2024 at 12:00 PM Transfusion Ended: 01/31 /2024 at 12:35 PM Baseline Vitals recorded at 12:00 PM: Blood Pressure: 151/69 mmHg Vitals recorded at 12:15 AM: Blood Pressure: 110/74 mmHg Decrease in systolic pressure: 41 mmHg The surveyor requested documentation of the possible transfusion protocol policy being implemented for the above patients on 06/25/2024 at 11:25 AM, and none was provided. 3. In an interview on 06/25/2024 at 11:25 AM, the laboratory supervisor confirmed the laboratory failed to follow their own policy for possible transfusion reaction investigations for 3 of 20 patients randomly reviewed in 2024. Word Key BP- Blood Pressure mmHg- millimeters of mercury
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (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. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (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. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: I. Based on review of manufacturer's instructions, laboratory policies, Innovin reagent lot roll over documentation, and confirmed in interview, the laboratory failed to have a policy for performing lot rollovers for one of one Innovin reagent tested on the Sysmex CS-2500 analyzer. Findings included: 1. Review of the Siemens Healthineers

	Sysmex CS Systems Lot Rollover Virtual Training workbook page 2-5 stated: "LOT ROLLOVER CONSIDERATIONS ... Your laboratory is responsible to develop internal policies and procedures for new lot implementation requirements in compliance with your respective accrediting agencies. The laboratory is responsible to determine what procedures are appropriate, and which performance limits or specifications are applicable. Verification of Reference Range ... Laboratories are responsible to determine appropriate studies (i.e. number of samples) for reference interval verification and method verification must be implemented ... Notes ... The MNPT for INR calculation must be the geometric mean." Review of the Siemens Healthineers Customer Bulletin (October 2018) stated: "Using Quality Control Features of Sysmex CS Systems to Prepare for Lot Rollover ... Important Information ... Your laboratory is responsible to develop internal policies and procedures for new lot implementation requirements in compliance with your respective accrediting agencies. The laboratory is responsible to determine what procedures are appropriate, and which performance limits or specifications are applicable ... Verification of Reference Interval ... Laboratories are responsible to determine appropriate studies (i. e. number of samples) for reference interval verification and method verification ... Notes ... The MNPT for INR calculation must be the geometric mean." 2. Review of the laboratory's policy "Sysmex CS-2500 Coag" revealed the laboratory did not have any procedures for conducting lot rollovers for Innovin reagent used in PT (prothrombin time) tests. 3. Review of Innovin reagent (Lot #564652; expiration date 05/16/2026) lot roll over documentation revealed the lot was placed in use December 2023. Further review of the documentation revealed a lot rollover study was conducted on 03/12/2024 obtaining the following PT patient results: Patient 2: 10.9 sec Patient 3: 10.9 sec Patient 4: 10.6 sec Patient 5: 19.3 sec Patient 6: 11.4 sec Patient 7: 10.3 sec Patient 8: 10.3 sec Patient 9: 10.3 sec Patient 10: 11 sec Patient 11: 10.6 sec Patient 12: 11.4 sec Patient 13: 11.4 sec Patient 14: 10.4 sec The MNPT was NOT calculated with the above PT patient results. The MNPT calculation was 11.3 seconds for the above PT patient results. This value was NOT the same value of 10.6 seconds as observed in the Sysmex CS-2500 analyzer on June 25, 2024, at 11:35 am. 4. During an interview on 06/24/2024 at 3:45 pm, the Laboratory Supervisor stated the laboratory did not have policies for performing lot rollovers for Innovin reagent. II. Based on review of manufacturer's instructions, laboratory policies, D-Dimer quality control (QC) material lot roll over documentation, QC records, and confirmed in interview, the laboratory failed to establish QC lot rollover policies for one of one D-Dimer analyte tested on the Sysmex CS-2500 analyzer. Findings included: 1. Review of the Innovance D-Dimer Controls instructions for use stated: "Assigned Constituent Values ... The ranges provided are intended only as guidelines." Review of the Innovance D-Dimer Controls assay sheet stated: Control 1: Lot # 562298, expiration date: 06/19/2024; Range: 0.26-0.38 mg/L Control 2: Lot # 562198, expiration date: 06 /19/2024; Range: 1.97-2.95 mg/L 2. Review of the laboratory's policy "Sysmex CS-2500 Coag" revealed the laboratory did not have any procedures for conducting QC lot rollovers for D-Dimer control. 3. Review of the Innovance D-Dimer QC lot rollover from 01/31/2024 revealed the following: Control 1: Lot # 562298, expiration date: 06/19/2024 Control 2: Lot # 562198, expiration date: 06/19/2024 Further review of the QC rollover revealed Control 1 and 2 were run 20 times for each lot. No other documentation demonstrating the establishment of new control ranges or verifying the manufacturer's ranges was available. 4. Review of QC records from 04/01/2025 through 06/15/2024 revealed the following: Control 1: Lot # 562298, acceptable range: 0.26-0.38 mg/L Control 2: Lot # 562198, acceptable range: 1.97-2.95 mg/L 5. During an interview on 06/24/2024 at 3:45 pm, the Laboratory Supervisor stated the laboratory did not have policies for performing quality control lot rollovers.

D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on direct observation, manufacturer instructions, review of laboratory policies, Innovin reagent lot roll over documentation, laboratory LIS records, and confirmed in interview, the laboratory failed to ensure the MNPT (mean normal prothrombin time) was calculated correctly for one of one lot of Innovin reagent in December 2023. Findings included: 1. During a tour of the laboratory on 06/25/2024 at 11:35 am, the surveyor observed the value for the MNPT entered in the Sysmex CS-2500 analyzer as "10.6" seconds for the current lot of Innovin reagent (Lot #564652; expiration date 05/16/2026). 2. Review of Siemens Healthineers Installation Package stated: "IV. REFERENCE INTERVAL A Reference Interval is the interval between and including two reference limits. Reference intervals vary from laboratory to laboratory depending on the population, the technique and reagent lot ... Your laboratory is responsible to develop internal policies and procedures for verification of performance specifications, in compliance with your respective accrediting agencies. The laboratory is responsible to determine what procedures are appropriate, and which performance limits or specifications are applicable. Requirements: Donors must be from a healthy population as determined by the laboratory per CLSI A3C guidelines [sic]" Review of the Siemens Healthineers Sysmex CS Systems Lot Rollover Virtual Training workbook page 2-5 stated: "LOT ROLLOVER CONSIDERATIONS ... Your laboratory is responsible to develop internal policies and procedures for new lot implementation requirements in compliance with your respective accrediting agencies. The laboratory is responsible to determine what procedures are appropriate, and which performance limits or specifications are applicable. Verification of Reference Range ... Laboratories are responsible to determine appropriate studies (i.e. number of samples) for reference interval verification and method verification must be implemented ... Notes ... The MNPT for INR calculation must be the geometric mean." Review of the Siemens Healthineers Customer Bulletin (October 2018) stated: "Using Quality Control Features of Sysmex CS Systems to Prepare for Lot Rollover ... Important Information ... Your laboratory is responsible to develop internal policies and procedures for new lot implementation requirements in compliance with your respective accrediting agencies. The laboratory is responsible to determine what procedures are appropriate, and which performance limits or specifications are applicable ... Verification of Reference Interval ... Laboratories are responsible to determine appropriate studies (i.e. number of samples) for reference interval verification and method verification ... Notes ... The MNPT for INR calculation must be the geometric mean." 3. Review of laboratory polices revealed the laboratory failed to have policies for performing lot rollovers for Innovin reagent to verify the reference interval for the MNPT. Refer to D5403, I. 4. Review of Innovin reagent (Lot #564652; expiration date 05/16/2026) lot roll over documentation revealed the lot was placed in use December 2023. Further review of the documentation revealed a lot rollover study was conducted on 03/12/204 obtaining the following PT patient results: Patient 2: 10.9 sec Patient 3: 10.9 sec Patient 4: 10.6 sec Patient 5: 19.3 sec Patient 6: 11.4 sec Patient 7: 10.3 sec Patient 8: 10.3 sec Patient 9: 10.3 sec Patient 10: 11 sec Patient 11: 10.6 sec Patient 12: 11.4 sec Patient 13: 11.4 sec Patient 14: 10.4 sec The

	MNPT was NOT calculated with the above PT patient results. The MNPT calculation was 11.3 seconds for the above PT patient results. This value was NOT the same value of 10.6 seconds as observed in the Sysmex CS-2500 analyzer. 5. Review of laboratory LIS records revealed 1,100 patients were tested and reported on the current lot of Innovin (Lot #564652; expiration date 05/16/2026) from December 1, 2023, through June 25, 2026. 6. During an interview on 06/25/2024 at 10:33 am, the Laboratory Supervisor stated that the facility had to contact the manufacturer for assistance in calculating the MNPT for their lot rollover of Innovin. She stated that the facility provided all the data to the manufacturer, and they performed the calculation and gave the facility the value over the phone. The Laboratory Supervisor was asked if she had any written documentation of the calculation and she stated "No". During an interview 06/25/2024 at 11:35 am, after a review of the MNPT value of 10.6 seconds in the Sysmex CS-2500 analyzer the Laboratory Supervisor confirmed the MNPT for the current lot of Innovin was inaccurate. Word Key: INR- international normalized ratio PT- prothrombin time sec- seconds LIS- laboratory information system
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: I. Based on review of manufacturer's instructions for use, environmental logs, and confirmed in interview, the laboratory failed to ensure room humidity ranges were within manufacturer's specifications for 70 of 120 days in 2023 and 104 of 152 days in 2024. Findings included: 1. Review of the Sysmex CS-2500 instructions for use revealed: "1.5 Product information 1.5.1 Specifications Operating environment ... Relative humidity: 30 - 85%" 2. Review of the laboratory's "NTMC Main Lab Temperature Log" from September 2023 through May 2025 revealed the laboratory had an established acceptable humidity range for the laboratory of 20-75%. The laboratory failed to ensure room humidity ranges were within manufacturer's specifications of 30-85%. 3. Further review of the laboratory's environmental logs revealed 70 of 120 days in 2023 and 104 of 152 days in 2024 when the humidity was out of the manufacture's acceptable range of 30-85%. The following was a random sampling of those readings: 10/08/2023: 29% 10/09/2023: 29% 10/14/2023: 27% 10 /15/2023: 26% 10/16/2023: 26% 11/01/2023: 22% 11/02/2023: 21% 11/03/2023: 22% 11/04/2023: 29% 11/10/2023: 29% 12/12/2023: 20% 12/13/2023: 21% 12/14/2023: 21% 12/15/2023: 22% 12/16/2023: 23% 01/01/2024: 20% 01/02/2024: 20% 01/03 /2024: 21% 01/04/2024: 21% 01/05/2024: 22% 02/11/2024: 24% 02/12/2024: 22% 02 /13/2024: 22% 02/14/2024: 22% 02/15/2024: 28% 03/18/2024: 23% 03/19/2024: 21% 03/20/2024: 23% 03/21/2024: 28% 03/22/2024: 29% 04/04/2024; 24% 04/05/2024: 25% 04/06/2024: 27% 04/07/2024: 29% 04/09/2024: 29% 05/09/2024: 29% 05/10 /2024: 29% 05/11/2024: 29% 05/12/2024: 29% 05/13/2024: 29% 4. During an interview on 06/26/2024 at 9:15 am, the Laboratory Supervisor after a review of records confirmed the laboratory failed to ensure room humidity ranges were within

	manufacturer's specifications for 70 of 120 days in 2023 and 104 of 152 days in 2024. II. Based on review temperature logs and confirmed in interview, the laboratory failed to ensure the microbiology temperatures, humidity, CO2 (carbon dioxide) concentration, were documented for 2 of 30 days in January 2024, 9 of 31 days in March 2024, and 3 of 31 days in May 2024. Findings included: 1. Review of the daily "Microbiology Temperature Log" revealed the following items which required monitoring: Lab Line Incubator- acceptable range 35-37 degrees C Ultra-Tech CO2 Incubator Digital - acceptable range 33-37 degrees C Manual Read CO2 Incubator - acceptable range 33-37 degrees C Ultra-Tech CO2% - acceptable range 5-10% Room Temperature- acceptable range 20-25 degrees C Humidity- acceptable range 30-80% BacT/Alert Temperature- acceptable range 35-37 degrees C Manual Refrigerator- acceptable range 2-8 degrees C Digital Refrigerator- acceptable range 2-8 degrees C 2. Further review of the daily "Microbiology Temperature Log" revealed the following dates in 2024 the laboratory failed to monitor the required items listed above: 01/09/2024 01/22/2024 03/08/2024 (only failed to document the BacT/Alert Temperature) 03/11/2024 (only failed to document the BacT/Alert Temperature) 03/12 /2024 (only failed to document the BacT/Alert Temperature) 03/13/2024 (only failed to document the BacT/Alert Temperature) 03/14/2024 (only failed to document the BacT/Alert Temperature) 03/15/2024 (only failed to document the BacT/Alert Temperature) 03/16/2024 (only failed to document the BacT/Alert Temperature) 03/17 /2024 (only failed to document the BacT/Alert Temperature) 03/19/2024 (only failed to document the BacT/Alert Temperature) 05/13/2024 05/14/2024 There was no corrective action documented for the failure to document temperatures, humidity, and CO2 concentration for the above dates. 3. During an interview on 06/26/2024 at 9:15 am, the Laboratory Supervisor after a review of records, confirmed the laboratory failed to monitor and document the required temperatures, humidity, and CO2 concentrations.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on direct observation and confirmed in interview, the laboratory failed to ensure two of two prepared reagents stored in secondary containers were labeled with identification, concentration, poured dates, preparation dates, and expiration dates. Findings included: 1. During a tour of the hematology area in laboratory on 06/26 /2024 at 11:08 am, the surveyor observed the following on the counter: 1 unlabeled coplin jar (secondary container) with a blue/purple liquid solution 1 coplin jar (secondary container) labeled "DISTILLED WATER" with a semi-clear liquid solution The laboratory failed to label the secondary containers with identification, concentration, poured dates, preparation dates, and expiration dates. 2. During an interview on 06/26/2024 at 11:15 am, the Laboratory Supervisor confirmed the above findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:
Based on review of manufacturer instructions, verification studies for the Sysmex CS-2500 analyzer, laboratory policies, patient records, laboratory LIS records, and confirmed in interview, the laboratory failed to ensure verification studies were completed for three of three analytes (PT, aPTT and D-Dimer) tested on the Sysmex CS-2500 analyzer prior to testing and reporting patients. Findings included: 1. Review of the Siemens Healthineers Installation Package stated: "IV. REFERENCE INTERVAL A Reference Interval is the interval between and including two reference limits. Reference intervals vary from laboratory to laboratory depending on the population, the technique and reagent lot ... Your laboratory is responsible to develop internal policies and procedures for verification of performance specifications, in compliance with your respective accrediting agencies. The laboratory is responsible to determine what procedures are appropriate, and which performance limits or specifications are applicable. Requirements: Donors must be from a healthy population as determined by the laboratory per CLSI A3C guidelines [sic]" "V. REPORTABLE RANGE Reportable Range determination is addressed both in CLIA requirements and CLSI Guidelines. While CLIA requires the laboratory to verify the Reportable Range, the method used is not explicit and leaves this up to the individual laboratories ... The laboratory is responsible to develop internal policies and procedures for establishing and verifying the performance limits and specifications, in compliance with your respective accrediting agencies." "VI. ACCURACY VERIFICATION (CLIA 493.1253 Standard: Establishment and verification of performance specifications. (b)(1)(i)(A) Accuracy). Verification of the accuracy of new quantitative procedures is a requirement prior to reporting patient results. "Accuracy" is the relationship to the true value. The concept of a true value is frequently not applicable to coagulation testing. This is especially true of the global screening tests. There is no standard for the PT and PTT. Standardization has been achieved for PT INR calculation. The laboratory is responsible for verifying that the method produces correct results ... The laboratory is responsible to develop internal policies and procedures for establishing and verifying the performance limits and specifications, in compliance with your respective accrediting agencies." "VIII. Analytical Measurement Range (AMR) Verification The Analytical Measurement Range (AMR) is the range of analyte values that a method can directly measure on the specimen without any dilution, concentration, or other pretreatment not part of the usual assay process ... AMR is required when a new method is placed in service, every six months thereafter and under certain conditions ... The laboratory is responsible to develop internal policies and procedures for establishing and verifying the performance limits and specifications, in compliance with your respective accrediting agencies." 2. According to verification studies, the laboratory added the Sysmex CS-2500 analyzer to their test menu on 08/2023 for the following coagulation analytes: PT, aPTT, and D-Dimer. Further review of the verification studies for the Sysmex CS-2500 analyzer revealed the laboratory did NOT perform the following required studies: PT analyte: accuracy and reportable range aPTT analyte: accuracy

	and reportable range D-Dimer analyte: reportable range, reference (normal) range and AMR 3. Review of laboratory policies revealed the laboratory failed to have policies for performing verification studies. Review of the laboratory's policy "Sysmex CS-2500 Coag" revealed the laboratory failed to include the laboratory's reportable and reference ranges for PT, aPTT and D-Dimer. 4. Review of patient records revealed the following reference ranges used by the laboratory: PT: 9.3-13.6 INR: 0.8-1.04 aPTT: 20.5-35.7 D-Dimer: 0.27-0.40 5. Review of laboratory LIS records revealed the number of tests performed on the Sysmex CS-2500 analyzer since the laboratory's implementation on 09/01/2023: PT/INR: 1,802 tests aPTT: 757 tests D-Dimer: 774 tests 6. During an interview on 06/24/2024 at 2:335 pm, the Laboratory Supervisor confirmed the laboratory failed to perform complete verification studies on the PT, aPTT and D-Dimer analytes. Word Key PT- prothrombin time aPTT- activated partial thromboplastin time LIS - laboratory information system INR: international normalized ratio 44278 II. Based on surveyor observation, review of laboratory policy, Cobas chemistry verification studies performed in 2024, Centers for Medicare and Medicaid Services (CMS) 116 form, and confirmed in interview, the laboratory failed to verify the reference range for ten of ten randomly selected analytes in 2024. Findings Included: 1. During a tour of the laboratory on 06/24/2024 at 9:08 AM, the surveyor observed 2 Cobas Chemistry analyzers performing patient testing (Serial Number Cobas 1: C1 7306-07; Serial Number Cobas 2: C2 7306-08). 2. Review of laboratory policy manual revealed the laboratory failed to have a policy in place for verification studies of non-modified Food and Drug Administration (FDA) approved testing. Refer to D5403. 3. Review of laboratory Cobas (Serial Number Cobas 1: C1 7306-07; Serial Number Cobas 2: C2 7306-08) chemistry verification studies (Approved by the technical consultant on 04/16/2024) revealed the laboratory failed to have documentation of performing reference range verification on the laboratory's patient population for the following randomly reviewed analytes: a. Albumin b. Ammonia c. CRP d. Ethanol (Alcohol) e. Folate f. Glucose g. Lactate h. Potassium i. Sodium j. Total Bilirubin The surveyor requested documentation of the laboratory performing reference range verification of the above analytes on 06/24/2024 at 02:25 PM, and none was provided. 4. Review of CMS-116 form submitted at time of survey, 06/24/2024, revealed the laboratory performed 251, 912 chemistry patient tests annually. 5. In an interview on 06/24/2024 at 02:30 PM, the Laboratory Supervisor confirmed the laboratory failed to verify the reference range for ten of ten randomly selected analytes in 2024.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g) (a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on surveyor observation, review of BioRad manufacturer's instructions,

laboratory policy, quality control (QC) documentation in 2024 (April-June), patient final reports and confirmed in interview, the laboratory failed to have a QC system in place to detect immediate errors for three of three QC lots randomly reviewed in 2024. Findings included: 1. During a tour of the laboratory on 06/24/2024 at 9:08 AM, the surveyor observed 2 Cobas Chemistry analyzers performing patient testing (Serial Number Cobas 1: C1 7306-07; Serial Number Cobas 2: C2 7306-08). 2. Review of BioRad insert QC insert sheet included in all QC material (Version 03 /2024) revealed the following, " INTENDED USE ...quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert. SUMMARY AND PRINCIPLE The use of quality control materials is indicated as an objective assessment of the precision of methods and techniques in use and is an integral part of good laboratory practices. ... ASSIGNMENT OF VALUES The mean values and corresponding 3SD ranges in the Assignment of Values Data Charts (available separately) were derived from replicate analyses and are specific for this lot of product. Data from Unity (Trademark) Interlaboratory Program are included in the determination of some ranges. The tests listed were performed by the manufacturer and/or independent laboratories using manufacturer supported reagents and a representative sampling of this lot of product." Further review of BioRad manufacturer's instructions revealed the following randomly selected 3SD QC ranges for the following analytes: a. BioRad Immunoassay Levels 1,2 Lot Number: 85381T Expiration Date: 05/31/2025 Analyte performed: Folate Level 1 Range: 1.75-4.27 ng /mL b. BioRad Assayed Multiqual Control Levels 2,3 Lot Number: 45923T Expiration Date: 11/30/2026 Analytes performed: Alanine Transaminase (ALT) Level 3 Range: 155-205 U/L Blood Urea Nitrogen (BUN) Level 2 Range: 32.8-41.2 mg/dL Creatine Kinase (CK) Level 2 Range: 232-264 U/L Potassium Level 2 Range: 3.78-4.29 mEq/L Sodium Level 2 Range: 134-146 mEq/L Total Protein Level 3 Range: 6.31-7.19 g/dL c. Cardiac Markers Plus Control Levels 1,3 Lot Number: 87192T Expiration: 06/30/2026 Analytes performed: CRP Level 1 Range: 2.05 - 3.19 ng/mL Troponin Level 3 Range: 2148-2276 ng/mL 3. Review of laboratory policy, "Quality Control & QC Remediation Policy" (Approved by the laboratory director on 08/2023) revealed the following: " ...Chemistry: ...3. New lots of controls will be run for a minimum of 20 times to establish a mean. The historical SD and CV will be used to determine the range. The SD will not change. The range must be within the published range." The surveyor requested documentation of the laboratory establishing a mean and acceptable range for the above QC lots of control used in 2024 on 06/24/2024 at 03:40 PM, and no documentation was provided. 4. Review of laboratory Cobas chemistry QC documentation in 2024 revealed the laboratory implemented the above 3SD QC ranges provided by the manufacturer for the following three of three reviewed QC lots and associated analytes in 2024: a. BioRad Immunoassay Levels 1,2 Lot Number: 85381T Expiration Date: 05/31/2025 Analytes performed: Folate Level 1 Range documented in LIS: 1.75-4.27 ng/mL SD: 0.42 ng/mL Further review revealed the following days QC was marked in the 3SD range and patients were tested: I. Performed on: 05/08/2024 Folate Level 1 Flagged: QC out of range Result: 2.14 ng/mL Testing Person comment: "WITHIN 3 SD" II. Performed on: 05/09/2024 Folate Level 1 Flagged: QC out of range Result: 2.00 ng/mL Testing Person comment: "WITHIN 3 SD" III. Performed on: 05/14/2024 Folate Level 1 Flagged: QC out of range Result: 2.14 ng/mL Testing Person comment: "WITHIN 3 SD" IV. Performed on: 05/17/2024 Folate Level 1 Flagged: QC out of range Result: 2.08 ng /mL Testing Person comment: "WITHIN 3 SD" b. BioRad Assayed Multiqual Control Levels 2,3 Lot Number: 45923T Expiration Date: 11/30/2026 Analytes performed: Alanine Transaminase (ALT) Level 3 Range: 155-205 U/L SD: 8.33 U/L Further review revealed the following days QC was marked in the 3SD range and patients were tested: V. Performed on: 05/01/2024 ALT Level 3 Flagged: QC out of range

Result: 163.00 U/L Testing Person comment: "WITHIN 3 SD" VI. Performed on: 05/02/2024 ALT Level 3 Flagged: QC out of range Result: 162.00 U/L Testing Person comment: "WITHIN 3 SD" VII. Performed on: 05/03/2024 ALT Level 3 Flagged: QC out of range Result: 160.00 U/L Testing Person comment: "WITHIN 3 SD" VIII. Performed on: 05/07/2024 ALT Level 3 Flagged: QC out of range Result: 162.00 U/L Testing Person comment: "WITHIN 3 SD" IX. Performed on: 05/08/2024 ALT Level 3 Flagged: QC out of range Result: 163.00 U/L Testing Person comment: "WITHIN 3 SD" X. Performed on: 05/10/2024 ALT Level 3 Flagged: QC out of range Result: 162.00 U/L Testing Person comment: "WITHIN 3 SD" XI. Performed on: 05/15/2024 ALT Level 3 Flagged: QC out of range Result: 163.00 U/L Testing Person comment: "WITHIN 3 SD" XII. Performed on: 05/17/2024 ALT Level 3 Flagged: QC out of range Result: 161.00 U/L Testing Person comment: "WITHIN 3 SD" Blood Urea Nitrogen (BUN) Level 2 Range: 32.8-41.2 mg/dL SD: 1.40 mg/dL Further review revealed the following days QC was marked in the 3SD range and patients were tested: XIII. Performed on: 05/03/2024 BUN Level 2 Flagged: QC out of range Result: 40.0 mg/dL Testing Person comment: "WITHIN 3 SD" XIV. Performed on: 05/09/2024 BUN Level 2 Flagged: QC out of range Result: 40.4 mg/dL Testing Person comment: "WITHIN 3 SD" XV. Performed on: 05/10/2024 BUN Level 2 Flagged: QC out of range Result: 40.4 mg/dL Testing Person comment: "WITHIN 3 SD" Creatine Kinase (CK) Level 2 Range: 232-264 U/L SD: 5.55 U/L Further review revealed the following days QC was marked in the 3SD range and patients were tested: XVI. Performed on: 05/03/2024 CK Level 2 Flagged: QC out of range Result: 235.00 U/L Testing Person comment: "WITHIN 3 SD" XVII. Performed on: 05/07/2024 CK Level 2 Flagged: QC out of range Result: 237.00 U/L Testing Person comment: "WITHIN 3 SD" XVIII. Performed on: 05/14/2024 CK Level 2 Flagged: QC out of range Result: 237.00 U/L Testing Person comment: "WITHIN 3 SD" Potassium (K) Level 2 Range: 3.78-4.29 mEq/L SD: 0.09 mEq/L Further review revealed the following days QC was marked in the 3SD range and patients were tested: XIX. Performed on: 05/01/2024 K Level 2 Flagged: QC out of range Result: 4.23 mEq/L Testing Person comment: "WITHIN 3 SD" XX. Performed on: 05/10/2024 K Level 2 Flagged: QC out of range Result: 4.25 mEq/L Testing Person comment: "WITHIN 3 SD" XXI. Performed on: 05/16/2024 K Level 2 Flagged: QC out of range Result: 4.25 mEq/L Testing Person comment: "WITHIN 3 SD" XXII. Performed on: 05/17/2024 K Level 2 Flagged: QC out of range Result: 4.25 mEq/L Testing Person comment: "WITHIN 3 SD" Sodium (Na) Level 2 Range: 134-146 mEq/L SD: 2.00 mEq/L Further review revealed the following days QC was marked in the 3SD range and patients were tested: XXIII. Performed on: 05/10/2024 Na Level 2 Flagged: QC out of range Result: 144.60 mEq/L Testing Person comment: "WITHIN 3 SD" XXIV. Performed on: 05/16/2024 Na Level 2 Flagged: QC out of range Result: 144.80 mEq/L Testing Person comment: "WITHIN 3 SD" XXVI. Performed on: 05/21/2024 Na Level 2 Flagged: QC out of range Result: 145.0 mEq/L Testing Person comment: "WITHIN 3 SD" Total Protein (TP) Level 3 Range: 6.31-7.19 g/dL SD: 0.15 g/dL Further review revealed the following days QC was marked in the 3SD range and patients were tested: XXVII. Performed on: 05/16/2024 TP Level 2 Flagged: QC out of range Result: 7.10 g/dL Testing Person comment: "WITHIN 3 SD" XXVIII. Performed on: 05/21/2024 TP Level 2 Flagged: QC out of range Result: 7.10 g/dL Testing Person comment: "WITHIN 3 SD" c. Cardiac Markers Plus Control Levels 1,3 Lot Number: 87192T Expiration: 06/30/2026 Analytes performed: CRP Level 1 Range: 0.75-1.23 ng/mL SD: 0.08 ng/mL Further review revealed the following days QC was marked in the 3SD range and patients were tested: XXIX. Performed on: 05/21/2024 CRP Level 1 Flagged: QC out of range Result: 0.78 ng/mL Testing Person comment: "WITHIN 3 SD" XXX. Performed on: 05/28/2024 CRP Level 1 Flagged: QC out of range Result: 0.78 ng/mL Testing Person comment:

"WITHIN 3 SD" XXXI. Performed on: 05/30/2024 CRP Level 1 Flagged: QC out of range Result: 0.78 ng/mL Testing Person comment: "WITHIN 3 SD" Troponin Level 3 Range: 2148-2276 ng/mL SD: 21.33 ng/mL Further review revealed the following days QC was marked in the 3SD range and patients were tested: XXXII. Performed on: 05/22/2024 Troponin Level 3 Flagged: QC out of range Result: 2168.00 ng/mL Testing Person comment: "WITHIN 3 SD" XXXIII. Performed on: 05/28/2024 Troponin Level 3 Flagged: QC out of range Result: 2167.00 ng/mL Testing Person comment: "WITHIN 3 SD" 5. Review of patient final reports revealed the following patient volumes reported since the above QC lot numbers for the following analytes and corresponding 3SD ranges were put into use by the laboratory (04/16/2024): a. BioRad Immunoassay Levels 1,2 Lot Number: 85381T Expiration Date: 05/31/2025 Analyte performed: Folate Patient Volume: 100 b. BioRad Assayed Multiqual Control Levels 2,3 Lot Number: 45923T Expiration Date: 11/30/2026 Analytes performed: Alanine Transaminase (ALT) Patient Volume: 3133 Blood Urea Nitrogen (BUN) Patient Volume: 3189 Creatine Kinase (CK) Patient Volume: 92 Potassium (K) Patient Volume: 3133 Sodium (Na) Patient Volume: 3133 Total Protein (TP) Patient Volume: 3133 c. Cardiac Markers Plus Control Levels 1,3 Lot Number: 87192T Expiration: 06/30/2026 Analytes performed: CRP Patient Volume: 49 Troponin Patient Volume: 1265 6. In an interview on 06/24/2024 at 02:35 PM, TP-2 stated the laboratory implemented the BioRad manufacturer provided 3SD QC ranges for the above analytes. This confirmed the laboratory failed to have a QC system in place to detect immediate errors for three of three QC lots randomly reviewed in 2024. Word Key SD- Standard Deviation CV- Coefficient of Variation 3SD- Plus or minus three standard deviations from the mean CRP- C-reactive protein LIS- Laboratory Information System ng/mL- nanograms per millilitre U/L- units per litre g/dL- grams per deciliter mEq/L- milliequivalents per litre mg/dL- milligrams per deciliter II. Based on surveyor observation, review of quality control (QC) documentation in 2024 (April-June), patient final reports and confirmed in interview, the laboratory failed to have a QC system in place to detect immediate errors for two of four QC lots randomly reviewed in 2024. Findings included: 1. During a tour of the laboratory on 06/24/2024 at 9:08 AM, the surveyor observed 2 Cobas Chemistry analyzers performing patient testing (Serial Number Cobas 1: C1 7306-07; Serial Number Cobas 2: C2 7306-08). 2. Review of Cobas QC documentation in 2024, revealed the laboratory performed QC from two separate manufacturer's, BioRad and Roche, for the same chemistry analytes as a troubleshooting step when BioRad QC was not within acceptable ranges. The following was documented for randomly reviewed analytes in the QC records: Cardiac Markers Plus Control Levels 1,3 Lot Number: 87192T Expiration: 06/30/2026 Analytes performed: CRP 1. Performed on: 05/23 /2024 Level 1 BioRad Flagged: QC out of range Result: 0.73 ng/mL Testing Person comment: "ROCHE QC PASSED" 2. Performed on: 05/24/2024 Level 1 BioRad Flagged: QC out of range Result: 0.73 ng/mL Testing Person comment: "ROCHE QC PASSED" 3. Performed on: 05/25/2024 Level 1 BioRad Flagged: QC out of range Result: 6.59 ng/mL Testing Person comment: "ROCHE QC OK" 4. Performed on: 05 /27/2024 Level 1 BioRad Flagged: QC out of range Result: 0.70 ng/mL Testing Person comment: "ROCHE QC OK" Analyte: Troponin 5. Performed on: 05/30/2024 Level 3 BioRad Flagged: QC out of range Result: 2132.0 ng/mL Testing Person comment: "BioRad QC failed 2X. Repeat with Roche QC" The surveyor requested documentation of acceptable BioRad QC prior to performing Roche QC on 06/24 /2024 at 03:55 PM, and no documentation was provided. 3. Review of patient final reports revealed the following patient volumes reported for the above analytes in 2024: Cardiac Markers Plus Control Levels 1,3 Lot Number: 87192T Expiration: 06 /30/2026 Analytes performed: a. CRP Patient Volume: 49 b. Troponin Patient Volume: 1265 4. In an interview on 06/24/2024 at 03:15 PM, Testing Person 2 (TP-2)

	stated when BioRad QC was out of acceptable range, Roche QC was performed as a troubleshooting step in QC processing. TP-2 further stated if the Roche QC was in acceptable ranges, patient results were reported. This confirmed the laboratory failed to have a QC system in place to detect immediate errors for two of three QC lots randomly reviewed in 2024. Word Key SD- Standard Deviation CRP- C-reactive protein ng/mL- nanograms per millilitre
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on review of laboratory policies, quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to document negative and positive control material at least once per day patient samples were tested for the Respiratory Panel 2.1 on the BioFire Torch analyzer for nine of nine days in 2023 (November-December) 19 of 19 days in 2024 (January-May). Findings included: 1. Review of the laboratory's "Biofire Procedure" stated: "Quality Control ... The frequency of QC testing has been determined as part of developing an individualized quality control plan, and in compliance with regulatory guidelines outlined below: The laboratory must comply with quality control requirements designated by the manufacturer and regulatory authorities (CLIA). For multiplex tests, the laboratory must verify at least two analytes individually for each new shipment and lot, and at random, rotate the analytes verified. The laboratory must perform daily verification of internal controls on each kit type being performed. Positive and negative controls will be verified every 30 days." Further review of laboratory policies revealed the laboratory did not document an individualized quality control plan (IQCP) to support its reduction in frequency to every 30 days for the Respiratory Panel 2.1 on the BioFire Torch analyzer. 2. A review of QC records and a random review of patient records from November 2023 through May 2024, revealed the following dates QC was NOT performed and patients were tested and reported for the Respiratory Panel 2.1 on the Biofire Torch analyzer: 11/20/2023 Patient IDs: 4043339; 4043381; 4043373; 4043399; 4043401 11/21/2023 Patient IDs: 4043452; 4043457; 4043450 11 /22/2023 Patient IDs: 4043616; 4043617; 4043633 11/23/2023 Patient IDs: 4043721; 4043724; 4043737 12/01/2023 Patient IDs: 4044723; 4044721; 4044752 12/04/2024 Patient IDs: 4044844; 4044852 QC was last performed on 11/19/2023 12/06/2023 Patient IDs: 4045110; 4045115; 4045116 12/07/2023 Patient IDs: 4045243; 4045261; 4045265; 4045279 12/09/2023 Patient IDs: 4045477; 4045479 01/01/2024 Patient ID: 4047774 01/08/2024 Patient ID: 4048488 QC was last performed on 12/05/2023 01/26 /2024 Patient ID: 4050484 02/01/2024 Patient ID: 4051332 02/04/2024 Patient ID: 4051600 QC was last performed on 01/12/2024 02/13/2024 Patient IDs: 4052469; 4052487 02/16/2024 Patient IDs: 4052786; 4052787; 4052789 02/29/2024 Patient ID: 4054039 QC was last performed on 02/10/2024 03/15/2024 Patient IDs: 4055784; 4055788 03/19/2024 Patient ID: 4056050 03/26/2024 Patient ID: 4056708 QC was last performed on 03/06/2024 04/08/2024 Patient ID: 4058308 04/19/2024 Patient IDs: 4059501; 4059550 04/25/2024 Patient ID: 4060051 04/28/2024 Patient ID: 4060339 QC was last performed on 04/01/2024 05/13/2024 Patient IDs: 4062218;

4062242 05/17/2024 Patient IDs: 4062625; 4062336 05/23/2024 Patient ID: 4063179 05/24/2024 Patient ID: 4063373 QC was last performed on 05/11/2024 The laboratory did not include a positive and negative control each day of patient testing for the Respiratory Panel 2.1 on the BioFire Torch analyzer. 4. During an interview on 06/25 /2024 at 10:33 am, the Laboratory Supervisor stated that an IQCP had not been developed and the laboratory only performed QC every 30 days, every new lot and shipment. These statements confirmed laboratory failed to document negative and positive control material at least once per day patient samples were tested for the Respiratory Panel 2.1 on the BioFire Torch analyzer. II. Based on review of laboratory policies, quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to document negative and positive control material at least once per day patient samples were tested for the Blood Culture Identification 2 (BCID2) Panel on the BioFire Torch analyzer for 12 of 12 days in 2023 (November-December) 22 of 22 days in 2024 (January-May). Findings included: 1. Review of the laboratory's "Biofire Procedure" stated: "Quality Control ... The frequency of QC testing has been determined as part of developing an individualized quality control plan, and in compliance with regulatory guidelines outlined below: The laboratory must comply with quality control requirements designated by the manufacturer and regulatory authorities (CLIA). For multiplex tests, the laboratory must verify at least two analytes individually for each new shipment and lot, and at random, rotate the analytes verified. The laboratory must perform daily verification of internal controls on each kit type being performed. Positive and negative controls will be verified every 30 days." Further review of laboratory policies revealed the laboratory did not document an individualized quality control plan (IQCP) to support its reduction in frequency to every 30 days for the BCID Panel on the BioFire Torch analyzer. 2. A review of QC records and a random review of patient records from November 2023 through May 2024, revealed the following dates QC was NOT performed and patients were tested and reported for the BCID2 Panel on the Biofire Torch analyzer: 11/17 /2023 Patient ID: 4043074 11/20/2023 Patient ID: 4043315 11/24/2023 Patient ID: 4043713 11/29/2023 Patient ID: 4044023 11/30/2023 Patient ID: 4044166 12/01/2023 Patient ID: 4044400 12/04/2024 Patient IDs: 4044817; 4044836 QC was last performed on 11/16/2023 12/07/2023 Patient ID: 4045059 12/08/2023 Patient IDs: 4045059; 4045420 12/15/2023 Patient IDs: 4045920; 4046035 12/23/2023 Patient ID: 4046921 12/27/2023 Patient ID: 4047134 01/01/2024 Patient IDs: 4047545; 4047471; 4047806 01/02/2024 Patient ID: 4047806 QC was last performed on 12/05/2023 01/09 /2024 Patient ID: 4048437 01/19/2024 Patient ID: 4049503 02/01/2024 Patient ID: 4051332 02/04/2024 Patient ID: 4051600 QC was last performed on 01/05/2024 02/15 /2024 Patient ID: 4052248 02/17/2024 Patient IDs: 4052795; 4052857 02/21/2024 Patient IDs: 4053142; 4053180 QC was last performed on 02/13/2024 03/12/2024 Patient IDs: 4055377; 4055362; 4055377 03/15/2024 Patient IDs: 4055678; 4055779; 4055851 03/19/2024 Patient ID: 4055902 03/26/2024 Patient ID: 4056678 04/03/2024 Patient ID: 4057781 QC was last performed on 03/07/2024 04/10/2024 Patient ID: 4058475 04/12/2024 Patient IDs: 4058718; 4058756 04/23/2024 Patient ID: 4059705 04/28/2024 Patient ID: 4059894 QC was last performed on 04/07/2024 05/13/2024 Patient IDs: 4062112; 4062081 05/18/2024 Patient ID: 4062645 05/24/2024 Patient ID: 4063298 05/28/2024 Patient IDs: 4063394; 4063586 QC was last performed on 05 /04/2024 The laboratory did not include a positive and negative control each day of patient testing for the BCID2 Panel on the BioFire Torch analyzer. 4. During an interview on 06/25/2024 at 10:33 am, the Laboratory Supervisor stated that an IQCP had not been developed and the laboratory only performed QC every 30 days, every new lot and shipment. These statements confirmed laboratory failed to document negative and positive control material at least once per day patient samples were tested for the BCID2 Panel on the BioFire Torch analyzer. III. Based on review of

laboratory policies, quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to document negative and positive control material at least once per day patient samples were tested for the Gastrointestinal (GI) Panel on the BioFire Torch analyzer for seven of seven days in 2023 (November-December) 17 of 17 days in 2024 (January-May). Findings included: 1. Review of the laboratory's "Biofire Procedure" stated: "Quality Control ... The frequency of QC testing has been determined as part of developing an individualized quality control plan, and in compliance with regulatory guidelines outlined below: The laboratory must comply with quality control requirements designated by the manufacturer and regulatory authorities (CLIA). For multiplex tests, the laboratory must verify at least two analytes individually for each new shipment and lot, and at random, rotate the analytes verified. The laboratory must perform daily verification of internal controls on each kit type being performed. Positive and negative controls will be verified every 30 days." Further review of laboratory policies revealed the laboratory did not document an individualized quality control plan (IQCP) to support its reduction in frequency to every 30 days for the GI Panel on the BioFire Torch analyzer. 2. A review of QC records and a random review of patient records from November 2023 through May 2024, revealed the following dates QC was NOT performed and patients were tested and reported for the GI Panel on the Biofire Torch analyzer: 11/30/2023 Patient ID: 4043947 12/02/2023 Patient IDs: 4044294; 4044755 12/06/2023 Patient ID: 4045173 12/11/2023 Patient ID: 4044948 12/15/2023 Patient ID: 4046176 12/19 /2024 Patient ID: 4046281 QC was last performed on 11/29/2023 12/24/2024 Patient ID: 4046978 01/07/2024 Patient ID: 4049140 QC was last performed on 12/22/2023 01/14/2024 Patient ID: 4049140 02/07/2024 Patient ID: 4051895 QC was last performed on 01/12/2024 02/22/2024 Patient ID: 4053416 03/11/2024 Patient IDs: 4055228; 4055350 03/21/2024 Patient ID: 4056280 03/22/2024 Patient ID: 4056117 03/24/2024 Patient ID: 4056509 QC was last performed on 02/21/2024 03/29/2024 Patient ID: 4057129 04/01/2024 Patient ID: 4056699 04/19/2024 Patient ID: 4059390 04/23/2024 Patient ID: 4059737 QC was last performed on 03/26/2024 05/04/2024 Patient ID: 4061229 05/08/2024 Patient ID: 4059438 05/20/2024 Patient ID: 4062823 05/21/2024 Patient ID: 4062979 QC was last performed on 04/26/2024 05/29/2024 Patient ID: 4063657 QC was last performed on 05/24/2024 The laboratory did not include a positive and negative control each day of patient testing for the GI Panel on the BioFire Torch analyzer. 4. During an interview on 06/25/2024 at 10:33 am, the Laboratory Supervisor stated that an IQCP had not been developed and the laboratory only performed QC every 30 days, every new lot and shipment. These statements confirmed laboratory failed to document negative and positive control material at least once per day patient samples were tested for the GI Panel on the BioFire Torch analyzer. IV. Based on review of laboratory policies, quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to document negative and positive control material at least once per day patient samples were tested for the Pneumonia Panel-IVD on the BioFire Torch analyzer for one of one day in 2023 (December) four of four days in 2024 (March-April). Findings included: 1. Review of the laboratory's "Biofire Procedure" stated: "Quality Control ... The frequency of QC testing has been determined as part of developing an individualized quality control plan, and in compliance with regulatory guidelines outlined below: The laboratory must comply with quality control requirements designated by the manufacturer and regulatory authorities (CLIA). For multiplex tests, the laboratory must verify at least two analytes individually for each new shipment and lot, and at random, rotate the analytes verified. The laboratory must perform daily verification of internal controls on each kit type being performed. Positive and negative controls will be verified every 30 days." Further review of laboratory policies revealed the laboratory did not document an individualized quality control plan (IQCP) to support

	its reduction in frequency to every 30 days for the Pneumonia Panel-IVD on the BioFire Torch analyzer. 2. A review of QC records and a random review of patient records from November 2023 through April 2024, revealed the following dates QC was NOT performed and patients were tested and reported for the Pneumonia Panel-IVD on the Biofire Torch analyzer: 12/04/2023 Patient ID: 4044745 QC was last performed on 11/29/2023 03/23/2024 Patient ID: 4056496 QC was last performed on 02/29/2024 04/04/2024 Patient ID: 4057921 QC was last performed on 03/26/2024 04 /17/2024 Patient ID: 4058989 04/18/2024 Patient ID: 4058989 QC was last performed on 04/16/2024 The laboratory did not include a positive and negative control each day of patient testing for the Pneumonia Panel-IVD on the BioFire Torch analyzer. 4. During an interview on 06/25/2024 at 10:33 am, the Laboratory Supervisor stated that an IQCP had not been developed and the laboratory only performed QC every 30 days, every new lot and shipment. These statements confirmed laboratory failed to document negative and positive control material at least once per day patient samples were tested for the Pneumonia Panel-IVD on the BioFire Torch analyzer.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, lack of Quality Control (QC) records, patient reports, and confirmed in interview, the laboratory failed to document for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for peripheral blood smears for 12 of 12 months in 2023 and six of six months in 2024 (January through June). Findings included: 1. Review of the laboratory's policy "Peripheral Blood Smear-Hematology" stated: "Procedure ... 3. Scan smear at 10X or low power for quality of staining procedure. Prior to starting manual differntial verify the quality of each stained smear: The red blood cells should be pink to salmon in color. Nuclei are dark blue to purple. Cytoplasmic granules of nuetrophils are lilac. Cytoplasmic granules of basophils are dark blue to black. Cytoplasmic granules of eosinophils are red to orange. The area between the cells should be clean and free of precipitated stain." 2. The laboratory was asked on 06/25 /2024 at 4:34 pm for documentation of stain QC for peripheral blood smears from January 2023 through June 2024. No documentation of QC records was provided. The laboratory failed to document the staining characteristics for the peripheral blood smears. 3. A random review of patient records revealed the following patients were tested and reported when no stain QC was performed: 12/18/2023 Patient IDs: 404350, 4045573 12/20/2023 Patient ID: 4046068 12/21/2023 Patient ID: 4046255 12 /22/2023 Patient ID: 4046255 12/26/2023 Patient IDs: 4046921, 4047093 12/28/2023 Patient ID: 4047301 12/31/2023 Patient IDs: 4047518, 4047159 05/07/2024 Patient IDs: 4061277, 4061263 05/09/2024 Patient ID: 4061771 05/10/2024 Patient ID: 4061980 05/13/2024 Patient ID: 4060647 05/15/2024 Patient ID: 4061893 05/16/2024 Patient ID: 4061893 05/30/2024 Patient ID: 4063375 05/31/2024 Patient IDs: 4063961, 4063556 06/17/2024 Patient IDs: 4064375, 4064317 06/18/2024 Patient IDs: 4066081, 4066109 4. During an interview on 06/25/2024 at 4:34 pm, the Laboratory Supervisor stated that stain QC for peripheral blood smears was NOT

	documented daily and that testing personnel only perform "visual checks". These statements confirmed the laboratory failed document for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for peripheral blood smears.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory test menu, laboratory policy, microbiology quality control (QC) documentation in 2024, microbiology reagent shipments in 2024, patient testing volumes, and confirmed in interview, the laboratory failed to perform quality control checks on each batch of media to include its ability to support growth, and as appropriate, select or inhibit specific organisms or produce a biochemical response, for 10 of 10 batches of Columbia NaladixicAcid Agar (CNA) media received in 2024. Findings included: 1. Review of laboratory test list submitted at time of survey, 06/24/2024, revealed the laboratory performed all urinalysis cultures on CNA media. 2. Review of laboratory policy, "Media/Reagent Quality Control Procedure" (Approved by the laboratory director on 02/2024) revealed the following: "Principle: All quality control will be reviewed on a monthly basis by the section supervisor or the designee. If any quality control test does not meet defined standards, then the test and results cannot be used for patient testing ... All Media (Each shipment or new lot) ...When each new lot or shipment of media is received it will be evaluated for: Sterility Its ability to support growth ... Selectivity/inhibition and/or biochemical response. The laboratory must document that the physical characteristics of the media are not compromised and report any deterioration in the media to the manufacturer." 3. Review of microbiology QC in 2024 revealed the laboratory failed to document the above media quality control on the following 10 of 10 CNA media batches received: CNA Media a. Lot Number: 711682 Date shipment received: 01/04/2024 b. Lot Number: 774416 Date shipment received: 01/09/2024 c. Lot Number: 787605 Date shipment received: 02/22/2024 d. Lot Number: 793538 Date shipment received: 02/29/2024 e. Lot Number: 799528 Date shipment received: 03/01/2024 f. Lot Number: 102084 Date shipment received: 04/22/2024 g. Lot Number: 106560 Date shipment received: 04/29/2024 h. Lot Number: 110349 Date shipment received: 05/03/2024 i. Lot Number: 117668 Date shipment received: 05/10/2024 j. Lot Number: 119957 Date shipment received: 06/03/2024 The surveyor requested documentation of CNA media QC for the above batches received on 06/26/2024 at 10:15 AM, and none was provided. 4. Review of patient urine culture volumes revealed the laboratory performed 638 urine cultures on CNA media with no QC documentation from 01/03/2024-06/26/2024. 5. In an interview on 06/26/2024 at 10:15 AM, the laboratory supervisor confirmed the laboratory failed to perform quality control checks on each batch of media to include its ability to support growth, and as appropriate, select or inhibit specific organisms or produce a biochemical response, for 10 of 10 batches of Columbia NaladixicAcid Agar (CNA) media received in 2024.

D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory policy, manufacturer's instructions, verification studies, quality control (QC) records, patient test reports, and confirmed in interview, the laboratory failed to ensure an effective quality assurance (QA) program was in place to monitor, assess, and correct problems in the laboratory for the analytical phase of testing for three of five specialties reviewed in 2024. Findings Included: 1. Review of laboratory policy, "Laboratory Quality Assurance Policy" (Approved by the laboratory director on 05/2024) revealed the following: "Policy: The scope of this policy is to monitor and improve all aspects of the clinical lab, including pre-analytic, analytical and post-analytical processes and procedures. Purpose: This plan will evaluate the processes put into place to ensure accurate test orders and results. It will review each aspect of the testing procedure; find issues if they exist and solutions for those issues. ...Quality Assessment Monitors: The following quality assessment monitors are actively evaluated to maintain an established standard of laboratory performance and compliance. Data from each monitored area is collected, recorded, and analyzed. The findings are evaluated to detect trends and overall compliance. When required, appropriate corrective action will be implemented and documented. ... Analytic: a. Review will include quality control calibrations and maintenance b. Review will also include proficiency testing/split sample testing c. Reference range and report format." 2. The laboratory failed to have a policy for performing lot rollovers for one of one Innovin reagent tested on the Sysmex CS-2500 analyzer. Refer to D5403 I. 3. The laboratory failed to establish QC lot rollover policies for one of one D-Dimer analyte tested on the Sysmex CS-2500 analyzer. Refer to D5403 II. 4. The laboratory failed to ensure the MNPT (mean normal prothrombin time) was calculated correctly for one of one lot of Innovin reagent in December 2023. Refer to D5411. 5. The laboratory failed to ensure verification studies were completed for three of three analytes (PT, aPTT and D-Dimer) tested on the Sysmex CS-2500 analyzer prior to testing and reporting patients. Refer to D5421 I. 6. The laboratory failed to verify the reference range for ten of ten randomly selected analytes in 2024. Refer to D5421 II. 7. The laboratory failed to have a QC system in place to detect immediate errors for three of three QC lots randomly reviewed in 2024. Refer to D5441 I. 8. The laboratory failed to have a QC system in place to detect immediate errors for two of four QC lots randomly reviewed in 2024. Refer to D5441 II. 9. The laboratory failed to document negative and positive control material at least once per day patient samples were tested for the Respiratory Panel 2.1 on the BioFire Torch analyzer for nine of nine days in 2023 (November-December) 19 of 19 days in 2024 (January-May). Refer to D5449 I. 10. The laboratory failed to document negative and positive control material at least once per day patient samples were tested for the Blood Culture Identification 2 (BCID2) Panel on the BioFire Torch analyzer for 12 of 12 days in 2023 (November-December) 22 of 22 days in 2024 (January-May). Refer to D5449 II. 11. The laboratory failed to document negative and positive control material at least once per day patient samples were tested for the Blood Culture Identification 2 (BCID2) Panel on the BioFire Torch analyzer for 12 of 12 days in

	2023 (November-December) 22 of 22 days in 2024 (January-May). Refer to D5449 III. 12. The laboratory failed document for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for peripheral blood smears for 12 of 12 months in 2023 and six of six months in 2024 (January through June). Refer to D5473. 13. The laboratory failed to perform quality control checks on each batch of media to include its ability to support growth, and as appropriate, select or inhibit specific organisms or produce a biochemical response, for 10 of 10 batches of Columbia NaladixicAcid Agar (CNA) media received in 2024. Refer to D5477.
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 surveyor observation, review of laboratory documentation, patient specimen logs, patient final reports, personnel records and confirmed in interview, the laboratory director failed to provide overall management and direction of moderate complexity testing for three of five specialties reviewed in 2024. Refer to D6004.
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory documentation, patient specimen logs, patient final reports, and confirmed in interview, the laboratory director failed to ensure testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance in moderate complexity testing three of five specialties reviewed in 2024, as evidenced by: 1. The laboratory director failed to ensure a quality control program was established and maintained for three of five specialties reviewed in 2024. Refer to D6020. 2. The laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytic performance two of five specialties reviewed in 2024. Refer to D6023. 3. The Laboratory Director failed to ensure that 1 of 22 Testing Persons (TP-12) received the appropriate training in moderate complexity testing prior to patient testing. Refer to D6029.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES

	CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policy, manufacturer's instructions, quality control (QC) documentation, patient final reports, and confirmed in interview, the laboratory director failed to ensure a quality control program was established and maintained for three of five specialties reviewed in 2024, as evidenced by: 1. The laboratory failed to have a policy for performing lot rollovers for one of one Innovin reagent tested on the Sysmex CS-2500 analyzer. Refer to D5403 I. 2. The laboratory failed to establish QC lot rollover policies for one of one D-Dimer analyte tested on the Sysmex CS-2500 analyzer. Refer to D5403 II. 3. The laboratory failed to ensure the MNPT (mean normal prothrombin time) was calculated correctly for one of one lot of Innovin reagent in December 2023. Refer to D5411. 4. The laboratory failed to ensure verification studies were completed for three of three analytes (PT, aPTT and D-Dimer) tested on the Sysmex CS-2500 analyzer prior to testing and reporting patients. Refer to D5421 I. 5. The laboratory failed to verify the reference range for ten of ten randomly selected analytes in 2024. Refer to D5421 II. 6. The laboratory failed to have a QC system in place to detect immediate errors for three of three QC lots randomly reviewed in 2024. Refer to D5441 I. 7. The laboratory failed to have a QC system in place to detect immediate errors for two of four QC lots randomly reviewed in 2024. Refer to D5441 II. 8. The laboratory failed to document negative and positive control material at least once per day patient samples were tested for the Respiratory Panel 2.1 on the BioFire Torch analyzer for nine of nine days in 2023 (November-December) 19 of 19 days in 2024 (January-May). Refer to D5449 I. 9. The laboratory failed to document negative and positive control material at least once per day patient samples were tested for the Blood Culture Identification 2 (BCID2) Panel on the BioFire Torch analyzer for 12 of 12 days in 2023 (November-December) 22 of 22 days in 2024 (January-May). Refer to D5449 II. 10. The laboratory failed to document negative and positive control material at least once per day patient samples were tested for the Blood Culture Identification 2 (BCID2) Panel on the BioFire Torch analyzer for 12 of 12 days in 2023 (November-December) 22 of 22 days in 2024 (January-May). Refer to D5449 III.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(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, review of laboratory policy, manufacturer's instructions, quality control (QC) documentation, patient final reports and confirmed in interview, the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytic performance two of five specialties reviewed in 2024, as evidenced by: 1. The laboratory failed to have a policy for performing lot rollovers for one of one Innovin reagent tested on the Sysmex CS-2500 analyzer. Refer to D5403 I. 2. The laboratory failed to establish QC lot rollover policies for one of one D-Dimer analyte tested on the Sysmex CS-2500 analyzer. Refer to D5403 II. 3. The laboratory failed to ensure the MNPT (mean normal prothrombin time) was calculated correctly for one of one lot of Innovin reagent in December 2023. Refer to D5411. 4. The laboratory failed to ensure verification studies were completed for three of three analytes (PT, aPTT and D-Dimer) tested on the Sysmex CS-2500 analyzer prior to testing and reporting patients. Refer to D5421 I. 5. The laboratory failed to verify the reference range for ten of ten randomly selected analytes in 2024. Refer to D5421 II. 6. The laboratory failed to have a QC system in place to detect immediate errors for three of three QC lots randomly reviewed in 2024. Refer to D5441 I. 7. The laboratory failed to have a QC system in place to detect immediate errors for two of four QC lots randomly reviewed in 2024. Refer to D5441 II.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of laboratory policies, personnel files, and confirmed in interview the Laboratory Director failed to ensure that 1 of 22 Testing Persons (TP-12) received the appropriate training in moderate complexity testing prior to patient testing. Findings included: 1. Review of the laboratory's policy titled "Competency Assessment and Training Policy" revealed: "PROCEDURE: 1. Upon orientation to the lab, employees will be directly observed by training personnel for every item on the employee's training checklist. Training personnel will be the technical supervisor, area supervisor for the specialty or their designee. Both the trainer and the trainee must sign and date the checklist items when they agree the employee is competent to perform the item. Once an item has been signed off the checklist, the employee may perform that function independently. New employees will be evaluated twice during the first year of performing patient testing." 2. Review of personnel files for TP-12 revealed a hire date of 09/2022. There was NO training documentation for testing performed on the ABL90 Flex Plus blood gas analyzer. The Laboratory Director failed to ensure TP-12 received the appropriate training in moderate complexity testing prior to patient testing. 3. During an interview on 06/24/2024 at 1:30 pm, the Laboratory Supervisor after a review of records confirmed the above findings.
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY

	CFR(s): 493.1409 The laboratory must have a technical consultant who meets the qualification requirements of 493.1411 of this subpart and provides technical oversight in accordance with 493.1413 of this subpart. This CONDITION is not met as evidenced by: Based on surveyor observation, review of laboratory documentation, patient specimen logs, patient final reports, and confirmed in interview, the technical consultant failed to provide technical oversight over the laboratory for two of five specialties reviewed in 2024. Refer to D6036.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policy, manufacturer's instructions, quality control (QC) documentation, patient final reports, and confirmed in interview, the technical consultant failed to provide technical and scientific oversight of the laboratory for three of five specialties reviewed in 2024, as evidenced by: 1. The technical consultant failed to ensure verification of test performance for two of five specialties reviewed in 2024. Refer to D6040. 2. The technical consultant failed to ensure appropriate QC programs were maintained throughout the entire testing process for two of five specialties reviewed in 2024. Refer to D6042. 3. The technical consultant (TC) failed to evaluate and document the performance 6 of 22 Testing Persons (TP-1, TP-2, TP-11, TP-12, TP-20, TP-22) responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. Refer to D6053. 4. The technical consultant (TC) failed to evaluate and document annual competency assessments for 10 of 22 Testing Persons (TP-7, TP-9, TP-10, TP-13, TP-14, TP-15, TP-16, TP-17, TP-18, TP-19) responsible for moderate complexity testing. Refer to D6054.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policy, manufacturer's instructions, quality control (QC) documentation, patient final reports, and confirmed in interview, the technical consultant failed to ensure verification of test performance for two of five specialties reviewed in 2024, as evidenced by: 1. The laboratory failed to have a policy for performing lot rollovers for one of one Innovin reagent tested on the Sysmex CS-2500 analyzer. Refer to D5403 I. 2. The laboratory failed to establish QC lot rollover policies for one of one D-Dimer analyte tested on the Sysmex CS-

	2500 analyzer. Refer to D5403 II. 3. The laboratory failed to ensure the MNPT (mean normal prothrombin time) was calculated correctly for one of one lot of Innovin reagent in December 2023. Refer to D5411. 4. The laboratory failed to ensure verification studies were completed for three of three analytes (PT, aPTT and D-Dimer) tested on the Sysmex CS-2500 analyzer prior to testing and reporting patients. Refer to D5421 I. 5. The laboratory failed to verify the reference range for ten of ten randomly selected analytes in 2024. Refer to D5421 II.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on surveyor observation, review of laboratory policy, manufacturer's instructions, quality control (QC) documentation, patient final reports, and confirmed in interview, the technical consultant failed to ensure appropriate QC programs were maintained throughout the entire testing process for two of five specialties reviewed in 2024, as evidenced by: 1. The laboratory failed to have a QC system in place to detect immediate errors for three of three QC lots randomly reviewed in 2024. Refer to D5441 I. 2. The laboratory failed to have a QC system in place to detect immediate errors for two of four QC lots randomly reviewed in 2024. Refer to D5441 II. 3. The laboratory failed to document negative and positive control material at least once per day patient samples were tested for the Respiratory Panel 2.1 on the BioFire Torch analyzer for nine of nine days in 2023 (November-December) 19 of 19 days in 2024 (January-May). Refer to D5449 I. 4. The laboratory failed to document negative and positive control material at least once per day patient samples were tested for the Blood Culture Identification 2 (BCID2) Panel on the BioFire Torch analyzer for 12 of 12 days in 2023 (November-December) 22 of 22 days in 2024 (January-May). Refer to D5449 II. 5. The laboratory failed to document negative and positive control material at least once per day patient samples were tested for the Blood Culture Identification 2 (BCID2) Panel on the BioFire Torch analyzer for 12 of 12 days in 2023 (November-December) 22 of 22 days in 2024 (January-May). Refer to D5449 III.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy, personnel files, and confirmed in interview the technical consultant (TC) failed to evaluate and document the performance 6 of 22 Testing Persons (TP-1, TP-2, TP-11, TP-12, TP-20, TP-22) responsible for moderate complexity testing at least semiannually during the first year the individual tests

	patient specimens. Findings included: 1. Review of the laboratory's policy titled "Competency Assessment and Training Policy" revealed: "POLICY: The performance of individuals responsible for waived, moderate, and/or high complexity testing is evaluated and documented twice during their first year of performing patient testing. Thereafter, competency assessment is performed annually unless test methodology or instrumentation changes, in which case, prior to reporting patient results, the individual's performance must be reevaluated to include the use of new methodology or instrumentation." 2. Review of personnel records for testing personnel responsible for moderate complexity testing revealed the following: a. TP-1 personnel records revealed an initial training assessment was performed from March through June 2023 on the following analyzers/test kits: Specialty: Chemistry- Vitros 5600 and Vitros 350 analyzers; i-Stat analyzer; Urine Drug Screen kit; Alere Triage analyzer; Rapid Fetal Fibronectin; microscopic urinalysis; serum HCG (human chorionic gonadotropin) kit Specialty: Immunology- mononucleosis test kit Specialty: Bacteriology- ImmunoCard Stat! EHEC and CAMPY kits; Leuko Ez Vue Lactoferin Test Semiannual competency was performed in May 2024 by TP-11 NOT the TC. There was no documentation of a semiannual performance for TP-1. b. TP-2 personnel records revealed an initial training assessment was performed from August through September 2022 on the following analyzers/test kits: Specialty: Chemistry- Vitros 5600 and Vitros 350 analyzers; Urine Drug Screen kit; microscopic urinalysis; serum HCG (human chorionic gonadotropin) kit Specialty: Hematology- STAGO coagulation analyzer, Beckman Coulter complete blood count (CBC) analyzers Specialty: Immunology- mononucleosis test kit Specialty: Bacteriology- ImmunoCard Stat! EHEC and CAMPY kits; Leuko Ez Vue Lactoferin Test Semiannual competency was performed in November 2023 by TP-10 NOT the TC. There was no documentation of a semiannual performance for TP-2. c. TP-11 personnel records revealed an initial training assessment was performed from February through March 2023 on the following analyzers/test kits: Specialty: Chemistry- Vitros 5600 and Vitros 350 analyzers; i-Stat analyzer; Urine Drug Screen kit; Alere Triage analyzer; Rapid Fetal Fibronectin; microscopic urinalysis; serum HCG (human chorionic gonadotropin) kit Specialty: Hematology- STAGO coagulation analyzer, Beckman Coulter complete blood count (CBC) analyzers Specialty: Immunology- mononucleosis test kit; RPR (rapid plasma regain) kit Specialty: Bacteriology- ImmunoCard Stat! EHEC and CAMPY kits; Leuko Ez Vue Lactoferin Test There was no documentation of a semiannual performance for TP-11. d. TP-12 personnel records revealed a hire date of 09/2022 and NO initial training documentation for testing performed on the ABL90 Flex Plus blood gas analyzer. Refer to D6029. Further review of personnel records for TP-12 revealed no documentation of semiannual performance on the ABL90 Flex Plus blood gas analyzer. e. TP-20 personnel records revealed training on the ABL90 Flex Plus blood gas analyzer on 04/2023. Further review of personnel records for TP-20 revealed no documentation of semiannual performance on the ABL90 Flex Plus blood gas analyzer. f. TP-22 personnel records revealed training on the ABL90 Flex Plus blood gas analyzer on 06/2022. Further review of personnel records for TP-20 revealed no documentation of semiannual performance on the ABL90 Flex Plus blood gas analyzer. 3. During an interview on 06/24/2024 at 1:30 pm, the Laboratory Supervisor after a review of records confirmed the above findings.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year.

	This STANDARD is not met as evidenced by: Based on review of laboratory policy, personnel files, and confirmed in interview the technical consultant (TC) failed to evaluate and document annual competency assessments for 10 of 22 Testing Persons (TP-7, TP-9, TP-10, TP-13, TP-14, TP-15, TP-16, TP-17, TP-18, TP-19) responsible for moderate complexity testing. Findings included: 1. Review of the laboratory's policy titled "Competency Assessment and Training Policy" revealed: "POLICY: The performance of individuals responsible for waived, moderate, and/or high complexity testing is evaluated and documented twice during their first year of performing patient testing. Thereafter, competency assessment is performed annually unless test methodology or instrumentation changes, in which case, prior to reporting patient results, the individual's performance must be reevaluated to include the use of new methodology or instrumentation." 2. Review of personnel files revealed the TC failed to perform annual competency assessments in 2022 and 2023 for the following TP: TP-7: 2023 annual competency assessment was performed by TP-10, not the TC TP-9: 2023 annual competency assessment was performed by TP-10, not the TC TP-10: 2023 annual competency assessment was performed by TP-9, not the TC TP-13: no documentation of annual competency assessments in 2022 and 2023 TP-14: no documentation of annual competency assessments in 2022 and 2023 TP-15: no documentation of annual competency assessments in 2023 TP-16: no documentation of annual competency assessments in 2022 and 2023 TP-17: no documentation of annual competency assessments in 2022 and 2023 TP-18: no documentation of annual competency assessments in 2022 and 2023 TP-19: no documentation of annual competency assessments in 2022 and 2023 The Technical Consultant had not performed and documented competency assessment for the above listed personnel to include: a) Direct observation of routine patient test performance, including patient preparation, specimen handling, processing and testing. b) Monitoring the recording and reporting of patient test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens or external proficiency testing samples. f) Assessment of problem-solving skills. 3. During an interview on 06/24/2024 at 1:30 pm, the Laboratory Supervisor after a review of records confirmed the above findings.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy, personnel files and confirmed in interview the technical supervisor (TS) failed to evaluate and document the performance 3 of 11 Testing Persons (TP-1, TP-2, TP-11) responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. Findings included: 1. Review of the laboratory's policy titled "Competency Assessment and Training Policy" revealed: "POLICY: The performance of individuals responsible for waived, moderate, and/or high complexity testing is evaluated and documented twice

	during their first year of performing patient testing. Thereafter, competency assessment is performed annually unless test methodology or instrumentation changes, in which case, prior to reporting patient results, the individual's performance must be reevaluated to include the use of new methodology or instrumentation." 2. Review of personnel records for testing personnel responsible for high complexity testing revealed the following: a. TP-1 personnel records revealed an initial training assessment was performed from March through June 2023 on the following analyzers /test kits: Specialty: Immunohematology to include ABO and RH grouping, antibody detection and compatibility testing Specialty: Bacteriology to include media culture interpretations, gram staining, identification and susceptibility testing on the Walkaway analyzer, rapid NH identification Semiannual competency was performed in May 2024 by TP-11 NOT the TS. There was no documentation of a semiannual performance for TP-1. b. TP-2 personnel records revealed an initial training assessment was performed from August through September 2022 on the following analyzers/test kits: Specialty: Immunohematology to include ABO and RH grouping, antibody detection and compatibility testing Specialty: Hematology- manual differentials Semiannual competency was performed in November 2023 by TP-10 NOT the TS. There was no documentation of a semiannual performance for TP-2. c. TP-11 personnel records revealed an initial training assessment was performed from February through March 2023 on the following analyzers/test kits: Specialty: Immunohematology to include ABO and RH grouping, antibody detection and compatibility testing Specialty: Hematology- manual differentials Specialty: Bacteriology to include media culture interpretations and gram staining There was no documentation of a semiannual performance for TP-11. 3. During an interview on 06 /24/2024 at 1:30 pm, the Laboratory Supervisor after a review of records confirmed the above findings.
D6128	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, 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 laboratory policy, personnel files, and confirmed in interview the technical supervisor (TS) failed to evaluate and document annual competency assessments for 3 of 11 Testing Persons (TP-7, TP-9, TP-10) responsible for high complexity testing. Findings included: 1. Review of the laboratory's policy titled "Competency Assessment and Training Policy" revealed: "POLICY: The performance of individuals responsible for waived, moderate, and/or high complexity testing is evaluated and documented twice during their first year of performing patient testing. Thereafter, competency assessment is performed annually unless test methodology or instrumentation changes, in which case, prior to reporting patient results, the individual's performance must be reevaluated to include the use of new methodology or instrumentation." 2. Review of personnel files revealed the TS failed to perform annual competency assessments in 2022 and 2023 for the following TP: TP-7: 2023 annual competency assessment was performed by TP-10, not the TS TP-9: 2023 annual competency assessment was performed by TP-10, not the TS TP-10: 2023 annual competency assessment was performed by TP-9, not the TS The Technical

	Supervisor had not performed and documented competency assessment for the above listed personnel to include: a) Direct observation of routine patient test performance, including patient preparation, specimen handling, processing, and testing. b) Monitoring the recording and reporting of patient test results. c) Review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. d) Direct observation of performance of instrument maintenance and function checks. e) Assessment of test performance through testing previously analyzed specimens or external proficiency testing samples. f) Assessment of problem-solving skills. 3. During an interview on 06/24 /2024 at 1:30 pm, the Laboratory Supervisor after a review of records confirmed the above findings.