Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	48D0699866	06/04/2025
Name of Provider or Supplier	**Street Address, City, State**	
Clinical Laboratory Inc	Island Med Ctr Suite 6, Sunny Isle, St Croix, VI	

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
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) (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 proficiency testing (PT), blood bank quality control worksheets, the laboratory's procedure manual, and in interview with the technical supervisor, the laboratory failed to test quality control (QC) before testing blood bank proficiency testing (PT) as they would with patients for 1 of 1 event in 2025. Findings included: 1. Review of American Association of Bioanalysts (AAB) Medical Laboratory Evaluation Blood Bank event 1 in 2025 included five PT samples analyzed on 02/07/2025 (ABO Group, D Typing, and Unexpected Antibody Detection). 2. Review of Immucor CorQC Data Sheets from 02/2025 included QC performed on 02/06/2025 and 02/08/2025, but not on the day PT was tested (02/07/2025). 3. Review of the laboratory's procedure manual stated, "QUALITY CONTROL FREQUENCY: Each patient run." The laboratory failed to ensure quality control was tested before performing PT as they would with patients. 4. During an interview on 06/04/2025 at 9:24 AM, the technical supervisor confirmed the above findings.
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)

	Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following: This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, direct observation, the laboratory failed to retain Kwik-Stik package insert to ensure American Type Culture Collection (ATCC) microorganisms used for QC were maintained per manufacturer's instructions and included in their written procedure. Findings included: 1. Review of the laboratory's microbiology procedure manual revealed it did not include step-by-step procedure for plating, maintaining, and labeling QC microorganism plates. 2. During a tour of the microbiology department on 06/04/2025 at 1:36 PM, the following QC microorganism plates did not include a lot number and expiration date of the original Kwik-Stik ATCC organisms (random sampling of 17): "K. Oxytoca, 700324, 6/3" on MacConkey media "P. aeruginosa, 27853, 6/3" on MacConkey media "K. pneumoniae, 700603, 6/3" on MacConkey media "P. aeruginosa BAA, 1744, 6/3" on MacConkey media "E. coli, 35218, 6/3" on MacConkey media "S. aureus, 29213, 6 /3" on Blood Agar media "S. pneumo, 49619, 6/3" on Blood Agar media The laboratory did not have a mechanism in place to track ATCC microorganisms that had been plated and used as QC, refer to D5415. 3. During a tour of the laboratory on 06 /04/2025 at 1:36 PM, packaged unused Kwik-Stik microorganisms were observed stored in a refrigerator. 4. During an interview on 06/04/2025 at 1:36 PM, the technical supervisor confirmed the laboratory did not have Kwik-Stik package insert to follow manufacturer's instructions when inoculating the microorganisms.
D5305	TEST REQUEST CFR(s): 493.1241(c) (c) The laboratory must ensure the test requisition solicits the following information: (c)(1) The name and address or other suitable identifiers of the authorized person requesting the test and, if appropriate, the individual responsible for using the test results, or the name and address of the laboratory submitting the specimen, including, as applicable, a contact person to enable the reporting of imminently life threatening laboratory results or panic or alert values. (c)(2) The patient's name or unique patient identifier. (c)(3) The sex and age or date of birth of the patient. (c)(4) The test(s) to be performed. (c)(5) The source of the specimen, when appropriate. (c)(6) The date and, if appropriate, time of specimen collection. (c)(7) For Pap smears, the patient's last menstrual period, and indication of whether the patient had a previous abnormal report, treatment, or biopsy. (c)(8) Any additional information relevant and necessary for a specific test to ensure accurate and timely testing and reporting of results, including interpretation, if applicable. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, manufacturer's instructions, patient test requisitions, patient final test reports, and interview with staff, the laboratory failed to ensure collection dates and times were included in patient test requisitions when requesting tests with specimen stability requirements for 4 of 4 patients (random sampling). Findings included: 1. Review of the laboratory's procedures and manufacturer's instructions for a random sampling of testing that the laboratory performed included the following for specimen stability: a) The laboratory's written

	procedure for Sickle Cell testing stated, "Specimens can be kept for 1 to 2 weeks at 2 to 8C." Sickledex manufacturer stated, "Blood samples stored at 1C to 10C for up to 45 days may be used for testing." b) The laboratory's written procedure for rapid plasma reagin (RPR) testing stated, "Serum samples should be tested within five (5) days of collection." The laboratory's procedure was consistent with Arlington Scientific RPR manufacturer's instructions. c) The laboratory's written procedure for Rubella Immunoglobulin G (IgG) testing stated, "If the test cannot be carried out on the same day, the serum must be stored between 2-8C for no longer than 8 days after collection." The laboratory's procedure was consistent with ASI Rubella manufacturer's instructions. d) The laboratory's written procedure for rheumatoid factor/rheumatoid arthritis (RF/RA) Latex testing stated, "If samples cannot be tested immediately, maintain them in their original tubes at 2-8C and test within 48 hours" (or can be frozen -20C or colder). The laboratory's procedure was consistent with Arlington Scientific RF/RA Latex manufacturer's instructions. e) The laboratory's written procedure for human chorionic gonadotropin (hCG) testing stated, "Serum specimen may be stored at 2-8C for up to 48 hours prior to testing." The laboratory's procedure was consistent with hCG Combo kit manufacturer's instructions. 2. Review of a random sampling of patient test requisitions did not include specimen date and time of collection to ensure specimens were not tested beyond their stability, as follows: Patient 00195960000 "Date: 02/27/2025" requested Sickle Cell testing, test results were reported on 02/28/2025 at 8:12 AM. Patient 0009145000 "Order Date: 02 /24/2025 03:10 PM" requested RPR and Rubella IgG testing, test results were reported on 02/24/2025 at 12:33 PM. Patient 0020720000 "Order Date: 02/03/2025 at 01:02 PM" requested RA Latex testing, test results were reported on 02/04/2025 at 2: 50 PM. Patient 205229 "Date: 1/27/25" requested hCG qualitative testing, test results were reported on 01/27/2025 at 12:53 PM. Reported dates and times were obtained from patient final test reports. 3. During the exit interview on 06/04/2025 at 4 PM, the laboratory staff (director of laboratory operations, the technical supervisor, billing supervisor and owner) reviewed and confirmed patient test requisitions did not include date and time of specimen collection.
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 observation, review of procedures, manufacturer's product inserts, quality control documentation and interview, the laboratory failed to follow their own written policy for performing quality control on three screen cells for 9 of 9 days (Refer to D5401); failed to include step-by-step procedures for media quality control, setting up cultures, and performing urine colony counts in microbiology (Refer to D5403); failed to follow manufacturer's instructions for washing the needle used for rapid plasma reagin (RPR) testing for 405 tests (Refer to D5411); failed to document room and refrigerator temperatures for 107 of 107 days where testing occurred, and kits were stored, failed to define an incubator temperature range for blood bank testing for 9 of 9 months reviewed, failed to define an acceptable freezer temperature range per

	manufacturer's instructions (Refer to D5413); failed to label 17 of 17 QC microorganism plates with a lot number and expiration dates to ensure American Type Culture Collection (ATCC) organisms were not used past their expiration dates (Refer to D5415); failed to ensure blood bank reagents were not used past their expiration date when 13 of 13 patients were tested, failed to ensure DensiChek plus Standards Kit was not used past its expiration date for 4 of 4 days (monthly frequency) in 2025, failed to ensure quality control was not used past the expiration date (Refer to D5417); failed to perform calibration verification procedures at least once every six months that included at least a minimal value, a mid-point value, and a maximum value near the upper limit to verify the laboratory's reportable range (Refer to D5439); failed to include two brain natriuretic peptide (BNP) control materials of different concentrations when patients were tested on 7 of 7 days in 2025, failed to include two controls materials of different concentrations each day of patient testing for erythrocyte sedimentation rate testing (Refer to D5447); failed to perform a positive and negative control each day of testing for moderately complex Chlamydia /Trichomonas(CT) and Neisseria gonorrhea (NG) (Refer to D5449); failed to use human chorionic gonadotropin (hCG) serum control material for the hCG Combo Rapid Test kit when used to test 5 of 5 patient serums in 2025 (Refer to D5465); and failed to check staining material each day of use (Refer to D5473).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's written procedure, blood bank QC data, patient worksheets, direct observation and interview with the technical supervisor, the laboratory failed to follow their own written policy for performing quality control on three screen cells for 9 of 9 days. Findings included: 1. Review of the laboratory's written procedure for blood bank stated, "Antibody Screen: REAGENTS: reagent Screening Cells I, II, III ...Antibody screening Procedure: Label 3 tubes 12 X 75 mm with Patient sample number; First three tubes add two drops of patient serum ..." 2. Review of Immucor corQC Data Sheets and patient worksheets from 2025 included the following (random sampling): 01/23/2025 - QC was performed on screening cells (lot S534) I, II, and III with "3+" results. 01/28/2025 - QC was performed on screening cells (lot S534) I, II, and III with "3+" results. Patient 3464102 antibody screen was performed with screening cells (lot S534) I and II. 02/24/2025 - QC was performed on screening cells (lot S539) I, II, and III with "3+" results. 02/26/2025 - QC was performed on screening cells (lot S539) I, II, and III with "3+" results. 02/27 /2025 - QC was performed on screening cells (lot S539) I, II, and III with "3+" results. 05/16/2025 - QC was performed on screening cells (lot S556) I, II, and II with "3+" results. 05/19/2025 - QC was performed on screening cells (lot S556) I, II, and II with "3+" results. Patient 355738 antibody screen was performed with screening cells (lot S556) I and II. 05/20/2025 - QC was performed on screening cells (lot S556) I, II, and II with "3+" results. 05/23/2025 - QC was performed on screening cells (lot S556) I, II, and II with "3+" results. 3. During a tour on 06/04/2025 at 8:25 AM, two Selectogen screening cells (lot S562) were observed stored in the refrigerator. 4. During an interview on 06/04/2025 at 9:24 AM, the technical supervisor confirmed

	there were only two screening cells and should have not been documenting QC for three screening cells.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's procedure manual, the test menu, media QC, patient worksheets, test volumes, and interview with the technical supervisor, the laboratory failed to include step-by-step procedures for media quality control, culture plating, and performing urine colony counts in microbiology. Findings included: 1. Review of the laboratory's microbiology procedure manual included one procedure, "Vitek 2 Compact." The procedure manual did not include step-by-step procedures for media quality control, culture plating, performing urine colony counts and patient preparation. 2. Review of the laboratory's test menu included urine culture, stool culture, and group B streptococcus. "Reagent, Media and Supplies Check" records from 08/2024 through 05/2025 included media QC performed for Blood agar, MacConkey agar, XLD agar, PEA agar, Selenite broth, and Thioglycolate broth. The laboratory's procedure manual did not include step-by-step procedures for setting up the cultures and performing media QC (including documentation of the organism used). 3. Review of a random sampling of "Bacteriology Patient Worksheets" from 10/2024 and 02/2025 included the following colony counts documented: 10/22/2024 - "Date Cultured/Plated" for patient 339825, "Colony Count (if apply) 24 hours: >100." 02/19/2025 - "Date Cultured/Plated" for patient 1200589, "Colony Count (if apply) 24 hours: >100 K"; patient 348073 "Colony Count (if apply) 24 hours: 30-40." 02/21/2025 - "Date Cultured/Plated" for patient 1201855, "Colony Count (if apply) 24 hours: 10-20." 02/22/2025 - "Date Cultured/Plated" for patient 1202635, "Colony Count (if apply) 24 hours: >100." The laboratory procedure manual did not include a step-by-step procedure for counting urine colonies and interpretation of results, reference intervals, requirements for patient preparation, specimen collection and handling. 4. Review of the annual volume for bacteriology was 2,402 patient cultures. 5. During an interview on 06/04/2025 at 12:16 PM, the technical supervisor confirmed the laboratory did not have step-by-step procedures, including patient preparation for

	urine colony counts, for the microbiology tests performed. 43831 II. Based on a review of the procedure manual and an interview with the technical supervisor (TS), the laboratory failed to include reference intervals (normal values) for complete blood cell counts (CBC). Findings: 1. Review of the CBC procedure manual revealed a lack of normal values for CBCs. 2. An interview with the TS on 6/4/2025 at 11:00 AM confirmed that the laboratory failed to include normal values for CBC patient tests. 3. The laboratory reports approximately 10,990 CBCs annually.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) (a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, the laboratory's procedure manual, interview with the TS, and review of annual test volumes, the laboratory failed to follow manufacturer's instructions for washing the needle used for rapid plasma reagin (RPR) testing for 405 tests. Findings included: 1. Review of Arlington Scientific RPR Card test for Syphilis kit stated, "HANDLING AND PROCEDURAL NOTES ...3. The needle assembly must be thoroughly washed in distilled or deionized water and air dried after each shift. Do not wipe the needle dry ..." 2. Review of the laboratory's procedure manual for RPR testing stated, "9. Remove and wash the needle at the end of each shift." 3. During an interview on 06/03/2025 at 2:48 PM, the technical supervisor was asked what kind of water do testing persons clean the needle with after the end of their shift. The TS stated the needle was not washed. 4. Review of the annual volume for RPR included 405 patient tests.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(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 temperature charts, manufacturer's instructions, direct observation, and interview with the technical supervisor, the laboratory failed to document room and refrigerator temperatures for 107 of 107 days where testing occurred, and kits were stored. Findings included: 1. Review of an Excel sheet (labeled "RTCH9M") with a room temperature range defined as 15-30C did not include temperatures documented for the following days in 2024: 09/18/2024 through 09/21/2024 10/03/2024 through 10/05/2024 10/07/2024 through 10/12/2024, 10/14 /2024 11/24/2024 through 12/31/2024 2. Review of manufacturer's instructions for

	handling reagents when testing included the following: ASI Rubella stated, "Remove reagents from refrigeration approximately 5 minutes prior to use; warm the latex reagent to room temperature (20-30C) by rolling vial between hands." Triage Brain natriuretic peptide (BNP) stated, "Optimal results will be achieved by performing testing at temperatures between 20C to 24C (68F to 75F.)" 3. Review of the laboratory's test volumes included Rubella 30 tests, and BNP 572 tests. 4. Review of an Excel sheet (labeled "RFCH7D") with a refrigerator temperature range defined as 2-8C did not include temperatures documented for the following days in 2024: 09/10 /2024 - 09/14/2024 09/25/2024 - 10/05/2024 11/16/2024 - 12/31/2024 5. During a tour of the laboratory on 06/04/2025 at 9:23 AM, the following random sampling of test kits were observed stored in the refrigerator (2-8C): ASI Color Mono II Test, lot 5B18B3, expiration date 07/31/2026, "Temperature Limitation 2C - 8C." ASI Rubella Test, lot 4J19G8, expiration date 12/31/2025, "Temperature Limitation 2C - 8C." 6. During an interview on 06/03/2025 at 1:07 PM, the technical supervisor confirmed the above findings. II. Based on review of the manufacturer's instructions, the laboratory's procedure manual, incubator temperature records, test volume records, and interview with the technical supervisor, the laboratory failed to define an incubator temperature range for blood bank testing for 9 of 9 months reviewed. Findings included: 1. Review of Immucor Bovine Albumin Solution 22% package insert (manufacturer's instructions) stated, "Procedure for Antibody Detection, Antibody Identification, or Crossmatch ... Add 2 drops of 22% Bovine Albumin to each tube. NOTE: If desired, tubes may be incubated at room temperature (15-30C) for 5-30 minutes, centrifuged and examined for agglutination prior to the addition of a potentiator or incubation at 36-38C. Mix the content of each tube thoroughly. Incubate at 36-38C for 30-60 minutes." 2. Review of the laboratory's Antibody Screening procedure stated, " ...Add two drops of Albumin; Incubate for 30 minutes at 37C." The procedure did not include an incubator temperature range. 3. Review of "Thermolyne Dri-Bath Daily Quality Control Temperature Register" incubator temperature records from 09/2024 through 06/2025 did not include a temperature range. 4. Review of the laboratory's annual volume for patient Antibody Screen was 50 tests. 5. During an interview on 06 /03/2025 at 12:48 PM, the technical supervisor confirmed the incubator used for blood bank testing did not include a defined temperature range. 43831 III. Based on observation of quality control (QC) material stored in the FRCH4BD freezer, review of manufacturer's instructions, documentation of freezer temperatures, and interview with the technical supervisor (TS), the laboratory failed to define a temperature range for 154 of 154 days. Findings: 1. Observation of the laboratory freezer labeled FRCH4BD showed one box of Bio-Rad Immunoassay Plus control level III (lot # C4089AN), one box of Bio-Rad Liquicheck Diabetes control level I (lot #89271), and four boxes Bio-Rad Liquicheck Diabetes contol level III (lot #89273). 2. Review of the manufacturer's instructions for Bio-Rad Immunoassay Plus control and Bio-Rad Liquicheck Diabetes control showed controls must be stored at minus 20 degrees Celsius (C) to minus 70 degrees C. 3. Review of the laboratory's temperature chart showed an undefined acceptable range for 154 of 154 days from 1/1/2025 to 6/4/2025 for the FRCH4BD freezer 4. Interview with the TS on 6/4/2025 at 1:00 PM confirmed the laboratory failed to define an acceptable freezer temperature range per manufacturer's instructions. 5. The laboratory reports approximately 42,000 chemistry patient results annually.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1)

	Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: I. Based on review of manufacturer's instructions, review of the laboratory's procedure, direct observation, and in interview with the technical supervisor, the laboratory failed to label one of one in-use carbon antigen dropper bottle with its identity and revised expiration date. Findings included: 1. Review of the Arlington Scientific RPR Card Test for Syphilis kit manufacturer's instructions stated, "In order to obtain reliable and consistent results, the instructions in the package insert must be strictly followed. Do not modify the handling and storage conditions for reagents or samples ...Carbon Antigen may be stored for up to one month in the dropping bottle at 2-8C ..." 2. Review of the laboratory's procedure for RPR testing and Carbon Antigen handling was consistent with the manufacturer's instructions. 3. During a tour of the laboratory on 06/03/2025 at 12:33 PM, a small dropper bottle of carbon antigen was observed stored with the in-use RPR kit supplies and did not include documentation of its identity and the revised expiration date. 4. Review of the annual volume for RPR included 405 patient tests. 5. During an interview on 06/03/2025 at 12:33 PM, the technical supervisor confirmed the above findings. II. Based on review of the laboratory's procedure manual, direct observation, and interview with the technical supervisor, the laboratory failed to label 17 of 17 QC microorganism plates with a lot number and expiration dates to ensure American Type Culture Collection (ATCC) organisms are not used past their expiration dates. Findings included: 1. Review of the laboratory's microbiology procedure manual did not include step-by-step procedure for plating, maintaining, and labeling QC microorganism plates. 2. During a tour of the microbiology department on 06/04/2025 at 1:36 PM, the following QC microorganism plates did not include a lot number and expiration date of the original Kwik-Stik ATCC organism (random sampling of 17): "K. Oxytoca, 700324, 6/3" on Maconkey media "P. aeruginosa, 27853, 6/3" on Maconkey media "K. pneumoniae, 700603, 6/3" on Maconkey media "P. aeruginosa BAA, 1744, 6/3" on Maconkey media "E. coli, 35218, 6/3" on Maconkey media "S. aureus, 29213, 6/3" on Blood Agar media "S. pneumo, 49619, 6/3" on Blood Agar media 3. During an interview on 06/04/2025 at 10:52 AM, the technical supervisor confirmed the laboratory did not have a procedure for QC microorganism plates and tracking the plates with a lot number and expiration date. She confirmed the ATCC organisms originated from Kwik-Stik and did not have the manufacturer's instructions.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: I. Based on direct observation, review of manufacturer's instructions, blood bank patient worksheets, and in interview with the laboratory manager, the laboratory failed to ensure blood bank reagents were not used past their expiration date when 13 of 13 patients were tested. Findings included: 1. During a tour of the laboratory on 06/03 /2025 at 12:30 PM, an opened 10L box of Buffered Blood Bank Saline (lot # 802763,

expiration date 11/30/2025) was observed stored near a sink. There was documentation of the box being opened for use on "2/7/25." 2. Review of the manufacturer's instructions on the Buffered Blood Bank Saline box stated, "Use within one month of date opened." There was an elapsed time of 88 days from the date of expiration (03/07/2025) to the observation. A random sampling of patients tested in blood bank included, 03/11/2025 - patient 3496673, 04/09/2025 - patients 3522063 and 3522183, and 04/23/2025 - patient 3532263. 3. Review of blood bank patient worksheets from 2023, 2024, and 2025 included, documented reagent lot numbers and expiration dates used for patient testing, as follows: 10/24/2023 - patients 315684, 315687, and 315687 tested with Cells A (lot 111474, expiration date "2023-10-23"), Cells B (lot 113474, expiration date "2023-10-23"), Checkcells (lot 32628, expiration date "2023-10-23") and Screening Cells (one of the lot numbers illegible, lot 298752, lot 398752, expiration date "2023-10-23"). 10/25/2023 - patient 3188052 was tested with Cells A (lot 111474, expiration date "2023-10-23"), Cells B (lot 113474, expiration date "2023-10-23"), Checkcells (lot 32628, expiration date "2023-10-23") and Screening Cells (one of the lot numbers illegible, lot 298752, lot 398752, expiration date "2023-10-23"). 10/28/2023 - patient 3159852 was tested with Checkcells (lot 32628, expiration date "2023-10-23"), Screening Cells (one of the lot numbers illegible, lot 298752, lot 398752, expiration date "2023-10-23"). 04/29/2024 - patients 3272273 and 3272453 - tested with Cells A (lot 111502, expiration date "2024-04-26"), Cells B (lot 113502, expiration date "2024-04-26"), and Checkcells (lot 08836, expiration date "2024-04-26"). 05/31/2024 - patient 329519 - tested with Cells A (lot 11536, expiration date "05-28-24"), Cells B (lot 11566, expiration date "05-28-24"), and Checkcells (lot 08978, expiration date "2024-05-28"). 04/23/2025 - patient 3532263 - tested with Screening Cells (lot S551, expiration date "2025-04-22"). 4. A review of Immucor package inserts (manufacturer's instructions) for Cells A, Cells B, Screen Cells (I, II, III) and Checkcells, stated, "PRECAUTION: Do not use past the expiration date." 5. During an interview on 06/04/2025 at 9:24 AM, the laboratory manager confirmed documentation of "SL" meant "same lot" and confirmed the documentation of the expiration dates for the above reagents used. II. Based on review of manufacturer's instructions, direct observation, review of Vitek 2 maintenance records, and in interview with staff, the laboratory failed to ensure DensiChek plus Standards Kit was not used past its expiration date for 4 of 4 days (monthly frequency) in 2025. Findings included: 1. Review of DensiChek plus manufacturer's instructions stated, "The kit can be used until the expiration date indicated on the packaging." 2. During a tour of the microbiology department on 06/04/2025 at 11:50 AM, DensiChek plus Standards Kit was observed stored on the Vitek 2 analyzer with lot number AK4031 and expiration date "2025-02-28" (three standards and one blank). 3. Review of the "Vitek 2 Compact Preventative Maintenance" records from 03/2025 through 06/2025 included the following dates DensiChek plus was used beyond the expiration date under "Densicheck Calibration: Monthly or change lot of plastic vials": 03/11/2025 04/07/2025 05/02/2025 06/03/2025 Note: the laboratory did not document the lot number and expiration date of the DensiChek plus used. 4. During an interview on 06/04/2025 at 12:01 PM, TP-3 confirmed the observed DensiCheck plus Standards Kit observed, was the only one the laboratory had. 5. During an interview on 06/04/2025 at 12:41 PM, the laboratory manager confirmed the expired DensiCheck plus Standards Kit was the one that had been used. 43831 III. Based on observation of the hematology reagent refrigerator, review of the Streck erythrocyte sedimentation rate (ESR) Chex Plus product insert, review of the ESR procedure, and interview with the technical supervisor (TS), the laboratory used ESR quality control past the expiration date. Findings: 1. Observation of the hematology reagent refrigerator showed two opened bottles of Streck ESR-Chex Plus level 1 and level 2 bottles with an open date of 4/4/2025. 2. Review of the Streck ESR-

	Chex Plus product insert revealed "Open vial stability 7 days." 3. Review of the procedure showed "ESR-Chex Plus is stable through the expiration date when stored at 2 to 10 degrees C....Monday both level controls are run. However, from Tuesday to Saturday the controls will rotate to test each level (1&2) only if there is a patient sample to run." 4. Interview with the TS on 6/3/2025 at 3:00 PM stated "The laboratory ran the controls on Mondays and alternated Tuesday through Saturday." The TS confirmed the ESR-Chex Plus QC was used past the expiration date. 5. The laboratory reports approximately 748 ESR tests annually.
D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) (a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following: This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, the laboratory's procedure, serology area checklist records, and in interview with the technical supervisor, the laboratory failed to include criteria for rotator and needle check accuracy as specified by the manufacturer for 22 of 22 months reviewed. Findings included: 1. Review of Arlington Scientific RPR Card test for Syphilis kit stated, "HANDLING AND PROCEDURAL NOTES: ...4. The needle should deliver 60 +/- 2 drops of antigen suspension per millimeter when held in a vertical position. To perform accuracy check on the needle, attach the needle to a 1 or 3 ml syringe. Fill the needle with the antigen suspension and, holding the syringe in a vertical position, count the number of drops delivered in 0.5 ml. The needle is considered satisfactory if 30 +/- 1 drops are obtained in 0.5 ml." "ASSAY PROTOCOL - QUALITITATIVE: ...5. ..Rotate at 100 +/- 5 rpm for 8 minutes (7 minutes 50 seconds to 8 minutes 30 seconds) ..." 2. Review of the laboratory's procedure manual for RPR testing did not include criteria for checking the needle and the rotator. 3. Review of "Serology area Checklist" records from 08/2023 through 06/2025 included, "RPR - Verify mechanical rotator - Daily; Verify the needle - When needed." The records did not include criteria to ensure the needle delivered the number of drops and the rotator speed and time was accurate, as stated by the manufacturer. 4. During an interview on 06/03/2025 at 2:48 PM, the technical supervisor reviewed and confirmed there was no criteria for verifying the mechanical rotator and the needle.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3)-- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can

	demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of the calibration records for the Siemens Atillica chemistry analyzer for the analytes of glucose, sodium, potassium, and chloride, and interview with the technical supervisor, the laboratory failed to perform at least a three-point calibration (a minimal, mid-point, and maximum) verification every six months. Findings: 1. Review of 2023, 2024, and to date 6/4/2025 calibration records for the Siemens Atillica chemistry analyzer for the analytes of glucose, sodium, potassium, and chloride revealed that the laboratory failed to perform a calibration every six months, to include at least a minimal, midpoint, and maximum value for the analytes of glucose, sodium, potassium, and chloride. 2. An interview with the technical supervisor on 6/4/2025 at 2:00 PM confirmed that the laboratory failed to perform at least a three-point calibration of the electrolytes on the Siemens Atillica analyzer every six months for glucose, sodium, potassium, and chloride. 3. The laboratory reports approximately 12,500 glucose, sodium, potassium, and chloride tests annually.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: I. Based on review of manufacturer's instructions, the laboratory's procedure, serology QC records, patient records, and in interview with the technical supervisor, the laboratory failed to include two Brain natriuretic peptide (BNP) control materials of different concentrations when patients were tested on 7 of 7 days in 2025. Findings included: 1. Review of Triage-BNP package insert (manufacturer's instructions) stated, "QUALITY CONTROL CONSIDERATIONS ...Users should follow government guidelines (for example, federal, state or local) and/or accreditation requirements for quality control." 2. Review of the laboratory's procedure manual for BNP testing stated, "Quality Control ...Frequency: ...The controls are tested: Each new lot, Every 30 days." 3. During an interview on 06/03/2025 at 2:48 PM, the technical supervisor confirmed the laboratory tested patient's plasma (moderate complexity) and not whole blood (waived). The TS confirmed Triage BNP QC was performed when they received a new shipment, and they did not have an IQCP to lessen the QC frequency. 4. Review of the serology section records, which included BNP testing, did not include documentation of BNP QC. When QC was analyzed, it was documented on "TestID Lists" that included, a list of patients pending for testing. 5. Review of "TestID Lists" from 05/2025 included BNP QC performed on 05/19 /2025 (lot numbers C4087, expiration date 09/25/2025; and C4089, expiration date 10 /04/2025). The following dates included patient plasma tested without BNP QC (random sampling): 04/17/2025 - five patients 04/21/2025 - one patient 05/27/2025 -

	four patients 05/28/2025 - four patients 05/29/2025 - one patient 05/30/2025 - three patients 05/31/2025 - one patient 43831 II. Based on a review of quality control (QC), review of the procedure, and an interview with the technical supervisor (TS), the laboratory failed to perform two control materials of different concentrations each day of testing for moderately complex erythrocyte sedimentation rate (ESR). Findings: 1. Review of 2023, 2024, and to date 6/4/2025, QC documentation for ESR testing revealed that the laboratory failed to perform two control materials of different concentrations each day of testing. 2. Review of the ESR procedure showed "On Mondays, both level controls are run. However, from Tuesday to Saturday, the controls will rotate to test each level (1&2) only if there is a patient sample to run." 3. Interview with the TS on 6/4/2025 at 1:00 PM confirmed that the laboratory did not test two control materials of different concentrations each day of ESR testing. 4. The laboratory reports approximately 748 ESR tests annually.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) (d)(3)(ii) Each qualitative procedure, include a negative and positive control material; This STANDARD is not met as evidenced by: Based on a review of quality control (QC), review of the procedure, and an interview with the technical supervisor (TS), the laboratory failed to perform a positive and negative control each day of testing for moderately complex Chlamydia/Trichomonas (CT) and Neisseria gonorrhea (NG). Findings: 1. Review of 2023, 2024, and to date 6 /4/2025, QC documentation for CT/NG testing revealed the laboratory failed to perform a positive and negative external control for each day of testing. 2. Review of the CT/NG procedure showed "To run QC with every shipment and lot change." 3. Interview with the TS on 6/4/2025 at 1:00 PM confirmed that the laboratory did not test a positive and negative control each day of CT/NG testing. 4. The laboratory reports approximately 753 CT/NG tests annually.
D5465	CONTROL PROCEDURES CFR(s): 493.1256(d)(8)(g) (d)(8) Test control materials in the same manner as patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's written procedure, interview with the technical supervisor, direct observation, QC records, and patient reports, the laboratory failed to use Human chorionic gonadotropin (hCG) serum control material for the hCG Combo Rapid Test kit when used to test 5 of 5 patient serums in 2025. Findings included: 1. Review of the laboratory's procedure for hCG Qualitative test stated, "Specimen Types: Serum" and "Quality Control: Kenlor Liquid Urine Control (Positive and Negative levels)." 2. During an interview on 06/03/2025 at 2:48 PM, the technical supervisor confirmed serum was the specimen type for the hCG test and not urine. 3. During a tour of the laboratory on 06/03/2025 at 12:41 PM, the following urine control material was observed stored in a refrigerator: "LIQUID URINE CONTROL Dipstick Positive [+] 10 ml. Lot 147434, Exp Date 05-2026, OP 5/1/25" "LIQUID URINE CONTROL Dipstick Negative [-] 10 ml. Lot 147433, Exp Date 05-2026, OP 5 /1/25" During an interview on 06/03/2025 at 12:41 PM, the technical supervisor confirmed the observed urine control material was used as QC before testing patient

	serum for hCG. 4. Review of a random sampling of QC (hCG kit lot 0000847686, expiration date 02/18/2026) and patient reports included the following: 01/16/2025 - patient tested for hCG was 223072 01/23/2025 - patient tested for hCG was 204754 01 /27/2025 - patients tested for hCG were 205229 and 223134 05/28/2025 - patient tested for hCG was 224002 The laboratory failed to use hCG serum control material for the hCG Combo Rapid Test kit.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (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. This STANDARD is not met as evidenced by: Based on review of the hematology maintenance documentation for staining white blood cell (WBC) manual differentials and interview with the technical supervisor (TS), the laboratory failed to check staining material each day of use. Findings: 1. No documentation was available for review for WBC stain quality checks for manual differentials. 2. Interview with the TS on 6/4/2025 at 2:00 PM confirmed the laboratory failed to check the staining material on each day of use for WBC manual differentials. 3. The laboratory reports approximately 100 manual differentials annually.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (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. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, media QC records, patient test volumes, and in interview with the technical supervisor, the laboratory failed to document the microorganism used for media QC for 9 of 9 months reviewed. Findings included: 1. Review of the laboratory's microbiology procedure manual did not include step-by-step procedure for performing QC on media, including documenting the organism, lot number and expiration date. 2. Review of "Reagent, Media and Supplies Check" records from 08/2024 through 05/2025 included "Support growth" and "Inhibit organism" for Blood agar, MacConkey agar, XLD agar, PEA agar, Selenite broth, and Thioglycolate broth. The "Support growth" and "Inhibit organism" sections included a checkmark and "A" for acceptable quality control. 3. Review of the annual volume for bacteriology was 2,402 patient cultures. 4. During an interview on 06/04/2025 at 10:52 AM, the technical supervisor confirmed the laboratory did not document the microorganism used for media QC.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(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, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 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 a review of the competency documentation and an interview with the technical supervisor (TS), the laboratory director failed to ensure that one of five testing personnel was competent to perform test procedures. Findings: 1. Review of the 2024 and 2025 competency documentation for testing personnel (TP) #1 showed no direct observation of moderate and high-complexity testing. 2. On 6/4/2025 at 1:00 PM, TP#1 stated, "The lab director has not been in the laboratory since 2023." TP #1 confirmed the LD failed to ensure the competency of TP #1 by direct observation.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) (e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and This STANDARD is not met as evidenced by: Based on a review of the coagulation procedures and an interview with the technical supervisor (TS), the laboratory director failed to ensure that an approved coagulation procedure was available to all testing personnel. Findings: 1. Review of the coagulation procedure for prothrombin time (PT) and partial thromboplastin time (PTT) showed no approval from the laboratory director. 2. Interview with the TS on 6 /4/2025, confirmed the LD failed to approve the coagulation testing procedures. 3. The laboratory reports approximately 1000 PT and PTT patient results annually.