Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0710168	07/17/2025
Name of Provider or Supplier	**Street Address, City, State**	
Trinity Medical Clinical Laboratory	6569 Hwy 84, Ferriday, LA	

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

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A Recertification survey was performed at Trinity Medical Clinical Laboratory, CLIA ID 19D0710168, on July 14, 2025 through July 17, 2025. Trinity Medical Clinical Laboratory was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.803: CONDITION: Successful participation 42 CFR 493.1441 CONDITION: Laboratories performing high complexity testing; Laboratory Director
D2016	SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c) (a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history. This CONDITION is not met as evidenced by: Based on review of proficiency testing records and interview with personnel, the laboratory failed to achieve a score of at least 80% for Bacteriology testing of

	anaerobic wound cultures for two consecutive events, resulting in an initial unsuccessful performance. Refer to D2021.
D2021	BACTERIOLOGY CFR(s): 493.823(b) (b) Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with personnel, the laboratory failed to successfully participate in wound culture testing for anaerobes for Bacteriology testing for two (2) consecutive events. Findings: 1. Review of the laboratory's American Proficiency Institute (API) proficiency testing records revealed the laboratory received the following unacceptable scores for Bacteriology testing: 2025 Microbiology 1st Event: Wound Culture-Anaerobic, score 0% 2024 Microbiology 3rd Event: Wound Culture-Anaerobic; score 0% 2. In interview on July 14, 2025 at 4:29 pm, Technical Consultant 2 stated the laboratory does not perform anaerobic testing and the PT results should not have been reported. Technical Consultant 2 confirmed the laboratory received two (2) consecutive unsuccessful PT scores for Wound Culture anaerobic Bacteriology testing.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on review of the nursing administration's transfusion policies, transfusion records, and interview with personnel, the facility failed to follow their established policy for transfusion services for blood products for two (2) of three (3) patients reviewed. Findings: 1. Review of Nursing Administration's "Blood Administration" policy revealed "Vital signs will be obtained just prior to administration of each unit, then q 15 minutes x 4, then q 30 minutes x 2, then hourly thereafter." 2. Review of random selection of patient transfusion records revealed vital signs were not documented per blood administration policy for the following patients: a) July 10, 2025: Patient 10396972: vital signs documented prior to administration, fifteen (15) minutes, thirty (30) minutes, and hourly until end of transfusion b) April 16, 2025: Patient 10388482: vital signs documented prior to administration, fifteen (15) minutes, thirty (30) minutes, and hourly until end of transfusion. 3. In interview on July 17, 2025 at 11:10 am, the ER Nurse Manager stated for transfusions performed in

	the ER they document vital signs, prior to administration, fifteen minutes, thirty minutes and hourly until end of transfusion as listed on the lab forms. The ER Nurse Manager confirmed the blood administration's policy for documentation of vital signs was not followed. 4. In interview on July 17, 2025 at 11:36 am, the Med Surg ICU Manager stated for the identified patient transfused on July 10, 2025, the vital signs were not documented per the Nursing Administration's Blood Administration policy.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 form, personnel records, and interview with personnel, the laboratory failed to ensure competency assessments for personnel serving as Technical Consultants, Technical Supervisors, and General Supervisors were complete for three (3) of four (4) personnel reviewed. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) form revealed the laboratory had three (3) personnel serving as Technical Consultants, three (3) personnel serving as Technical Supervisors, and four (4) personnel serving as General Supervisors. 2. Review of the laboratory's personnel records revealed the laboratory utilized forms that included columns for description of responsibilities, assessment method, and director's review for the performance of annual competency assessments for Technical Consultants, Technical Supervisors, and General Supervisors. The form stated "A checkmark or initials in the Director Review column indicates the associate fulfills the required responsibility." 3. Further review of the laboratory's competency assessment forms for the Technical Consultants, Technical Supervisors, and General Supervisors revealed the following were not complete: a) Technical Consultant 1, who also serves as a Technical Supervisor and General Supervisor: 2024 Technical Consultant Competency, the Laboratory Director did not include a check mark or initials in the "Director Review" column indicating competency. The Laboratory Director signed the form on February 25, 2024. 2025 Technical Consultant competency, the Laboratory Director did not include a check mark or initials in the "Director Review" column indicating competency. The Laboratory Director signed the form on February 26, 2025. 2025 General Supervisor Competency, the the Laboratory Director did not include a check mark or initials in the "Director Review" column indicating competency. The Laboratory Director signed the form on February 21, 2025. b) General Supervisor 4: 2025 Microbiology General Supervisor competency, the Laboratory Director did not include a check mark or initials in the "Director Review" column indicating competency. The Laboratory Director signed the form on January 8, 2025. c) Technical Consultant 2, who also serves as a Technical Supervisor and General Supervisor: 2025 Technical Consultant competency, the Laboratory Director did not include a check mark or initials in the "Director Review" column indicating competency. The Laboratory Director signed the form on January 8, 2025. 2025 General Supervisor Competency, the Laboratory Director did not include a check mark or initials in the "Director Review" column indicating competency. The Laboratory Director signed the form on February 21, 2025 4. In interview on July 15, 2025 at 10:44 am, Technical Consultant 1 confirmed the identified competency assessments for personnel serving as Technical Consultants, Technical Supervisors, and General Supervisors were not complete.

D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) (b) The laboratory must verify the accuracy of the following: (b)(1) Any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy, proficiency testing records, and interview with personnel, the laboratory failed to evaluate non graded proficiency testing (PT) scores. Findings: 1. Review of the laboratory's "Proficiency testing policy" revealed the laboratory did not include detailed written instructions related to evaluation of educational and not graded proficiency testing scores. 2. Review of the laboratory's American Proficiency Institute (API) proficiency testing records revealed the laboratory did not evaluate the following non graded PT scores: 2025 1st event Microbiology-Bacteriology: Educational Culture ID, Educational Susceptibility, MIC Value A, MIC Value B 2025 1st event Hematology/Coagulation: Not graded Nucleated RBC's 2024 3rd event Hematology/Coagulation: Educational Blood cell identification, lymphocyte, metamyelocyte, monocytes, myelocyte, neutrophil, NRBC, platelet estimates, RBC morphology for differentials 2024 3rd event Microbiology-Bacteriology: Educational Culture ID, Educational Susceptibility, ESBL, MIC Value 2024 2nd event Microbiology-Bacteriology: Educational Culture ID, Educational Susceptibility, MIC Value 2024 2nd event Hematology/Coagulation: Educational Blood cell identification, lymphocyte, metamyelocyte, monocytes, myelocyte, neutrophil, NRBC, platelet estimates, RBC morphology for differentials 2024 1st event Hematology/Coagulation: Educational Blood cell identification, lymphocyte, metamyelocyte, monocytes, myelocyte, neutrophil, NRBC, platelet estimates, RBC morphology for differentials 2024 1st event Microbiology-Bacteriology: Educational Culture ID, Educational Susceptibility, MIC Value (BL), MIC Value (Sf), and MIC Value (UR) 3. Review of the laboratory's PT evaluation forms for the identified events revealed the laboratory stated the results for ungraded and educational are reviewed; however, the acceptability of the results were not included. 4. In interview on July 14, 2025 at 4:29 pm, Technical Consultant 2 stated for non graded PT results the data summaries are reviewed. Technical Consultant 2 stated she does not maintain the data summaries with the PT records. Technical Consultant 2 confirmed she did not include the acceptability of the non graded and educational results.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the manufacturer's package insert, laboratory's patient test logs, and interview with personnel, the laboratory failed to

ensure patient samples for Lactic Acid testing were centrifuged within fifteen (15) minutes of collection per the manufacturer's instructions for thirty eight (38) of one hundred forty nine (149) reviewed. Findings: 1. Observation by surveyor during the laboratory tour on July 14, 2025 at 1:37 pm revealed the laboratory utilizes the Beckman Coulter AU 700 and Beckman Coulter AU 480 analyzers for Lactic Acid patient testing. 2. Review of the Beckman Coulter package insert for Lactic Acid under "Specimen Collection and Preparation" revealed the following: "Keep the sample on ice and separate plasma from cells within 15 minutes of collection." 3. Review of the laboratory's "Lactate Daily Log" revealed the laboratory documents the collection date/time and the centrifugation date/time. 4. Review of the laboratory's patient test logs for Lactic Acid testing from April 2025 to May 2025 revealed the following thirty eight (38) of one hundred forty nine (149) patients were not centrifuged within fifteen (15) minutes of collection per manufacturer's instructions: a) Acct #10387085: collected April 3, 2025 at 10:39 am and centrifuged at 10:59 am (exceeds the manufacturer's instructions by four (4) minutes) b) Acct # 10388000: collected April 11, 2025 at 14:23 and centrifuged at 14:40 (exceeds the manufacturer's instructions by two (2) minutes) c) Acct # 10388173: collected April 14, 2025 at 16: 45 and centrifuged at 17:04 (exceeds the manufacturer's instructions by four (4) minutes) d) Acct # 10388235: collected April 14, 2025 at 18:36 and centrifuged at 18: 55 (exceeds the manufacturer's instructions by four (4) minutes) e) Acct # 10388180: collected April 14, 2025 at 14:00 and centrifuged at 14:18 (exceeds the manufacturer's instructions by three (3) minutes) f) Acct # 10388203: collected April 14, 2025 at 15: 50 and centrifuged at 16:10 (exceeds the manufacturer's instructions by five (5) minutes) g) Acct # 10388323: collected April 15, 2025 at 12:50 pm and centrifuged at 13:16 (exceeds the manufacturer's instructions by eleven (11) minutes) h) Acct # 10388334: collected April 15, 2025 at 18:36 and centrifuged at 14:25 (exceeds the manufacturer's instructions by eleven (11) minutes) i) Acct # 10388879: collected April 21, 2025 at 15:19 and centrifuged at 15:39 (exceeds the manufacturer's instructions by five (5) minutes) j) Acct # 10388900: collected April 21, 2025 at 15:08 and centrifuged at 15:39 (exceeds the manufacturer's instructions by sixteen (16) minutes) k) Acct # 10388808: collected April 21, 2025 at 10:17 am and centrifuged at 10:39 am (exceeds the manufacturer's instructions by seven (7) minutes) l) Acct # 10388872: collected April 21, 2025 at 13:22 and centrifuged at 13:42 (exceeds the manufacturer's instructions by five (5) minutes) m) Acct # 10389174: collected April 23, 2025 at 22:25 and centrifuged at 22:42 (exceeds the manufacturer's instructions by two (2) minutes) n) Acct # 10389183: collected April 23, 2025 at 23:00 and centrifuged at 23:17 (exceeds the manufacturer's instructions by two (2) minutes) o) Acct # 10389165: collected April 23, 2025 at 18:50 and centrifuged at 19:06 (exceeds the manufacturer's instructions by one (1) minute) p) Acct # 10389168: collected April 23, 2025 at 18:47 and centrifuged at 19:06 (exceeds the manufacturer's instructions by four (4) minutes) q) Acct # 10389166: collected April 23, 2025 at 19: 34 and centrifuged at 19:50 (exceeds the manufacturer's instructions by one (1) minute) r) Acct # 10389171: collected April 23, 2025 at 20:12 and centrifuged at 20: 30 (exceeds the manufacturer's instructions by three (3) minutes) s) Acct # 10389547: collected April 28, 2025 at 11:16 am and centrifuged at 11:33 am (exceeds the manufacturer's instructions by two (2) minutes) t) Acct # 10389540: collected April 28, 2025 at 12:08 pm and centrifuged at 12:25 pm (exceeds the manufacturer's instructions by two (2) minutes) u) Acct # 10390350: collected May 5, 2025 at 11:23 am and centrifuged at 11:40 am (exceeds the manufacturer's instructions by two (2) minutes) v) Acct # 10390186: collected May 2, 2025 at 13:17 and centrifuged at 13: 36 (exceeds the manufacturer's instructions by four (4) minutes) w) Acct # 10390384: collected May 5, 2025 at 14:47 and centrifuged at 15:03 (exceeds the manufacturer's instructions by one (1) minute) x) Acct # 10390390: collected May 5, 2025 at 15:28

	and centrifuged at 15:45 (exceeds the manufacturer's instructions by two (2) minutes) y) Acct # 10390419: collected May 5, 2025 at 17:32 and centrifuged at 17:48 (exceeds the manufacturer's instructions by one (1) minute) z) Acct # 10390689: collected May 7, 2025 at 18:53 and centrifuged at 19:10 (exceeds the manufacturer's instructions by two (2) minutes) aa) Acct # 10390715: collected May 8, 2025 at 08:19 am and centrifuged at 08:35 am (exceeds the manufacturer's instructions by one (1) minute) bb) Acct # 10390734: collected May 8, 2025 at 11:20 am and centrifuged at 11:38 am (exceeds the manufacturer's instructions by three (3) minutes) cc) Acct # 10390826: collected May 8, 2025 at 19:40 and centrifuged at 19:56 (exceeds the manufacturer's instructions by one (1) minute) dd) Acct # 10390901: collected May 9, 2025 at 16:47 and centrifuged at 17:05 (exceeds the manufacturer's instructions by three (3) minutes) ee) Acct # 10391129: collected May 12, 2025 at 18:24 and centrifuged at 18:44 (exceeds the manufacturer's instructions by five (5) minutes) ff) Acct # 10391278: collected May 13, 2025 at 17:55 and centrifuged at 18:15 (exceeds the manufacturer's instructions by five (5) minutes) gg) Acct # 10391862: collected May 4, 2025 at 13:42 and centrifuged at 14:00 (exceeds the manufacturer's instructions by three (3) minutes) hh) Acct # 10392151: collected May 21, 2025 at 18: 56 and centrifuged at 19:13 (exceeds the manufacturer's instructions by two (2) minutes) ii) Acct # 10392397: collected May 23, 2025 at 18:00 and centrifuged at 18: 16 (exceeds the manufacturer's instructions by one (1) minutes) jj) Acct # 10392401: collected May 23, 2025 at 19:40 and centrifuged at 19:57 (exceeds the manufacturer's instructions by two (2) minutes) kk) Acct # 10392705: collected May 28, 2025 at 09: 35 am and centrifuged at 10:09 am (exceeds the manufacturer's instructions by nineteen (19) minutes) ll) Acct # 10392718: collected May 28, 2025 at 10:43 am and centrifuged at 11:04 am (exceeds the manufacturer's instructions by six (6) minutes) 5. In interview on July 16, 2025 at 2:43 pm, the Technical Consultant confirmed the laboratory did not follow the manufacturer's instructions for Lactic Acid sample collection and handling.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) (d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's client service manual, test menu, and interview with personnel, the laboratory failed to ensure that current written instructions for providers to maintain integrity of samples were established. Findings: 1. Review of the laboratory's test menu and client service manual for providers revealed the laboratory failed to include written instructions for the following Chemistry analytes: amylase, alanine aminotransferase (ALT). 2. In interview on July 16, 2025 at 11:05 am, the Technical Consultant confirmed the identified analytes were not included in the client service manual.
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) (b) The preanalytic systems 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 preanalytic systems

	quality assessment reviews with appropriate staff. (c) The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the laboratory's policies, patient test logs, manufacturer's package insert, and interview with personnel, the laboratory failed to ensure their monitors identified issues within the preanalytic system. Findings: 1. Review of the laboratory's "Quality Assurance Plan" revealed "Indicators must monitor all aspects of laboratory service, and must specifically cover pre-analytic, and post-analytic activities, as well as patient, physician, nursing, and administrative personnel satisfaction, proficiency testing, environmental issues, and other issues. The Laboratory General Supervisor will review the QA activities each month and make comments, give directions, or take specific actions as he deems appropriate." 2. Observation by surveyor during the laboratory tour, review of the laboratory's policies, patient test logs, manufacturer's package insert, and interview with personnel revealed the laboratory did not identify the following issues within the preanalytic system: a) The laboratory failed to ensure patient samples for Lactic Acid testing were centrifuged within fifteen (15) minutes of collection per the manufacturer's instructions for thirty eight (38) of one hundred forty nine (149) reviewed. Refer to D5311. b) The laboratory failed to ensure that current written instructions for providers to maintain integrity of samples were established. Refer to D5317.
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 policy and procedure manual and interview with personnel, the laboratory failed to establish a complete policy and procedure manual. Findings: 1. Review of the laboratory's policy and procedure manual revealed the "Proficiency Testing Policy" did not include detailed witten instructions that included assessment of educational and not graded results, unsuccessful scores, and scores less than 100 percent (%). 2. In interview on July 17, 2025 at 3:16 pm, the Technical Consultant 2 confirmed the labortory's proficiency testing policy did not include the identified items.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (b) The procedure manual must include the following when applicable to the test procedure: (b)(1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains,

	and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (b)(14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, manufacturer's instructions, and interview with personnel, the laboratory failed to establish complete policies and procedures for blood gas testing. Findings: 1. Review of the laboratory's "ABG" policy revealed "If sample is not ran within 10 minutes, sample may be placed in ice water bath for up to 30 minutes." 2. Review of the manufacturer's instructions revealed "It is recommended that plastic syringes not be iced; they should be kept at room temperature as long as the blood is analyzed in 30 minutes or less." 3. In interview on July 15, 2025 at 1:08 pm, Technical Consultant 1 stated the laboratory's policy needed to be updated to match 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 observation by surveyor and interview with personnel, the laboratory failed to ensure laboratory supplies had not exceeded their expiration dates. Findings: 1. Observation by surveyor during laboratory tour of the main laboratory on July 14, 2025 at 1:37 pm revealed the following expired items: BACT/Alert PF Plus blood culture bottle, lot 0004102688, Expiration date: 2025-05-19, Quantity: two (2) boxes 2. In interview on July 14, 2025 at 2:08 pm, the Technical Consultant 1 confirmed the identified items were expired. II. Based on review of the laboratory's blood bank records and interview with personnel, the laboratory failed to ensure blood bank reagents were not utilized past their expiration date. Findings: 1. Review of the laboratory's 2025 blood bank records revealed the following expired reagents were utilized: April 16, 2025: Screening cells, Lot VS692, Expiration date April 15, 2025 June 11, 2025: Saline, Lot 2433062, Expiration date June 6, 2025 June 12, 2025: Saline, Lot 2433062, Expiration date June 6, 2025 June 13, 2025: Saline, Lot 2433062, Expiration date June 6, 2025 June 15, 2025: Saline, Lot 2433062, Expiration date June 6, 2025 June 16, 2025: Saline, Lot 2433062, Expiration date June 6, 2025 June 17, 2025: Saline, Lot 2433062, Expiration date June 6, 2025 2. In interview on July 16, 2025, General Supervisor 3 stated the wrong saline expiration date was written for the identified dates. General Supervisor 3 confirmed the identified blood bank reagents were expired. 3. Review of the laboratory's blood bank log revealed the following twelve (12) patients had blood bank testing performed

	utilizing the identified expired reagents: April 16, 2025: Patient 00134422 Patient 00138145 June 11, 2025: Patient 00134278 Patient 00101951 June 12, 2025: Patient 00094545 Patient 00134278 June 13, 2025: Patient 00040411 Patient 00138003 June 15, 2025: Patient 00138830 June 16, 2025: Patient 00080185 June 17, 2025: Patient 00134425 Patient 00075074
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) (b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's quality control records, performance specification studies, and interview with personnel, the laboratory failed to have complete performance specification studies for serum human chorionic gonadotropin (hCG) studies for the Consult Diagnostics test kits. Findings: 1. Review of the laboratory's quality control (QC) records revealed the laboratory utilized the Consult Diagnostics test kits for serum hCG testing in December 2024. 2. Further review of the laboratory's QC records revealed the laboratory ran QC multiple days for the Consult Diagnostics hCG test kit using multiple personnel. The records did not include a summary, review of findings, acceptability, and approval by the Laboratory Director to indicate performance verification studies. 3. In interview on July 15, 2025 at 3:07 pm, the Technical Consultant 2 stated the laboratory used the Consult Diagnostics hCG test kits because they were unable to get the Alere hCG test kits listed on their test menu. The Technical Consultant 2 confirmed the identified records did not include the listed information, including review/approval by the Laboratory Director. The Technical Consultant stated she was unable to tell how long the Consult Diagnostic hCG test kits were utilized at the time of the survey. II. Based on review of the laboratory's policies, performance specification studies, and interview with personnel, the laboratory failed to have complete precision studies for the Vitek II AST-N807 and XN-30 cards. Findings: 1. Review of the laboratory's "AST-N807 and XN-30 Validation Study" policy revealed "Run to run/Overtime/Operator Variance precision was determined by repeating the within run precision on days 2-5 and once a day on days 6 and 7." 2. Review of the laboratory's performance verification precision studies for the Vitek II AST -N807 and XN-30 cards revealed operator variance was not performed. The Laboratory Director approved the performance specification studies on February 21, 2025. 3. In interview on July 16, 2025 at 1:47 pm, General Supervisor 4 confirmed there was no documentation of operator variance for the precision studies for the Vitek II AST-N807 and XN-30 cards.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in

	facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the nursing administration transfusion policies, laboratory's blood bank policies, and interview with personnel, the laboratory failed to make recommendations to medical staff regarding improvements in the nursing administration transfusion reaction policy. Findings: 1. Review of the Nursing Administration's "Blood Administration policy included "The RN starting the transfusion should constantly monitor the patient for the first five (5) minutes of the transfusion and document the patient's toleration of the beginning transfusion with the first 15 minute vital signs. Signs and symptoms of reaction include: urticaria, chills, burning sensation at the infusion site (usually occurs with ABO incompatibility), fever, facial flushing, edema, bronchial spasm, elevated pulse, decreased blood pressure, abdominal cramping (numerous transfusions in a short period of time may lower the body's ionized calcium enough to produce tetany), throbbing headache,, backache, hemoglobinuria, feeling of anxiety or 'Impending Doom' and untoward oozing of wound in anesthetized patients." 2. Further review of the Nursing Administration's "Blood Administration" policy revealed there were no defined limits of changes in vital signs to include, but not limited to, change in temperature for febrile reaction or blood pressure change identifying hypotension, for indication of transfusion reactions. 3. Review of the "Nursing Service Transfusion Reaction Form" revealed the following signs and symptoms for a suspected transfusion reaction: temperature spikes of greater than two (2) degrees Fahrenheit, shaking chills with or without fever, pain at infusion site, chest pain, back pain, abdominal pain, flank pain, hypotension, abnormal bleeding/hematuria, circulatory shock, circulatory collapse, respiratory distress, skin changes, nausea with or without vomiting, darkened urine, and jaundice. 4. Review of the laboratory's "Transfusion Reactions" policy revealed a form that included the following signs and symptoms of a suspected transfusion reaction: chills, urticaria, hypotension, chest/back pain, rash dyspnea, hempglobiimuria, heat at infusion site, itching, nausea, abnormal bleeding, and fever (>1 degree). 5. Further review of the nursing administration policy revealed the signs and symptoms for suspected transfusion reactions did not align with the laboratory's transfusion reaction policy. 6. In interview on July 17, 2025 at 9:30 am, the Med Surg ICU manager confirmed the identified transfusion reaction policies and forms for Nursing Administration and laboratory did not include defined criteria or match each other.
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 observation by surveyor, review of the laboratory's policies, nursing administration policies, records, and interview with personnel, the laboratory failed to ensure their monitors identified issues within the analytic system. Findings: 1. Review of the laboratory's "Quality Assurance Plan" revealed "Indicators must monitor all aspects of laboratory service, and must specifically cover pre-analytic, and post-analytic activities, as well as patient, physician, nursing, and administrative personnel satisfaction, proficiency testing, environmental issues, and other issues. The Laboratory General Supervisor will review the QA activities each month and make comments, give directions, or take specific actions as he deems appropriate." 2. Observation by surveyor during the laboratory tour, review of the laboratory's policies, nursing administration policies, records, and interview with personnel, the laboratory failed to identify the following issues within the analytic system: a) The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. b) The laboratory failed to establish complete policies and procedures for blood gas testing. Refer to D5403. c) The laboratory failed to ensure laboratory supplies had not exceeded their expiration dates. Refer to D5417 I. d) The laboratory failed to ensure blood bank reagents were not utilized past their expiration date. Refer to D5417 II. e) The laboratory failed to have complete performance specification studies for serum human chorionic gonadotropin (hCG) studies for the Consult Diagnostics test kits. Refer to D5421 I. f) The laboratory failed to have complete precision studies for the Vitek II AST-N807 and XN-30 cards. Refer to D5421 II. g) The laboratory failed to make recommendations to medical staff regarding improvements in the nursing administration transfusion reaction policy. Refer to D5559.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure performance specification studies were complete. Refer to D5421 I.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to ensure patient samples for Lactic Acid testing were centrifuged with fifteen (15) minutes of collection per the manufacturer's instructions for thirty eight (38) of one hundred forty nine (149) reviewed. Refer to D5311. 2. The laboratory failed to ensure that current written instructions for providers to maintain integrity of samples were established. D5317.

D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure the quality assessment programs were maintained to assure the quality of laboratory testing. Findings: 1. The laboratory failed to ensure their monitors identified issues within the preanalytic system. Refer to D5393. 2. The laboratory failed to ensure their monitors identified issues within the analytic system. Refer to D5793.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D5209.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) (e)(13) 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 record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to establish complete policies and procedures for blood gas testing. Refer to D5403.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test

	performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to provide written job descriptions for all laboratory personnel. Findings: 1. Review of the laboratory's personnel records and laboratory policies revealed the laboratory did not have written job descriptions for Laboratory Director and Clinical Consultant duties. 2. In interview on July 17, 2025 at 12:00 pm, Technical Consultant 2 confirmed the laboratory did not have job descriptions for the identified personnel.
D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. The technical consultant is not required to be onsite at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide consultation, as specified in paragraph (a) of this section. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Consultants failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to ensure patient samples for Lactic Acid testing were centrifuged within fifteen (15) minutes of collection per the manufacturer's instructions for thirty eight (38) of one hundred forty nine (149) reviewed. Refer to D5311. 2. The laboratory failed to ensure that current written instructions for providers to maintain integrity of samples were established. Refer to D5317. 3. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 4. The laboratory failed to establish complete policies and procedures for blood gas testing. Refer to D5403.
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) (b)(2) Verification of the test procedures performed and the establishment of the laboratorys test performance characteristics, including the precision and accuracy of each test and test system; This STANDARD is not met as evidenced by: Based on review of the laboratory's performance verification studies and interview with personnel, the Technical Consultants failed to ensure performance specification verification studies were complete. Refer to D5421 I.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.

	This CONDITION is not met as evidenced by: Based on observation by surveyors, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure performance specification studies were complete. Refer to D6086. 2. The Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D6087. 3. The Laboratory Director failed to ensure that proficiency testing scores achieved satisfactory performance as required. Refer to D6089. 4. The Laboratory Director failed to ensure non graded proficiency testing results were evaluated. Refer to D6091. 5. The Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6103. 6. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6106. 7. The Laboratory Director failed to provide written job descriptions for all laboratory personnel. Refer to D6107.
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 record review and interview with laboratory personnel, the Laboratory Director failed to provide overall management and direction to the laboratory. Refer to D2016.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) (e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure performance specification studies were complete. Refer to D5421 II.
D6087	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(iii) (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;

	This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The facility failed to follow their established policy for transfusion services for blood products for two (2) of three (3) patients reviewed. Refer to D3025. 2. The laboratory failed to ensure laboratory supplies had not exceeded their expiration dates. Refer to D5417 I. 3. The laboratory failed to ensure blood bank reagents were not utilized past their expiration date. Refer to D5417 II.
D6089	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(i) (e)(4)(i) The proficiency testing samples are tested as required under subpart H of this part; This STANDARD is not met as evidenced by: Based on review of proficiency testing records and interview with personnel, the Laboratory Director failed to ensure that proficiency testing scores achieved satisfactory performance as required. Refer to D2021.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) (e)(4)(iii) All proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratorys performance and to identify any problems that require corrective action; and This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure non graded proficiency testing results were evaluated. Refer to D5213.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure the quality assessment programs were maintained to assure the quality of laboratory testing. Refer to D5793.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) (e)(13) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform

	test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D5209.
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 record review and interview with personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Findings: 1. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 2. The laboratory failed to make recommendations to medical staff regarding improvements in the nursing administration transfusion reaction policy. Refer to D5559.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) (e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Laboratory Director failed to provide written job descriptions for all laboratory personnel. Findings: 1. Review of the laboratory's personnel records and laboratory policies revealed the laboratory did not have written job descriptions for Laboratory Director and Clinical Consultant duties. 2. In interview on July 17, 2025 at 12:00 pm, Technical Consultant 2 confirmed the laboratory did not have job descriptions for the identified personnel.
D6112	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451 The technical supervisor is responsible for the technical and scientific oversight of the laboratory. The technical supervisor is not required to be on site at all times testing is performed; however, he or she must be available to the laboratory on an as needed basis to provide supervision as specified in (a) of this section.

	This STANDARD is not met as evidenced by: Based on record review and interview with personnel, the Technical Supervisors failed to provide technical and scientific oversight to the laboratory. Findings: 1. The facility failed to follow their established policy for transfusion services for blood products for two (2) of three (3) patients reviewed. Refer to D3025. 2. The laboratory failed to establish a complete policy and procedure manual. Refer to D5401. 3. The laboratory failed to ensure laboratory supplies had not exceeded their expiration dates. Refer to D5417 I. 4. The laboratory failed to ensure blood bank reagents were not utilized past their expiration date. Refer to D5417 II. 5. The laboratory failed to make recommendations to medical staff regarding improvements in the nursing administration transfusion reaction policy. Refer to D5559.
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) (b)(2) Verification of the test procedures performed and establishment of the laboratorys test performance characteristics, including the precision and accuracy of each test and test system; This STANDARD is not met as evidenced by: Based on review of the laboratory's performance verification studies and interview with personnel, the Technical Supervisors failed to ensure performance specification verification studies were complete. Refer to D5421 II.