Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D0710168	01/21/2022
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 on January 18, 2022 through January 21, 2022 at Trinity Medical Clinical Laboratory, CLIA ID # 19D0710168. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(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, manufacturer package inserts and interview with laboratory personnel, the laboratory failed to establish current written instructions for providers to maintain the integrity of samples. Findings: 1. Review of the laboratory's "Client Service Manual" which includes written instructions for sample requirements revealed the laboratory did not include the following (not an all inclusive list) requirements: a) Lactic Acid specimen handling requirements that reflect the manufacturer's instructions b) Ammonia specimen handling requirements that reflect the manufacturer's instructions c) CO2 specimen handling requirements that reflect the manufacturer's instructions d) Calcium specimen handling requirements that reflect the manufacturer's instructions e) Alkaline Phosphatase specimen handling requirements that reflect the manufacturer's instructions f) Albumin specimen handling requirements that reflect the manufacturer's instructions g) ISE (Sodium, Potassium, Chloride) specimen handling requirements that reflect the manufacturer's instructions 2. In interview on January 19, 2022 at 3:45 pm, Personnel 6 stated the laboratory is updating the client service manual. Personnel 6 confirmed the laboratory's client service manual did not include the identified specimen requirements.

D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to establish complete policies and proceures. Findings: 1. Review of the laboratory's policies and procedures revealed the laboratory did not have written procedures to include the following: a) Detailed, written instructions for Arterial Blood Gas (ABG) testing to include but not limited to: step by step performance of the procedure, quality control practices (QC), time frame for testing patient samples, acceptability criteria for samples and testing procedures... b) Detailed, written instructions for Emergency Release of Uncrossmatched Blood products to include but not limited to: step by step procedure, testing procedures for laboratory and nursing personnel, time frame for testing to be performed, handling of emergency release forms... c) Detailed, written procedures for updated instrumentation for each specialty area of the laboratory 2. In interview on January 19, 2022 at 2:27 pm, Personnel 6 stated the laboratory was in the process of updating all policies and procedures for the laboratory. Personnel 6 confirmed the above identified policies were not included.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: I. Based on direct observation, review of manufacturer's package inserts and patient records as well as interview with personnel, the laboratory failed to ensure that patient samples for Lactic Acid testing are analyzed immediately according to the manufacturer for thirty three (33) of one hundred seventy two (172) patients reviewed.

Findings: 1. Direct observation by the surveyor during the laboratory tour on January 18, 2022 at 10:22 am revealed the laboratory was performing Lactic Acid testing on the Beckman Coulter AU480 Chemistry analyzer. 2. Review of the Beckman Coulter package insert for Lactic Acid revealed "Keep the sample on ice and separate plasma from cells within 15 minutes of collection. Analyze the sample immediately." 3. In interview on January 20, 2022 at 1:22 pm, Personnel 6 stated that patient samples are to be analyzed within 30 minutes of receiving the specimens. 4. Review of patient records for Lactic Acid testing from October 1, 2021 through November 30, 2021 revealed the laboratory did not analyze Lactic Acid samples within 30 minutes for the following thirty three (33) of one hundred seventy two (172) patients reviewed: a) On October 1, 2021 Patient 21849 was collected at 11:40 am, received at 11:57 am, and resulted at 12:19 pm - exceeding the analyze immediately time frame of thirty (30) minutes by six (6) minutes. b) On October 4, 2021 Patient 22659 was collected at 15: 45 pm, received at 15:57 pm and resulted at 16:36 pm - exceeding the analyze immediately time frame of thirty (30) minutes by nine (9) minutes. c) On October 4, 2021 Patient 22740 was collected at 21:15 pm, received at 21:25 pm and resulted at 22:00 pm - exceeding the analyze immediately time frame of thirty (30) minutes by five (5) minutes d) On October 6, 2021 Patient 23564 was collected at 20:05 pm, received at 21:05 pm and resulted at 22:04 pm - exceeding the analyze immediately time frame of thirty (30) minutes by twenty nine (29) minutes. e) On October 6, 2021 Patient 23358 was collected at 11:42 am, received at 11:52 am and resulted at 12:30 pm - exceeding the analyze immediately time frame of thirty (30) minutes by eight (8) minutes. f) On October 7, 2021 Patient 23813 was collected at 16:10 pm, received at 16:22 pm and resulted at 20:45 pm - exceeding the analyze immediately time frame of thirty (30) minutes by three (3) hours fifty three (53) minutes. g) On October 8, 2021 Patient 23963 was collected on October 7, 2022 at 22:59 pm, received on October 7, 2022 at 23:15 pm and resulted on October 8, 2022 at 22:04 pm - exceeding the analyze immediately time frame of thirty (30) minutes by twenty nine (29) minutes. h) On October 9, 2021 Patient 24482 was collected at 18:05 pm, received at 18:15 pm and resulted at 18:56 pm - exceeding the analyze immediately time frame of thirty (30) minutes by eleven (11) minutes. i) On October 11, 2021 Patient 24905 was collected at 11:12 am, received at 11:20 am and resulted at 11:56 am - exceeding the analyze immediately time frame of thirty (30) minutes by six (6) minutes. j) On October 11, 2021 Patient 24922 was collected at 12:13 pm, received at 12:25 pm and resulted at 13:02 pm - exceeding the analyze immediately time frame of thirty (30) minutes by seven (7) minutes. k) On October 4, 2021 Patient 22730 was collected at 20:49 pm, received at 20:56 pm and resulted at 22:12 pm - exceeding the analyze immediately time frame of thirty (30) minutes by forty six (46) minutes. l) On October 7, 2021 Patient 23749 was collected at 8:51 am, received at 9:00 am and resulted at 23:20 pm - exceeding the analyze immediately time frame of thirty (30) minutes by thirteen (13) hours fifty (50) minutes. m) On October 7, 2021 Patient 23879 was collected at 18:00 pm, received at 18:15 pm and resulted at 19:05 pm - exceeding the analyze immediately time frame of thirty (30) minutes by twenty (20) minutes. n) On October 8, 2021 Patient 24176 was collected at 14:27 pm, received at 14:41 pm and resulted at 16:35 pm - exceeding the analyze immediately time frame of thirty (30) minutes by one (1) hour twenty four (24) minutes. o) On October 10, 2021 Patient 24733 was collected at 21:20 pm, received at 21:32 pm and resulted at 22:16 pm - exceeding the analyze immediately time frame of thirty (30) minutes by fourteen (14) minutes. p) On October 11, 2021 Patient 25119 was collected at 21:48 pm, received at 22:03 pm and resulted at 22:55 pm - exceeding the analyze immediately time frame of thirty (30) minutes by twenty two (22) minutes. q) On October 12, 2021 Patient 25279 was collected at 9:45 am, received at 9:59 am and resulted at 10:36 am - exceeding the analyze immediately time frame of thirty (30) minutes by seven (7)

minutes. r) On October 12, 2021 Patient 25319 was collected at 11:20 am, received at 11:33 am and resulted at 12:09 pm - exceeding the analyze immediately time frame of thirty (30) minutes by six (6) minutes. s) On October 13, 2021 Patient 25672 was collected at 9:55 am, received at 10:10 am and resulted at 11:17 am - exceeding the analyze immediately time frame of thirty (30) minutes by thirty seven (37) minutes. t) On October 13, 2021 Patient 25852 was collected at 17:03 pm, received at 17:10 pm and resulted at 17:45 pm - exceeding the analyze immediately time frame of thirty (30) minutes by five (5) minutes. u) On October 13, 2021 Patient 25783 was collected at 13:13 pm, received at 13:25 pm and resulted at 15:49 pm - exceeding the analyze immediately time frame of thirty (30) minutes by one (1) hour fifty four (54) minutes. v) On October 15, 2021 Patient 26366 was collected at 02:19 am, received at 02:31 am and resulted at 03:36 am - exceeding the analyze immediately time frame of thirty (30) minutes by thirty five (35) minutes. w) On October 23, 2021 Patient 28997 was collected at 15:20 pm, received at 15:33 pm and resulted at 16:20 pm - exceeding the analyze immediately time frame of thirty (30) minutes by seventeen (17) minutes. x) On October 20, 2021 Patient 28008 was collected at 14:39 pm, received at 14:51 pm and resulted at 15:56 pm - exceeding the analyze immediately time frame of thirty (30) minutes by thirty five (35) minutes. y) On October 25, 2021 Patient 29488 was collected at 22:43 pm, received at 22:56 pm, and resulted at 23:34 pm - exceeding the analyze immediately time frame of thirty (30) minutes by ten (10) minutes. z) On October 28, 2021 Patient 30407 was collected at 15:32 pm, received at 15:45 pm, and resulted at 16:40 pm - exceeding the analyze immediately time frame of thirty (30) minutes by twenty five (25) minutes. aa) On October 31, 2021 Patient 31078 was collected at 09:08 am, received at 09:18 am, and resulted at 09:55 am - exceeding the analyze immediately time frame of thirty (30) minutes by seven (7) minutes. bb) On November 10, 2021 Patient 34514 was collected at 12:08 pm, received at 12:10 pm, and resulted at 13:21 pm - exceeding the analyze immediately time frame of thirty (30) minutes by forty one (41) minutes. cc) On November 11, 2021 Patient 35083 was collected at 14:45 pm, received at 14:57 pm, and resulted at 16:10 pm - exceeding the analyze immediately time frame of thirty (30) minutes by forty three (43) minutes. dd) On November 21, 2021 Patient 37824 was collected at 00:23 am, received at 00:34 am, and resulted at 01:22 am - exceeding the analyze immediately time frame of thirty (30) minutes by eighteen (18) minutes. ee) On November 24, 2021 Patient 38780 was collected at 07:11 am, received at 07:20 am, and resulted at 07:56 am - exceeding the analyze immediately time frame of thirty (30) minutes by six (6) minutes. ff) On November 29, 2021 Patient 39883 was collected at 16:30 pm, received at 16:45 pm, and resulted at 17:22 pm - exceeding the analyze immediately time frame of thirty (30) minutes by seven (7) minutes. gg) On November 30, 2021 Patient 39921 was collected on November 29, 2021 at 23:23 pm, received on November 29, 2021 at 23: 28 pm, and resulted on November 30, 2021 at 00:08 am - exceeding the analyze immediately time frame of thirty (30) minutes by ten (10) minutes. 5. In interview on January 20, 2022 at 1:22 pm, Personnel 6 confirmed the above identified patients were not analyzed immediately per manufacturer's recommendations for Lactic Acid testing. 6. Review of the Task 1 & 3 form provided to surveyor revealed the laboratory performs 989 Lactic Acid tests annually. II. Based on observation during laboratory tour, review of operator's manual, laboratory policy, and patient records as well as interview with personnel, the laboratoray failed to perform patient samples for D Dimer testing within four (4) hours of collection as required by manufacturer for two (2) of ninety two (92) patients reviewed. Findings: 1. Observation by surveyor during the laboratory tour on January 18, 2022 at 10:58 am revealed the laboratory utilizes the Instrumentation Laboratory ACL Top 350 Coagulation analyzer for D Dimer testing. 2. Review of the Instrumentation Laboratory ACL Top 350 operator's manual under specimen storage revealed for D Dimer testing "samples should be

	analyzed within four (4) hours of collection". 3. Review of the laboratory's Coagulation policy and Procedure Manual for D Dimer testing under specimen storage revealed "Specimens for D-Dimer assays uncentrifuged or centrifuged with plasma remaining on top of the cells in an unopened tube kept at 18 degrees celsius to 24 degrees celsius should be tested within 4 hours from time of specimen collection". 4. Review of patient records for D Dimer testing from October 1, 2021 through November 30, 2021 revealed the following two (2) of ninety two (92) patients reviewed were not tested within four (4) hours of collection as required by the manufacturer: a) Patient 10268912 collected on November 7, 2021 at 13:23 pm and resulted at 18:44 pm - exceeding the four (4) hours required by manufacturer by one (1) hour twenty one (21) minutes b) Patient 10268920 collected on November 7, 2021 at 14:10 pm and resulted at 18:44 pm - exceeding the four (4) hours required by manufacturer by thirty four (34) minutes 5. In interview on January 21, 2022 at 09:57 am, Personnel 1 stated she did not understand what happened other than the specimens possibly needed to be recollected. Personnel 1 confirmed the above identified patients were not tested within four (4) hours as required by manufacturer. 6. Review of the Task 1 & 3 form provided to surveyor revealed the laboratory performs 750 D Dimer tests annually.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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: Based on direct observation by surveyor and interview with personnel, the laboratory failed to ensure supplies did not exceed their expiration date. Findings: 1. Direct observation by surveyor during the laboratory tour on January 18, 2022 at 10:22 am revealed the following expired supplies: a) BD vacutainer UA preservative tubes, Lot 0167199, Expiration 11/30/21, Quantity: seven (7) b) BD vacutainer Sodium Citrate tubes, Lot 1074689, Expiration 12/31/21, Quantity: two (2) 2. In interview on January 18, 2022 at 10:36 am, Personnel 2 confirmed the above identified supplies were expired.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on observation during laboratory tour, review of laboratory policy and procedure, Quality Control (QC) and patient records, and interview with personnel, the laboratory failed to document external reactive and non-reactive controls for Rapid Plasma Reagin (RPR) patient testing for three (3) of fifty two (52) patients reviewed. Findings: 1. Observation by surveyor during laboratory tour on January 18,

	2022 at 10:15 am revealed the laboratory utilizes the BD Macro-vue RPR Card Test for Rapid Plasma Reagin (RPR) patient testing. 2. Review of the laboratory's Quality Control Procedures for moderate kit testing revealed "External Quality Controls are performed each day of use, prior to or parallel with patient testing. All results of Internal and External Quality Control and Patient Results are logged in the kit testing book". 3. Review of the Quality Control (QC) and patient records log book from July 2021 through December 2021 revealed the laboratory did not document external reactive and non-reactive controls each day of patient testing for the following three (3) of fifty two (52) patients reviewed: a) Patient 10270922 performed November 5, 2021 at 23:49 pm b) Patient 10270925 performed November 5, 2021 at 23:32 pm c) Patient 10270477 performed November 5, 2021 at 23:49 pm 4. In interview on January 20, 2022 at 1:20 pm, Personnel 6 confirmed the laboratory external reactive and non-reactive controls was not performed for the above identified patients. 5. Review of the Task 1 & 3 form provided to surveyor revealed the laboratory performs 106 RPR tests annually. II. Based on observation during laboratory tour, review of laboratory policy and procedure, Quality Control (QC) and patient records, and interview with personnel, the laboratory failed to document external positive and negative controls for Clostridium Difficile (C Diff) patient testing for one (1) of thirty six (36) patients reviewed. Findings: 1. Observation by surveyor during laboratory tour on January 18, 2022 at 10:15 am revealed the laboratory utilizes the TechLab C-Diff Quik Chek Comp test kit for Clostridium Difficile Antigen (C Diff Ag) and Clostridium Difficile Toxin (C Diff Toxin) patient testing. 2. Review of the laboratory's Quality Control Procedures for moderate kit testing revealed "External Quality Controls are performed each day of use, prior to or parallel with patient testing. All results of Internal and External Quality Control and Patient Results are logged in the kit testing book". 3. Review of the Quality Control (QC) and patient records log book from July 2021 through December 2021 revealed the laboratory did not document external positive and negative quality controls each day of patient testing for the following one (1) of thirty six (36) patients reviewed: a) Patient 10271833 performed on November 13, 2021 at 01:52 am 4. In interview on January 20, 2022 at 1:20 pm, Personnel 6 confirmed the laboratory external positive and negative quality control was not performed for the above identified patient. 5. Review of the Task 1 & 3 form provided to surveyor revealed the laboratory performs 67 C Diff Ag/Toxin tests annually.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: I. Based on observation during laboratory tour, review of laboratory policy, blood bank high and low temperature monitoring records and interview with personnel, the laboratory failed to perform quarterly blood bank refrigerator alarm checks for one (1) of seven (7) quarters reviewed in 2019, 2020 and 2021. Findings: 1. Observation by surveyor during the laboratory tour revealed the laboratory utilizes two (2) Blood Bank refrigerators with the following serial numbers: a) Blood Bank Refrigerator #1:

	SN 24260989 b) Blood Bank Refrigerator #2: SN 24260990 2. Review of the laboratory's policy "Testing Blood Storage Refrigerator/Freezer Alarms" revealed the alarm on each blood storage refrigerator/freezer should be checked quarterly or every 3 months for proper functioning. 2. Review of the laboratory's Blood Bank High and Low Monitor Record (Fire and Ice) records for 2019, 2020, and 2021 on both refrigerators in use revealed the laboratory did not perform alarm checks for the following one (1) of seven (7) quarters reviewed: a) Refrigerator #1: no alarm check performed in August 2021 b) Refrigerator #2: no alarm check performed in August 2021 3. In interview on January 21, 2022 at 10:49 am, Personnel 6 stated the laboratory moved to another facility on February 23, 2021 with one refrigerator relocated from previous location and the other refrigerator installed with new facility. Personnel 6 further stated the laboratory installed a continuous temperature monitoring system which takes the temperature every hour so the testing personnel was not aware that a blood bank alarm check would still be required. 4. In further interview on January 21, 2022 at 10:49 am, Personnel 6 confirmed the laboratory did not perform a quarterly alarm check on both blood bank refrigerators for the identified quarter. II. Based on review of laboratory policy, blood bank high and low temperature monitoring records and interview with personnel, the laboratory failed to perform quarterly blood bank alarm checks for the Fresh Frozen Plasma (FFP) Freezer for three (3) of four (4) quarter reviewed in 2021. Findings: 1. Review of the laboratory's policy "Testing Blood Storage Refrigerator/Freezer Alarms" revealed the alarm on each blood storage refrigerator/freezer should be checked quarterly or every 3 months for proper functioning. 2. Review of the laboratory's Blood Bank High and Low Monitor Record (Fire and Ice) records for the FFP freezer in 2021 revealed the laboratory did not perform alarm checks for the following three (3) of four (4) quarters: a) Alarm check due May 2021 b) Alarm check due August 2021 c) Alarm check due December 2021 3. In interview on January 21, 2022 at 10:49 am, Personnel 6 stated the laboratory installed a new FFP freezer upon relocation to new facility in February 23, 2021. Personnel 6 further stated the laboratory installed a continuous temperature monitoring system which takes the temperature every hour so the testing personnel was not aware that a an alarm check would still be required. 4. In further interview on January 21, 2022 at 10:49 am, Personnel 6 confirmed the laboratory did not perform a quarterly alarm check on the FFP freezer for the above identified quarters.
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 during laboratory tour, review of laboratory policies and records and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified within the analytic system. Findings: 1. The laboratory failed to establish complete policies and proceures. Refer to D5403. 2. The laboratory failed to ensure that patient samples for Lactic Acid testing are analyzed immediately according to the manufacturer for thirty three (33) of one hundred seventy two (172) patients reviewed. Refer to D5411 I. 3. The laboratoray failed to perform patient

	samples for D Dimer testing within four (4) hours of collection as required by manufacturer for two (2) of ninety two (92) patients reviewed. Refer to D5411 II. 4. The laboratory failed to ensure supplies did not exceed their expiration date. Refer to D5417. 5. The laboratory failed to document external reactive and non-reactive controls for Rapid Plasma Reagin (RPR) patient testing for three (3) of fifty two (52) patients reviewed. Refer to D5449 I. 6. The laboratory failed to document external positive and negative controls for Clostridium Difficile (C Diff) patient testing for one (1) of thirty six (36) patients reviewed. Refer to D5449 II. 7. The laboratory failed to perform quarterly blood bank refrigerator alarm checks for one (1) of seven (7) quarters reviewed in 2019, 2020 and 2021. Refer to D5555 I. 8. The laboratory failed to perform quarterly blood bank alarm checks for the Fresh Frozen Plasma (FFP) Freezer for three (3) of four (4) quarter reviewed in 2021. Refer to D5555 II.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (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 during laboratory tour, review of laboratory records and interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to establish current written instructions for providers to maintain the integrity of samples. Refer to D5317. 2. The laboratory failed to ensure that patient samples for Lactic Acid testing are analyzed immediately according to the manufacturer for thirty three (33) of one hundred seventy two (172) patients reviewed. Refer to D5411 I. 3. The laboratoray failed to perform patient samples for D Dimer testing within four (4) hours of collection as required by manufacturer for two (2) of ninety two (92) patients reviewed. Refer to D5411 II. 4. The laboratory failed to ensure supplies did not exceed their expiration date. Refer to D5417.
D6020	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control program is established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation by surveyor, record review, and interview with personnel, the Laboratory Director failed to ensure that a quality control program was maintained to assure quality laboratory services were provided. Findings: 1. The laboratory failed to document external reactive and non-reactive controls for Rapid Plasma Reagin (RPR)

	patient testing for three (3) of fifty two (52) patients reviewed. Refer to D5449 I. 2. The laboratory failed to document external positive and negative controls for Clostridium Difficile (C Diff) patient testing for one (1) of thirty six (36) patients reviewed. Refer to D5449 II.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory records, and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5793.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system; This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory records, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Findings: 1. The laboratory failed to perform quarterly blood bank refrigerator alarm checks for one (1) of seven (7) quarters reviewed in 2019, 2020 and 2021. Refer to D5555 I. 2. The laboratory failed to perform quarterly blood bank alarm checks for the Fresh Frozen Plasma (FFP) Freezer for three (3) of four (4) quarter reviewed in 2021. Refer to D5555 II.
D6029	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can

	perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 (Laboratory Personnel Report) and personnel records as well as interview with personnel, the Laboratory Director failed to ensure Testing Personnel had appropriate training documentation prior to patient testing. Findings: 1. Review of the laboratory's CMS-209 (Laboratory Personnel Report) and personnel records revealed the following testing personnel did not have documentation of the Laboratory Director's approval/signature for patient testing: a) Main Lab Testing Personnel 4: Training completetion 3/20/2020 - Laboratory Director did not approve/sign assessment b) Respiratory Testing Personnel 14: Training completetion 10/28/2020 - Laboratory Director did not approve/sign assessment until 5/18/2021 2. In interview on January 18, 2022 at 1:29 pm, Personnel 6 confirmed the laboratory did not have documentation of initial training for the identified testing personnel approved/signed by the Laboratory Director prior to performing patient testing.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(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 review of laboratory policy, personnel records and interview with personnel, the Laboratory Director failed to ensure policies and procedures for assessing personnel competency were maintained. Refer to D6054.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of laboratory policy and procedure manual and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5403.

D6036	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413 The technical consultant is responsible for the technical and scientific oversight of the laboratory. This STANDARD is not met as evidenced by: Based on observation during the laboratory tour, review of laboratory records and interview with personnel, the Technical Consultant failed to provide technical and scientific oversight to the laboratory. Findings: 1. The laboratory failed to ensure that patient samples for Lactic Acid testing are analyzed immediately according to the manufacturer for thirty three (33) of one hundred seventy two (172) patients reviewed. Refer to D5411 I. 2. The laboratoray failed to perform patient samples for D Dimer testing within four (4) hours of collection as required by manufacturer for two (2) of ninety two (92) patients reviewed. Refer to D5411 II. 3. The laboratory failed to ensure supplies did not exceed their expiration date. Refer to D5417. 4. The laboratory failed to perform quarterly blood bank refrigerator alarm checks for one (1) of seven (7) quarters reviewed in 2019, 2020 and 2021. Refer to D5555 I. 5. The laboratory failed to perform quarterly blood bank alarm checks for the Fresh Frozen Plasma (FFP) Freezer for three (3) of four (4) quarter reviewed in 2021. Refer to D5555 II.
D6042	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(4) (b) The technical consultant is responsible for-- (b)(4) Establishing a quality control program appropriate for the testing performed and establishing the parameters for acceptable levels of analytic performance and ensuring that these levels are maintained throughout the entire testing process from the initial receipt of the specimen, through sample analysis and reporting of test results; This STANDARD is not met as evidenced by: Based on review of laboratory quality control records and interview with personnel, the Technical Consultant failed to ensure the quality control program was established to assure the quality of laboratory testing. Findings: 1. The laboratory failed to document external reactive and non-reactive controls for Rapid Plasma Reagin (RPR) patient testing for three (3) of fifty two (52) patients reviewed. Refer to D5449 I. 2. The laboratory failed to document external positive and negative controls for Clostridium Difficile (C Diff) patient testing for one (1) of thirty six (36) patients reviewed. Refer to D5449 II.
D6054	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least annually, after the first year. This STANDARD is not met as evidenced by: Based on review of laboratory policy, personnel records and interview with personnel, the Technical Consultant failed to evaluate competency annually in 2020 for one (1)

	of sixteen (16) testing personnel reviewed. Findings: 1. Review of the laboratory's Personnel Qualification sheet revealed the laboratory performs competency assessment upon initial hiring, at six (6) months and then annually thereafter. 2. Review of personnel records revealed the laboratory did have documentation of an annual competency assessment in 2020 for Personnel 2; however, the competency assessment was not approved/signed by a qualified technical consultant. 3. In interview on January 18, 2022 at 1:29 pm, Personnel 6 confirmed the 2020 annual competency assessment for Personnel 2 was not completed by a qualified personnel.