Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	44D0690507	04/29/2022
Name of Provider or Supplier	**Street Address, City, State**	
Laboratory Corporation Of America	1924 Alcoa Hwy Box U-108, Knoxville, TN	

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

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The facility was found to be NOT in compliance with the following 42 CFR Part 493, Requirements for Laboratories for the specialties/subspecialties for which it was surveyed: 493.1240 Pre-Analytic Systems 493.1250 Analytic Systems
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 a review of personnel files and interview of personnel, the laboratory failed to document competency assessments for all testing personnel. Findings: 1. A review of personnel files revealed that five of five laboratory assistants performing patient testing did not have any documentation of competency assessments. 2. An interview on 04/28/2022 at 2:00 PM with the Quality Manager confirmed the above findings.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by:

	Based on direct observation, review of laboratory policies and records, manufacturer's instructions, patient test reports and staff interview, the laboratory failed to meet the requirements for the preanalytical system, as evidenced by: 1. The laboratory failed to ensure patients were processed according to their policy and Cobas manufacturer's instructions for the preanalytic phase of testing (Ammonia and Lactic acids). Refer to D5311, I 2. The laboratory failed to centrifuge serum chemistry specimens within the allotted 1-hour processing time frames per their policy. Refer to D5311, II 3. The laboratory failed to follow the manufacturer's instructions for specimen stability and storage for Partial Thromboplastin Time (PTT) patient samples. Refer to D5311, III. 4. The laboratory failed to follow their own written procedure and reject visibly hemolyzed prothrombin time and activated partial thromboplastin time patient samples. Refer to D5311, IV 5. The laboratory failed to accurately document the date and time it received Ammonia and Lactic acid specimens. Refer to D5313. 6. The laboratory failed to provide clients with defined storage and transport instructions for coagulation tests (D-Dimer, PT, and PTT). Refer to D5317.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policy, laboratory's testing menu website, manufacturer's instructions, patient test reports, and interviews with Processing Manager, Emergency Room (ER) Nursing, the laboratory failed to ensure patients samples were processed according to their policy and Cobas manufacturer's instructions for the preanalytic phase of testing (Ammonia and Lactic acids) for the month of April 2022 as evidenced by: Ammonia a. In review of the manufacturer's instructions for the Cobas instrument states (version 11.0) under Specimen Collection and Preparation stated , "Place immediately on ice and centrifuge, preferably at 4 degrees C.Perform analysis within 20-30 minutes of venipuncture or freeze separated plasma immediately...Ammonia concentrations can increase in vitro due to breakdown of nitrogen-containing plasma components." b. In review of the laboratory's policy stated, "Place in immediately on ice and centrifuge....15-25 degree C 30 minutes... 2-8 degrees C 2 hours..." The policy did not follow the manufacturer's instructions. c.In review of the laboratory's website on 4/28/2022 at 1400 stated the following under stability requirement for ammonia: "2 hours (stability provided by manufacturer or literature reference)." d. In review of patients for the Month of April 2022 until the start of the survey, the laboratory had 50 of 198 patients that were not centrifuged within the 30 minute time frame. The following patients are a select listing of those: 1. Accession #22-094-0024471;collection date and time: 4-4-2022 1340; receive date and time: 4-4-2022 1619 total time elapsed: 159 minutes 2. Accession #22-096-000692 ;collection date and time: 4-6-2022 0630; receive date and time: 4-6-2022 712; total time elapsed: 42 minutes 3. Accession #22-098-001374;collection date and time: 4-8-2022 1140; receive date and time: 4-8-2022 1309; total time elapsed: 89 minutes 4. Accession #22-098-001477;collection date and time: 4-8-2022 1101; receive date and time: 4-8-2022 1153; total time elapsed: 52 minutes 5. Accession

#22-100-000350;collection date and time: 4-9-2022 2343; receive date and time: 4-10-2022 053; total time elapsed: 70 minutes 6. Accession #22-103-001810;collection date and time: 4-13-2022 0909; receive date and time: 4-13-2022 1000; total time elapsed: 51 minutes 7. Accession #22-104-000629;collection date and time: 4-14-2022 0501; receive date and time: 4-14-2022 546; total time elapsed: 45 minutes 8. Accession #22-104-000424;collection date and time: 4-14-2022 0054; receive date and time: 4-14-2022 129; total time elapsed: 35 minutes 9. Accession #22-107-002270;collection date and time: 4-17-2022 2051; receive date and time: 4-17-2022 2145; total time elapsed: 54 minutes 10. Accession #22-108-001696;collection date and time: 4-18-2022 0939; receive date and time: 4-18-2022; 1022 total time elapsed: 43 minutes e. In interview with an ER nurse 4-27-2022 at 1348 the federal surveyor asked how long do they have until the ammonia specimen could not be tested in the laboratory. He stated he wasn't sure for ammonia and would have to refer to the procedure order. f. In review the procedure order document referred to by the ER nurse stated, "Lavender top keep on ice deliver immediately." The document failed to state the 30 minute limitation specified in the manufacturer's instructions. g.In interview with Processing Manager on 04-26-2022 at 1150 she stated that it was on them (processing) to reject the specimen if it did not meet the 30 minute time frame. Lactic Acid a. In review of the manufacturer's instruction for the Cobas instrument version 13.0 states under specimen collection and preparation, "Centrifuge within 15 minutes of collecting the specimen." b. In review of the laboratory's policy stated, "The venipuncture samples should be kept on ice and centrifuged as soon as possible after collection (15 minutes) " c. In review of the laboratory's website on 4/28/2022 at 1405 stated the following under causes for rejection for lactic acid, "Specimen not separated from cells within 15 minutes of draw" d. In review of patients for the Month of April 2022 until the start of the survey, the laboratory had 149 of 1616 patients were not centrifuged within the 15 minute time frame. The following patients are a select listing of those: 1. Accession #22-092-001084;collection date and time: 4-2-2022; 617; receive date and time: 4-2-2022 635; total time elapsed:18 minutes 2. Accession #22-092-00519;collection date and time: 4-2-2022 520;receive date and time: 4-2-2022 545; total time elapsed: 25 minutes 3. Accession #22-092-001124; collection date and time: 4-2-2022 747;receive date and time: 4-2-2022 0806; total time elapsed: 19 minutes 4. Accession #22-092-001435 ;collection date and time: 4-2-2022 1127; receive date and time: 4-2-2022 1143; total time elapsed: 16 minutes 5. Accession #022-092-002066;collection date and time: 4-2-2022 1943; receive date and time: 4-2-2022 2007; total time elapsed: 24 minutes 6. Accession #022-092-00088;collection date and time: 4-2-2022 1915; receive date and time: 4-2-2022 1933; total time elapsed: 18 minutes 7. Accession #22-108-001035;collection date and time: 4-18-2022 1039; receive date and time: 4-18-2022 1118; total time elapsed: 39 minutes 8. Accession #22-108-000858 ;collection date and time: 4-18-2022 1650; receive date and time: 4-18-2022 1755; total time elapsed: 65 minutes 9. Accession #22-108-001591;collection date and time: 4-18-2022 907; receive date and time:4-18-2022 946; total time elapsed: 39 minutes 10. Accession #22-108-003252;collection date and time: 4-18-2022 1729; receive date and time: 4-18-2022 1847; total time elapsed:78 minutes e. In interview with ER nurse 04-27-2022 at 1349, federal surveyor asked how long do they have until the specimen could not be tested for lactic acid in the laboratory. He stated he wasn't sure for lactic acid but thought 15 minutes to the laboratory. The ER nurse stated he would have to refer to the procedure order. f. In review the procedure order document referred to by the ER nurse stated, "Gray top on ice delivered within 30 minutes." This document failed to follow manufacturer's instructions or laboratory policy. II. Based on review of the laboratory's policy, direct observation, and review of patient test reports, the laboratory failed to centrifuge two serum chemistry specimens within the allotted 1 hour processing time frames per their

policy as evidenced by: Unspun Specimens a. In review of the laboratory's policy for Vitamin B12, TSH, AST, ALT, CO2 states "The venipuncture sample should be centrifuged as soon as possible after collection (1 hr). The serum portion of the sample may be transported in an appropriately separated barrier tube (SST) or transferred in a transfer tube...." b. In direct observation at 4-27-2022 1825 in the accessing room, two tiger top (serum separate tubes) were unspun and on the clot (patient 1978716) . In review of the patient's test record (test ordered TSH, 25 OH Vitamin D, Vitamin B12) , it showed the documented specimen collection date and time was 04/27/2022 1600 and the specimen received date was 04/28/2022.The time the specimen was observed to be at the laboratory (1825) was 2 hours and 25 minutes after the collection time (1600). The documented received date (04/28/2022) was more than 8 hours after the time that the specimen was observed to be at the laboratory. c. In interview with the LabCorp courier on 4-27-2022 at 1826, he stated that the doctor's office didn't have time to spin the specimen. d. In direct observation on 04-27-2022 at 1850 in the accessing room, one tiger top tube (serum separator tube) was unspun and on the clot (patient 7846432) . In review of the patient's test record (test order complete metabolic panel (CMP) which includes AST, ALT, CO2). The documented collection date and time was 04-27-2022 at 0000 and the specimen received date was 04-27-2022 (no time indicated). The time the specimen was observed to be in the laboratory (1850) was more than 18 hours after the collection time (0000). The laboratory failed to ensure specimens was centrifuged within the 1-hour time limit. 41090 III. Based on a review of the manufacturer's instructions, the laboratory's policy and procedures, patient final reports, and an interview with General Supervisor #2, the laboratory failed to follow the manufacturer's instructions for specimen stability and storage for 14 of 15 partial thromboplastin time (PTT) patient samples in April 2022. a. A review of the package insert Dade Actin FSL Activated PTT Reagent (B4219G1E11 Rev. 10) page 2, revealed "Specimen Collection and Preparation ...Centrifuge the blood specimen at 1500 x g for no less than 15 minutes at room temperature as soon as possible after collection. Store in unopened tube at room temperature. If immediate testing is to be done, the plasma may remain on the packed cells. Otherwise plasma should be separated from the cells. Do not store on ice. Nonheparinized plasma should be tested within four (4) hours of blood collection ...Please refer to CLSI document H21-A5 for detailed information on sample preparation and storage." b. A review of the CLSI document H21-A5 (released Jan 2012) page 13, revealed "7. Storage...7.1.1 Short-Term Storage of Plasma and Coagulation Testing ...Specimens for routine APTT assays from nonheparinized patients can be maintained uncentrifuged or centrifuged, with plasma remaining on top of the cells in an unopened tube kept at room temperature for up to four hours from time of specimen collection. If laboratories choose to maintain APTT samples for more than four hours before testing, in-house studies should be performed." c. A review of the laboratory's procedure Sysmex CS Series Prothrombin Time and Activated Partial Thromboplastin Time (LC-TN-HEM-PRO-110.03) pages 4-5, revealed "Specimen Requirements ...Storage: Unopened (whole blood) tubes are stable for at least 24 hours at room temperature 15-25C." The laboratory's procedure was not consistent with the manufacturer's instructions. d. A review of the LabCorp Test Menu Prothrombin Time (PT) and Partial Thromboplastin Time (PTT) Test 020321 revealed "Storage Instructions: Specimens are stable at room temperature for 24 hours. If testing cannot be completed within 24 hours, specimens should be centrifuged for at least 10 minutes at 1500xg. Plasma should then be transferred to a LabCorp PP transpak frozen purple tube with screw cap (LabCorp N). Freeze immediately and maintain frozen until tested." e. A review of final reports from April 2022 revealed the laboratory tested and reported 14 of 15 PTT patient samples beyond the manufacturer's defined stability (greater than or equal to 4 hours stored as whole

blood). 1. Sample Number 1179700792, Collected April 27, 2022, at 3:27 PM, Received April 27, 2022, at 7:39 PM, Analyzed April 28, 2022, at 2:42 AM, Reported April 28, 2022, at 08:07 AM, Elapsed Time 11 hours, 15 minutes from the time of collection to the time of analysis. 2. Sample Number 1179700770, Collected April 27, 2022, at 2: 59 PM, Received April 27, 2022, at 7:39 PM, Analyzed April 27, 2022, at 11:47 PM, Reported April 28, 2022, at 08:07 AM, Elapsed Time 8 hours, 48 minutes from the time of collection to the time of analysis. 3. Sample Number 1179700767, Collected April 27, 2022, at 3:06 PM, Received April 27, 2022, at 7:39 PM, Analyzed April 27, 2022, at 11:46 PM, Reported April 28, 2022, at 08:07 AM, Elapsed Time 8 hours, 40 minutes from the time of collection to the time of analysis. 4. Sample Number 1179700773, Collected April 27, 2022, at 2:32 PM, Received April 27, 2022, at 7:39 PM, Analyzed April 27, 2022, at 11:51 PM, Reported April 28, 2022, at 07:05 AM, Elapsed Time 9 hours, 19 minutes from the time of collection to the time of analysis. 5. Sample Number 1179700769, Collected April 27, 2022, at 2:27 PM, Received April 27, 2022, at 7:39 PM, Analyzed April 27, 2022, at 11:52 PM, Reported April 28, 2022, at 08:07 AM, Elapsed Time 9 hours, 25 minutes from the time of collection to the time of analysis. 6. Sample Number 1179700768, Collected April 27, 2022, at 3:30 PM, Received April 27, 2022, at 7:39 PM, Analyzed April 27, 2022, at 11:50 PM, Reported April 28, 2022, at 08:07 AM, Elapsed Time 8 hours, 20 minutes from the time of collection to the time of analysis. 7. Sample Number 1179700796, Collected April 27, 2022, at 4:42 PM, Received April 27, 2022, at 7:39 PM, Analyzed April 28, 2022, at 2:33 AM, Reported April 28, 2022, at 8:07 AM, Elapsed Time 21 hours, 51 minutes from the time of collection to the time of analysis. 8. Sample Number 1179701350, Collected April 27, 2022, at 4:38 PM, Received April 27, 2022, at 7:39 PM, Analyzed April 28, 2022, at 2:41 AM, Reported April 28, 2022, at 08:07 AM, Elapsed Time 22 hours, 3 minutes from the time of collection to the time of analysis. 9. Sample Number 1179700759, Collected April 27, 2022, at 4: 20 PM, Received April 27, 2022, at 7:39 PM, Analyzed April 27, 2022, at 11:09 PM, Reported April 28, 2022, at 08:07 AM, Elapsed Time 6 hours, 49 minutes from the time of collection to the time of analysis. 10. Sample Number 1179700761, Collected April 27, 2022, at 4:13 PM, Received April 27, 2022, at 7:39 PM, Analyzed April 27, 2022 at 11:08 PM, Reported April 28, 2022 at 8:07 AM, Elapsed Time 6 hours, 55 minutes from the time of collection to the time of analysis. 11. Sample Number 1179700772, Collected April 27, 2022, at 3:09 PM, Received April 27, 2022, at 7:39 PM, Analyzed April 27, 2022, at 11:48 PM, Reported April 28, 2022, at 8:07 AM, Elapsed Time 8 hours, 39 minutes from the time of collection to the time of analysis. 12. Sample Number 1179700774, Collected April 27, 2022, at 2:00 PM, Received April 27, 2022, at 7:39 PM, Analyzed April 27, 2022, at 10:54 PM, Reported April 28, 2022, at 8:07 AM, Elapsed Time 8 hours, 54 minutes from the time of collection to the time of analysis. 13. Sample Number 1179700723, Collected April 27, 2022, at 10:28 AM, Received April 27, 2022, at 7:22 PM, Analyzed April 27, 2022, at 11:11 PM, Reported April 28, 2022, at 7:05 AM, Elapsed Time 12 hours, 43 minutes from the time of collection to the time of analysis. 14. Sample Number 1179701047, Collected April 27, 2022, at 11:47 AM, Received April 27, 2022, at 7:22 PM, Analyzed April 28, 2022, at 1:00 AM, Reported April 28, 2022, at 7:05 AM, Elapsed Time 13 hours, 13 minutes from the time of collection to the time of analysis. f. An interview with General Supervisor #2, as listed on the CMS Form 209, on April 28, 2022, at 2:46 PM in their office confirmed these findings. *Word Key: C=degrees Celsius; g=gravity IV. Based on a review of the manufacturer's instructions, the laboratory's policy and procedures, patient reports, and interviews with staff, the laboratory failed to follow their own written procedure and reject four of four visibly hemolyzed prothrombin time and activated partial thromboplastin time patient samples on April 27, 2022. a. A review of Sysmex Automated Blood Coagulation

	Analyzer CS-2500 Instructions for Use (Revised February 2018), revealed "Chapter 8 Troubleshooting ...8.5.3 Displaying sample information ...The [Joblist] screen and the [Detail] dialog box display the result of the inhibitor check in the sample (normal mode only) ...Code: 1000.1000.0000 ...Display/Message [Detail] dialog box: [Hemolyzed Sample] ...Possible cause: Sample suspected of hemolysis ...Corrective actions/Countermeasures: Check the reaction curve and follow judgment criteria for the institution." b. A review of the laboratory's policy Sysmex CS Series Prothrombin Time and Activated Partial Thromboplastin Time (LC-TN-HEM-PRO-110.03), page 5, revealed "Causes for rejection: ...4. Visibly hemolyzed samples." c. A review of patient reports (sampling) on April 27, 2022, revealed the laboratory failed to reject four of four patient samples flagged by the instrument with "Detail: 1000.1000.0000 Hemolyzed Sample". 1. Sample Number: 22117001057; Test: PTT; Reported April 27, 2022, at 9:24 AM 2. Sample Number: 22116005147; Test: PTT; Reported April 27, 2022, at 12:15 AM 3. Sample Number: 22117000197; Test: PT with INR; Reported April 27, 2022, at 4:52 AM 4. Sample Number: 22116005015; Test: PTT; Reported April 27, 2022, at 12:27 AM d. An interview with testing personnel #24, as listed on the CMS Form 209, on April 27, 2022, at 2:05 PM in the coagulation laboratory revealed when the technologist encounters a hemolyzed sample code, they check for clots and use their judgment to determine if the specimen is too hemolyzed to report. e. An interview with General Supervisor #2, as listed on the CMS Form 209, on April 27, 2022, at 2:40 PM in the coagulation laboratory confirmed the four patient samples were visibly hemolyzed and the laboratory failed to reject the specimens. *Word Key: PT with INR= prothrombin time with International Normalized Ratio, PTT= partial thromboplastin time
D5313	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(b) The laboratory must document the date and time it receives a specimen. This STANDARD is not met as evidenced by: Based on review of the laboratory testing records and interview with the laboratory director, the laboratory failed to accurately document the date and time it received ammonia and Lactic acid specimens for the month of April 2022 as evidenced by: Ammonia a. In review of the following patients' testing record, the laboratory failed to accurately document the date and time it received ammonia samples for the following patients: 1. accession#22-093-001398; Collection time and date: 4-3-2022 2222; Received time and date: 4-3-2022 1337 The receipt time documented was before the specimen collection and time. 2. accession#22-094-002021; Collection time and date: 4-4-2022 1710; Received time and date: 4-4-2022 1411 The receipt time documented was before the specimen collection and time. 3. accession#22-095-002333; Collection time and date: 4-5-2022 1749; Received time and date: 4-5-2022 1256 The receipt time documented was before the specimen collection and time. 4. accession#22-101-004239; Collection time and date: 4-11-2022 1649; Received time and date:4-11-2022 1649 The collection time and date same as receipt time and date. 5. accession#22-101-004454; Collection time and date: 4-11-2022 1804; Received time and date: 4-11-2022 1804.The collection time and date same as receipt time andvdate. 6. accession#22-103-002673; Collection time and date: 4-13-2022 1252; Received time and date: 4-13-2022 1252. The collection time and date same as receipt time and date. 7. accession# 22-103-002900; Collection time and date:4-13-2022 1427; Received time and date: 4-13-2022 427 The collection time and date same as receipt time and date. 8. accession# 22-104-004439; Collection time and date:4-14-2022 1847;

	Received time and date: 4-14-2022 1847 The collection time and date same as receipt time and date. Lactic acid a. In review of the following patient's testing record, the laboratory failed to accurately document the date and time it received lactic acid samples for the following patients: 1. accession#22-094-005027; Collection time and date: 4-4-2022 2329; Received time and date: 4-4-2022 2329 The collection time and date same as receipt time and date. 2. accession #22-108-004018; Collection time and date: 4-18-2022 1651; Received time and date: 4-18-2022 1651.The collection time and date same as receipt time and date. 3. accession#22-108-004282; Collection time and date: 4-18-2022 1907; Received time and date: 4-18-2022 1907. The collection time and date same as receipt time and date. 4. accession#22-108-004293; Collection time and date: 4-18-2022 1817; Received time and date: 4-18-2022 1817. The collection time and date same as receipt time and date. 5. accession#22-108-004315; Collection time and date: 4-18-2022 1857; Received time and date: 4-18-2022 1857. The collection time and date same as receipt time and date. 6. accession#22-108-004416; Collection time and date: 4-18-2022 1944; Received time and date: 4-18-2022 1944. The collection time and date same as receipt time and date. 7. accession#22-108-4452; Collection time and date: 4-18-2022 2048; Received time and date: 4-18-2022 2048 The collection time and date same as receipt time and date. 8. accession#22-108-004864; Collection time and date:4-18-2022 2308; Received time and date: 4-18-2022 2308 The collection time and date same as receipt time and date. b. In an interview on 4-28-2022 at 0915, the laboratory director confirmed the findings that the laboratory failed to accurately document specimen receipt time
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 the manufacturer's instructions, laboratory's policies and procedures, and interview with General supervisor #2, the laboratory failed to provide clients with defined storage and transport instructions for three of three coagulation tests reviewed. Findings include: 1. D-Dimer a. A review of the package insert Siemens INNOVANCE D-Dimer (OPBPG09U11 Rev. 09) page 5 revealed "Stability of the Samples: 15 to 25C 4 hours, 2 to 8C 24 hours, less than or equal to -18C 4 weeks if frozen within 4 hours of blood collection." b. A review of the laboratory's policy Innovance D-Dimer (LC-TN-HEM-PRO-422.05) pages 2-3, revealed "Storage: Whole blood can be stored up to 4 hours at room temperature. Plasma can be stored up to 8 hours at room temperature. If testing is not complete within 4 hours for whole blood or 8 hours for plasma, specimens must be frozen at -20C or below for short term storage (up to 2 weeks) or -70C or below for long term storage." The laboratory failed to define "room temperature" and "long term storage". The laboratory's defined plasma storage conditions exceed the manufacturer's requirements. c. A review of the LabCorp Test Menu D-Dimer Test 115188 revealed "Storage Instructions ...Freeze, Stability Requirements ...Temperature Frozen...Period 4 weeks." The laboratory did not define "Frozen". d. An interview with General Supervisor #2, as listed on the CMS Form 209, on April 28, 2022, at 2:46 PM in their office confirmed these findings. 2. PT a. A review of the package insert Siemens Dade Innovin (10873566GU11 Rev. 03) page 3 revealed "Store in an unopened tube at room temperature. Do not store on ice or at 2 to 8C ...Plasma should be tested within 24

	hours of blood collection ...Please refer to CLSI document H21-A5 for detailed information on sample preparation and storage." b. A review of the CLSI document H21-A5 (released Jan 2012) in the Table on page 15, revealed "Assay PT ...Stored As Whole Blood ...Room Temp Up to 24 hr ...Processed and Plasma Aliquoted ...Room Temp Up to 24 hr ...Frozen -20 C 2 wk ...Frozen -70C or colder 12 mo." c. A review of the laboratory's procedure Sysmex CS Series Prothrombin Time and Activated Partial Thromboplastin Time (LC-TN-HEM-PRO-110.03) pages 4-5, revealed "Specimen Requirements ...Storage: Unopened (whole blood) tubes are stable for at least 24 hours at room temperature 15-25C ...It has been reported that frozen plasma is stable for up to two weeks at -20 to -30C and up to six months at less than or equal to -70C." d. A review of the LabCorp Test Menu Prothrombin Time (PT) and Partial Thromboplastin Time (PTT) Test 020321 revealed "Storage Instructions: Specimens are stable at room temperature for 24 hours. If testing cannot be completed within 24 hours, specimens should be centrifuged for at least 10 minutes at 1500xg. Plasma should then be transferred to a LabCorp PP transpak frozen purple tube with screw cap (LabCorp N). Freeze immediately and maintain frozen until tested." The laboratory did not define "room temperature" and "frozen". e. An interview with General Supervisor #2, as listed on the CMS Form 209, on April 28, 2022, at 2:46 PM in their office confirmed these findings. 3. PTT a. A review of the package insert Dade Actin FSL Activated PTT Reagent (B4219G1E11 Rev. 10) page 2, revealed "Specimen Collection and Preparation ...Centrifuge the blood specimen at 1500 x g for no less than 15 minutes at room temperature as soon as possible after collection. Store in unopened tube at room temperature. If immediate testing is to be done, the plasma may remain on the packed cells. Otherwise plasma should be separated from the cells. Do not store on ice. Nonheparinized plasma should be tested within four (4) hours of blood collection ...Platelet-poor plasma may be frozen at less than or equal to -20C for up to two (2) weeks in a no frost-free freezer ...Please refer to CLSI document H21-A5 for detailed information on sample preparation and storage." b. A review of the CLSI document H21-A5 (released Jan 2012) in the Table on page 15 revealed "Assay APTT ...Stored as Whole Blood ...Room Temp Up to 4 hr ... Processed and Aliquoted ...Room Temp 4 hr ... Frozen -20 C 2 wk ...Frozen -70C or colder 12 mo". c. A review of the laboratory's procedure Sysmex CS Series Prothrombin Time and Activated Partial Thromboplastin Time (LC-TN-HEM-PRO-110.03) pages 4-5, revealed "Specimen Requirements ...Storage: Unopened (whole blood) tubes are stable for at least 24 hours at room temperature 15-25C ...It has been reported that frozen plasma is stable for up to two weeks at -20 to -30C and up to six months at less than or equal to -70C." d. A review of the LabCorp Test Menu Prothrombin Time (PT) and Partial Thromboplastin Time (PTT) Test 020321 revealed "Storage Instructions: Specimens are stable at room temperature for 24 hours. If testing cannot be completed within 24 hours, specimens should be centrifuged for at least 10 minutes at 1500xg. Plasma should then be transferred to a LabCorp PP transpak frozen purple tube with screw cap (LabCorp N). Freeze immediately and maintain frozen until tested." The laboratory did not define "room temperature" and "frozen". e. An interview with General Supervisor #2, as listed on the CMS Form 209, on April 28, 2022, at 2:46 PM in their office confirmed these findings. *Word Key: C=degrees Celsius; g=gravity; hr=hour, wk=week; mo=month; APTT= activated partial thromboplastin time
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 direct observation, review of laboratory policies and records, manufacturer's instructions, patient records, and staff interview, the laboratory failed to meet analytic systems requirements, as evidenced by: 1. The laboratory failed to include a procedure for documenting the acceptability of Hematoxylin & Eosin stained slides in their Histopathology procedure manual. Refer to D5403, I 2. The laboratory failed to follow its own procedure for ensuring hematology specimen integrity of patient specimens stored at room temperature. Refer to D5403, II. 3. The laboratory failed to follow its own procedure for the establishment of QC ranges for control levels for the Sysmex XS-100i hematology analyzer. Refer to D5403, III. 4. The laboratory failed to follow manufacturer's instructions to perform and calculate the mean normal prothrombin time for the Sysmex CS-2500 coagulation instruments. Refer to D5411 5. The laboratory failed to define the storage temperature according to the manufacturer's instructions for areas where reagents were stored. Refer to D5413. 6. The laboratory failed to label in-use reagents with open and new expiration dates. Refer to D5415. 7. The laboratory failed to verify the precision of the PFA-1000 analyzer. Refer to D5421. 8. The laboratory failed to establish performance specifications for body fluid tests (i.e. Lactate Dehydrogenase (LDH), Glucose synovial and pleural, Cholesterol, triglyceride) tests with the Cobas chemistry analyzer. Refer to D5423 9. The laboratory failed to include controls with titered reactivity when patient samples were titered. Refer to D5451. 10. The laboratory failed to test control materials in the same manner as patient specimens with similar matrix for (i.e. LDH, Glucose, Cholesterol) tests for body fluid. Refer to D5465 11. The laboratory failed to establish quality control specifications for the Sysmex CS-2500 coagulation instruments. Refer to D5469. 12. The laboratory failed to test QC material in duplicate. Refer to D5543. 13. The laboratory failed to evaluate all patient test results after performing test system adjustments for QC flags since the last acceptable quality control test run to ensure accurate and reliable test results. Refer to D5783, I. 14 The laboratory failed to evaluate patient test results between the last successful quality control (QC) run and failed QC run. Refer to D5783, II.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values.

	(12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: I. Based on a review of the Histopathology procedure manual and interview with personnel the laboratory failed to include a procedure for documenting the acceptability of Hematoxylin & Eosin stained slides in their Histopathology procedure manual. Findings: 1. A review of the Histopathology procedure manual revealed no mention of how to document the acceptability of Hematoxylin & Eosin stained slides. 2. An interview on 04/27/2022 at 11:00 AM with the Anatomic Pathology Manager confirmed the above findings. 41221 II. Based on patient record review, direct observation, laboratory procedure review and personnel interview the laboratory failed to follow its own procedure for ensuring hematology specimen integrity of one day stored at room temperature for 2 of 2 specimens observed. Findings: 1) Review of the laboratory's standard operating procedure titled: Sysmex XN-9100 Standard Operating Procedure adopted on 4/24/2020 under Specimen Requirements states Storage: Temperature Period Room 1 day Refrigerated 3 days Frozen Unstable 2) Direct observation of specimen receiving and processing on 4/27/2022 at 1910 in the specimen processing area showed a specimen bin labeled Manual Accessioning Bin with approximately 36 specimens placed inside. A random sampling of 6 hematology specimens were pulled and observed for collection times. Two of six samples indicated the following collection times: Patient ID:15479, collection time 4/26/22 at 1205, Patient ID: GSDYI80RF, collection time 4/26/22 at 0001. 3) Interview with specimen processing personnel on 4/27/2022 at 1930 revealed that specimens placed in the Manual Accessioning Bin were processed by one staff member each night. The particular staff member was not on duty until 2130 that evening. 4) Review of final test reports indicated laboratory specimen receive date and report time to be: Patient ID:15479, received 4/28/2022, reported 4/28/2022 at 0806, Patient ID: GSDYI80RF, received 4/28/2022, reported 4/28/2022 at 0817. The laboratory performs approximately 393,924 hematology tests annually. III. Based on review of laboratory policy, hematology control manufacturer instructions, Levey - Jennings reports and staff interview, the laboratory failed to follow its own procedure for the establishment of QC ranges for 3 out of 3 control levels for it's Sysmex XS-100i hematology analyzer. Findings: 1) Review of manufacturer insert for e-Check (XS)- Hematology control for Sysmex XS-1000iC Analyzers Lot numbers 20670804, 20670805, and 20670806, expiration date 5/29/2022 under performance characteristics and limitations states: "The mean values obtained on e-Check (XS) should be within the expected ranges." 2) Review of laboratory procedure title: Sysmex XS-100i Analyzer adopted 7/1/2016 for the Hematology/Satellite Lab under Quality Control for Procedure for entering new lot of QC material states in step 14. "Verify new QC target values are within expected range from package insert for each parameter." 3) Review of Levey-Jennings charts from XS-1000i of laboratory established ranges between dates 3/22/2022 and 4/28/2022 revealed the following parameters beyond manufacturer's expected ranges: RBC, lab range low level 2- 4.19, manufacturer's range-4.23 RBC, lab range low level 3- 4.95, manufacturer-5.02 HGB, lab range low level 1- 4.0, manufacturer- 4.7 HCT, lab range low level 3-44.6, manufacturer- 45.3 WBC-D, lab range low level 2- 6.42, manufacturer- 6.54 4) Interview with the testing person 13 on page 1 of CMS 209 in the main lab hematology department on 4/28 /2022 at 1328 and laboratory manager on 4/28/2022 at 1348 confirmed the findings.

D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on the manufacturer's instruction, the laboratory's coagulation lot roll-over studies, instrument input settings, and interview with General Supervisor #2 revealed the laboratory failed to follow the manufacturer's instructions to perform and calculate the mean normal prothrombin time for one of two Sysmex CS-2500 coagulation instruments. a. A review of Siemens Dade Innovin (10873566GU11 Rev. 03) revealed on page 7, "The mean normal PT (MNPT) ...must be determined specifically for each thromboplastin lot using the method used to analyze the patient samples and ...using the coagulation analyzer used for the analysis." b. A review of the laboratory's 2021-LC16 Coagulation Lot Roll-over Prothrombin Time and INR signed by the laboratory director on June 28, 2021, revealed "Instrument Model: CS-2500 ...Serial number: 22361 ...New Lot Arithmetic Mean (M): 10.7 seconds". No data points were gathered on instrument CS-2500 serial number 22360. c. A review of the instruments INR Calibration Curve (ISI Input) revealed: 1. CS-2500 22361 "Normal Val.: 10.7" 2. CS-2500 22360 "Normal Val.: 10.7" The MNPT established on instrument 22361 was used for 22360. d. An interview with General Supervisor #2, as listed on the CMS Form 209, on April 28, 2022, at 2:46 PM in their office confirmed these findings. *Word Key: ISI=International Sensitivity Index; INR= International Normalized Ratio; Val.-value
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's temperature specifications, laboratory environmental records and a staff interview, revealed the laboratory failed to monitor and document for acceptable temperatures actions when the freezer temperatures were not within storage and stability specifications for five of twelve months for laboratory chemistry testing controls stored in the small chemistry freezer in the laboratory from May 2021 through April 2022. Findings include: 1. Observed on a tour of the chemistry section of the cancer laboratory on April 26, 2022 at 11:45 AM were chemistry testing controls kept frozen in the chemistry freezer. The following chemistry controls, BioRad Liquichek Unassayed Control (Human) Levels 1 and 2 (Lot #92920: Level 1 92921 and Level 2 92922 with an expiration date of 2023-06-30), found stored were: a. Two bottles of Aliquot-Frozen Level 1 chemistry

controls of the Lot Number/Expiration Date listed above. b. Three bottles of Aliquot-Frozen Level 2 chemistry controls of the Lot Number/Expiration Date listed above. 2. Review of the manufacturer's instructions for the BioRad Liquichek Unassayed Control (Human) Levels 1 and 2 (Lot #92920: Level 1 92921 and Level 2 92922 with an expiration date of 2023-06-30) that acceptable storage temperature range specified on the package insert stated: a. "Storage and Stability: This product will be stable until the expiration date when stored unopened at -20 to -70 degrees Celsius." b. "Limitations: This product should not be used past the expiration date." c. "Specific Performance Characteristics: This product is a stabilized liquid product manufactured under rigid control standards. To obtain consistent assay values, the control requires proper storage and handling as described." 3. Review of the laboratory's Temperature Log for the Chemistry Freezer for the period May 1, 2021 - April 26, 2022, showed the Acceptable Temperature Ranges -15 degrees Celsius to -25 degrees Celsius with daily testing personnel written temperature entries and initials. Review of the daily temperature monitoring logs for May 2021-April 2022 found the chemistry freezer temperatures were out of range for the storage and stability of the BioRad Liquichek Unassayed (Human) Control Levels 1 and 2. 4. The staff did not monitor and document acceptable temperatures for the controls for 30 days of 365 temperature dates: a. May 1-31, 2021: 14 of 31 days temperatures documented out of range for the controls i. May 3, 2021 - Temperature documented -19.0 degrees Celsius ii. May 3, 2021 - Temperature documented -19.0 degrees Celsius iii. May 11, 2021 - Temperature documented -19.0 degrees Celsius iv. May 12, 2021 - Temperature documented -19.0 degrees Celsius v. May 13, 2021 - Temperature documented -19.0 degrees Celsius vi. May 14, 2021 - Temperature documented -19.0 degrees Celsius vii. May 17, 2021 - Temperature documented -19.0 degrees Celsius viii. May 18, 2021 - Temperature documented -19.0 degrees Celsius ix. May 20, 2021 - Temperature documented -19.0 degrees Celsius x. May 21, 2021 - Temperature documented -19.0 degrees Celsius xi. May 25, 2021 - Temperature documented -19.0 degrees Celsius xii. May 26, 2021 - Temperature documented -19.0 degrees Celsius xiii. May 27, 2021 - Temperature documented -19.0 degrees Celsius xiv. May 28, 2021 - Temperature documented -19.0 degrees Celsius b. June 1-30, 2021: 10 of 30 days temperatures documented out of range for the controls i. June 1, 2021 - Temperature documented -19.0 degrees Celsius ii. June 4, 2021 - Temperature documented -19.0 degrees Celsius iii. June 7, 2021 - Temperature documented -19.0 degrees Celsius iv. June 9, 2021 - Temperature documented -19.0 degrees Celsius v. June 10, 2021 - Temperature documented -19.0 degrees Celsius vi. June 11, 2021 - Temperature documented -19.0 degrees Celsius vii. June 14, 2021 - Temperature documented -19.0 degrees Celsius viii. June 25, 2021 - Temperature documented -18.0 degrees Celsius ix. June 28, 2021 - Temperature documented -18.0 degrees Celsius c. July 1-31, 2021 - 4 of 31 recorded days temperatures documented out of range for the controls i. July 7, 2021 - Temperature documented -19.0 degrees Celsius ii. July 18, 2021 - Temperature documented -19.0 degrees Celsius iii. July 26, 2021 - Temperature documented -19.0 degrees Celsius iv. July 28, 2021 - Temperature documented -19.0 degrees Celsius d. December 1-31, 2021: 1 of 31 recorded days temperatures documented out of range for the controls i. December 21, 2021 - Temperature documented -16.0 degrees Celsius 1. Documentation written "12-21-21 Freezer door not closing completely, removed ice from door trim, closing now, KHS" e. January 1-31, 2022: 1 of 31 recorded days temperatures documented out of range for the controls i. January 7, 2022 - Temperature documented -19 degrees Celsius 5. During an interview on April 26, 2022, at approximately 12:10 PM (EST) with the Laboratory Assistant (LA) confirmed the out of range temperatures listed above. LA stated the Temperature Log for the Chemistry Freezer inaccurately portrayed the correct temperature ranges to monitor for the BioRad Liquichek Unassayed (Human)

	Control Levels 1 and 2 stored in the small chemistry freezer during May 2021 - April 2022. LA indicated she would go to the Core Lab and restock more chemistry controls, as needed over the past two years working in the laboratory. 6. During an interview on April 28, 2022, at 10:00 AM (EST) with the General Supervisor, Core Lab Chemistry Department, stated: "Cancer lab techs are not supposed to store any controls in freezer in the lab, but only maintain one bottle of control, as needed." Further questioning about the specific Quality Control Policy or written instructions that clarified this information resulted in "No instructions/inventory of what controls to maintain in the Cancer Laboratory." 41090 Based on a review of the laboratory's temperature records, direct observation, manufacturer's package insert, and interview with General Supervisor #2, the laboratory failed to define the storage temperature according to the manufacturer's instructions for one of three areas observed where reagents were stored. a. A review of the laboratory's temperature form (LC-TN-COR-F-012.03) revealed "Year: 2022 ...Month: April ...Refrigerator: WALK-IN ... Temperature Range: 2.0-8.0". b. A sampling of reagents observed stored in the Walk-in refrigerator included: 1. 16 boxes of Sysmex CA Clean II; Lot number A1024, Expiration Date: December 7, 2022, Storage: +5C to + 35C. c. A review of the package insert CA CLEAN II (Revised March 2020) revealed "Storage and shelf life of unopened product Storage and shelf life after first opening ...Store the product from 5 to 35C (Do not freeze)." The laboratory's defined refrigerated range of 2.0-8.0 was beyond the stored reagents requirements as listed above (5 to 35C). e. An interview with General Supervisor #2, as listed on the CMS Form 209, on April 27, 2022, at 9: 00 AM in their office confirmed these findings. *Word Key: C=degrees Celsius
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on the manufacturer's instructions, direct observation, and interview with testing personnel #31, the laboratory failed to label two of five in-use reagents with open and new expiration dates. a. A review of Siemens INNOVANCE Heparin (11541651_en Rev. 03) revealed on page 2, "Reagent: INNOVANCE Heparin Reagent ...Stability once opened: 2-8C 8 weeks ...Reagent: INNOVANCE Heparin Substrate ...Stability once opened: 2-8C 8 weeks". b. A sampling of reagents observed stored in refrigerator LCTN CL 0094 included: 1. 1 open bottle of INNOVANCE Substrate, Lot number 554152 2. 1 open bottle of INNOVANCE Reagent, Lot number 554052 The laboratory failed to label the bottles with open and new expiration dates described by the manufacturer (at 2-8C for 8 weeks). c. An interview with testing personnel #31, as listed on the CMS Form 209, on April 26, 2022, at 1:15 PM in the coagulation laboratory confirmed these findings. *Word Key: C=degrees Celsius
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it

	can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on the laboratory's verification studies, record review, and interview with General Supervisor #2 the laboratory failed to verify the precision of the PFA-1000 analyzer (serial number 01496). a. A review of the laboratory's verification studies for the PFA-1000 analyzer revealed a no documentation of precision studies. b. CMS requested precision studies for the PFA-1000. No documentation was provided. c. A review of instrument printouts of patient results from January 2022 to April 27, 2022, revealed 17 tests were performed. d. An interview with General Supervisor #2, as listed on the CMS Form 209, on April 28, 2022, at 2:46 PM in their office confirmed the instrument was installed before May 2016, and precision studies were not provided.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on lack of documentation, manufacturer's instructions, and interview with the Chemistry supervisor, the laboratory failed to establish performance specifications for body fluid tests (i.e. Lactate Dehydrogenase (LDH), Glucose synovial and pleural, Cholesterol, triglyceride) tests with the Cobas chemistry analyzer as evidenced by: a. In review of the manufacturer's instruction for LDH on the Cobas system stated under intended use, "In vitro testing for the quantitative determination of lactate dehydrogenase in human serum and plasma on Roche/Hitachi cobas c systems." b In review of the manufacturer's instruction for Glucose on the Cobas system states under intended use, "In vitro testing for the quantitative determination of glucose human serum, plasma, urine and Cerebrospinal Fluid (CSF) on roche/hitachi cobas c systems." c.In review of the manufacturer's instruction for Cholesterol on the Cobas system states under intended use "In vitro testing for the quantitative determination of cholesterol in human serum and plasma on Roche/Hitachi Cobas c systems" d. In review of the manufacturer's instruction for triglyceride on the Cobas system stated under intended use "In vitro testing for the quantitative determination of triglycerides in human serum and plasma on Roche/Hitachi Cobas c systems" e. The laboratory could not provide performance specifications for accuracy, precision, analytical sensitivity, analytic specificity to include interfering substances, any other

	performance characteristic required for the LDH, glucose (synovial, pleural), cholesterol, triglycerides, creatinine body fluid tests. g. In interview on 4-27-2022 at 1510, the chemistry supervisor stated that they did not have establishment studies for the any of the body fluid tests. h. In the month of March 2022, the laboratory performed 3 Body fluid cholesterol tests, 55 glucose body fluid tests, 61 LDH body fluid tests, 5 creatinine body fluid, and 6 triglyceride body fluid tests.
D5451	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(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-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the Rapid Plasma Reagin (RPR) procedure and worksheets, and interview of personnel, the laboratory failed to include controls with titered reactivity when patient samples were titered. Findings: 1. A review of the RPR procedure revealed that there was no instructions for running controls with titered reactivity when patients were titered. 2. A review of the RPR worksheets revealed that there were no results for any RPR controls with titered reactivity when RPR positive patients were titered. 3. An interview on 04/26/2022 at 2:30 PM with the Core Lab Manager confirmed the above findings.
D5465	CONTROL PROCEDURES CFR(s): 493.1256(d)(8)(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-- Test control materials in the same manner as patient specimens. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory quality control (QC) program, QC package inserts, and interview with the Chemistry supervisor, the laboratory failed to test control materials in the same manner as patient specimens with similar matrix for (i.e. LDH, Glucose, Cholesterol) tests for body fluid in the month of April 2022 as evidenced by: a. In review of the QC package inserts for chemistry Biorad liquicheck unassayed control lot #92920 (level 1 and 2) stated under intended use, "liquicheck unassayed chemistry control is intended for use as an unassayed quality control serum to monitor of laboratory testing procedures for the analytes listed in this package insert." b. In review of the laboratory quality control program, the laboratory utilized the same quality control data and quality control material for serum, plasma, and body fluid specimens. c. In interview with the Chemistry Supervisor on 4-27-2022 at 1515, the chemistry supervisor stated that she used the serum and urine controls for the all body fluid tests. She was unable to show actual bottles of "body fluid" matrix controls used

	for their quality control program. d. In the month of March 2022, the laboratory performed 3 Body fluid cholesterol tests, 55 glucose body fluid tests, 61 LDH body fluid tests, 5 creatinine body fluid, and 6 triglycerides body fluid tests.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on record review, the laboratory's policy and procedures, and an interview with General Supervisor #2, the laboratory failed to establish quality control parameters for one of two Sysmex CS-2500 coagulation instruments. a. No quality control data points were gathered or used to perform calculations for instrument CS-2500 serial number 22360. The laboratory used the data obtained from CS-2500 serial number 22361 to establish day-to-day quality control acceptability for CS-2500 serial number 22360. b. A review of the laboratory's policy Sysmex CS Series Coagulation Reagent Rollover Studies Prothrombin Time, Activated Partial Thromboplastin Time, ad Fibrinogen (LC-TN-HEM-PRO-106.04) revealed there were no procedures to establish quality control for each duplicate or backup instrument separate from the primary use instrument. c. An interview with General Supervisor #2, as listed on the CMS Form 209, on April 28, 2022, at 2:46 PM in their office confirmed these findings.
D5543	HEMATOLOGY CFR(s): 493.1269(a)(d) (a) For manual cell counts performed using a hemocytometer-- (a)(1) One control material must be tested each 8 hours of operation; and (a)(2) Patient specimens and control materials must be tested in duplicate. (d) 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 patient test records, review of laboratory hemacytometer quality control (QC) records, documentation received via email, and interview with the core lab manager, the laboratory failed to test hemacytometer QC material in duplicate beginning 01.04.2021 until the date of the survey on 04.28.2022 with approximately 85 patients reported. The findings include: 1. Review of patient numbers 21-145-000096 (performed on 05.25.2021) and 22-099-002015A (performed on 04.09.2022) revealed patient testing for body fluid cell count using a hemacytometer. 2. Review of

	the laboratory's hemacytometer QC records for the dates of 05.25.2021 and 04.09.2022 revealed no documentation that the hemacytometer QC was performed in duplicate. Further review of the hemacytometer QC records revealed no documentation that hemacytometer QC was performed in duplicate from 01.04.2021 until the survey date on 04.28.2022. 3. Review of documentation received via email from the core laboratory manager on 06.06.2022 revealed approximately 85 patients were reported during the period when hemacytometer QC was not performed in duplicate. 4. Interview on 04.28.2022 at 12:15 pm with the core lab manager confirmed the laboratory's records for hemacytometer QC did not include documentation of testing hemacytometer QC in duplicate from 01.04.2021 until the date of the survey on 04.28.2022. Approximately 85 patient body fluid cell counts were performed and reported using the hemacytometer during the period.
D5553	IMMUNOHEMATOLOGY CFR(s): 493.1271(b)(f) (b) Immunohematological testing and distribution of blood and blood products. Blood and blood product testing and distribution must comply with 21 CFR 606.100(b)(12); 606.160(b)(3)(ii) and (b)(3)(v); 610.40; 640.5(a), (b), (c), and (e); and 640.11(b). (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 laboratory policy, a random review of patient emergency release records (05/2021 through 03/2022), and in interview with staff, the laboratory failed to ensure signatures of the requesting physicians were obtained before or after emergency release of blood products [21 CFR 606.160(b)(3)(v)] for 4 of 10 patients. Findings included: 1. The laboratory policy titled, "Emergency Issue of Blood" (LC-TN-TRM-PRO-102.05, Adopted 10/31/2019), stated the following: "Clinical Significance: On occasion hospital personnel may appear in the Blood Bank requesting issue of one or more units of blood for immediate transfusion for a patient in extremis due to acute blood loss. Usually this will be a request from the Emergency room for a 'Full Alert Trauma' patient. Occasionally, a patient on a nursing unit may also need blood before the current compatibility specimen can be obtained and tested. This procedure describes the actions to be taken in these events ...Procedure: I. Cooler Preparation for Emergency Release of Whole Blood ...B. Prepare a pink Authorization for Emergency Transfusion Form for the two units of whole blood making sure to circle 'WHOLE BLOOD' on the pink tag ...II. Cooler Preparation for Emergency Release of Packed Red Blood Cells ...B. Prepare a pink Authorization for Emergency Transfusion form for both the selected O negative and O positive group of Red Blood Cell units ...III. Dispensing Emergency Release of Whole Blood ...B .... Send the pink authorization for emergency release blood form with the cooler ...IV. Dispensing Emergency Release of Packed Red Blood Cells ...A ... Send the pink authorization for emergency release blood form with the cooler ...Records: The authorization for emergency transfusion forms are returned to the blood bank whether or not the units are transfused. If the blood was administered, the form must be signed by the physician ..." 2. The laboratory's (Pink) emergency release record titled "Authorization for the Release of Blood Products Prior to Complete Processing" stated, " ...Note 2: This form must be signed by the requesting physician and returned promptly to the Blood Bank." 3. A further random review of the laboratory's emergency release records from 05/2021 through 03/2022 revealed the following 4 of 10 "Authorization for the Release of Blood Products" forms in which the laboratory

	failed to obtain the signature of the requesting physician before or after release of blood products: Patient 2195074; Date of emergency release 05/07/2021 Patient 1683034; Date of emergency release 08/14/2021 Patient 2243555; Date of emergency release 02/02/2022 Patient 2250700; Date of emergency release 03/15/2022 The laboratory failed to ensure the signature of the physician requesting emergency release of blood products was obtained before or after the release of the blood products per Code of Federal Regulations 606.160(b)(3)(v). 4. In an interview on 04/28/2022 at 1: 45 pm in the Resident's Conference Room, the Quality and Transfusion Manager was asked if the laboratory obtained the requesting physician's signature on the "Authorization for the Release of Blood Products" form for the 4 emergency releases listed above. The Quality and Transfusion Manager stated that if the blood products were not transfused, the laboratory did not obtain the requesting physician's signature. This confirmed the above findings.
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: Based on review of laboratory policy, a review of quarterly alarm check records, and confirmed in interview, the laboratory failed to ensure documentation of alarm checks on the thermograph recording charts for 3 of 10 alarms checks (10/2021 and 01/2022). Findings included: 1. The laboratory policy titled, "Validation of Alarm Function of Blood Storage Refrigerators" (LC-TN-TRM-PRO-813.04, Adopted Date 10/15/2020) stated the following: "Frequency of Testing ...B. All of the blood storage refrigerators located in the LifeStar hangers will be functionally checked with an ice bath quarterly ...Procedure ...A. Quarterly Temperature High and Low Alarm Validation for Blood Bank Refrigerators ...5. Procedure for all LifeStar Refrigerators ...a. To test the high and low temperature alarms, remove the bottle with the alarm sensor from the refrigerator along with the NIST standard thermometer. B. Place the bottle and the thermometer in a pan with ice cold tap water and 2-3 T of table salt (NaCl). Carefully agitate the pan at intervals. When the alarm sounds, read the temperature. The temperature should be between 1.5 C and 1.0 C. Record the results on LC-TN-TRM-F-034. C. Place the bottle and thermometer in a pan of cool tap water. When the alarm sounds, read the temperature. The temperature should be between 5.5 C and 6.0 C. Record the results on the form ..." 2. The laboratory's quarterly alarm check form titled, "LifeStar Blood Bank Refrigerator and Temperature Chart" stated, "Quarterly Alarm and Power Checks (January, April, July and October) ...Alarm Check Date ... High ...Low ...Interpretation ...Tech ...ALARM INTERPRETATION: High Alarm Activation: S=Satisfactory, temperature sounds at or between 5.5 C to 6.0 C, other temperatures of activation are U-Unsatisfactory. Low Alarm Activation: S=Satisfactory, temperature sounds at or between 1.0 C to 1.5 C, other temperatures of activation are U-Unsatisfactory ..." 3. Further review of the laboratory's quarterly alarm check records revealed the following: a. Location of helicopter hanger: Sweetwater LifeStar LifeStar Blood Bank Refrigerator and Temperature Chart entries: Alarm Check Date: 10/18/2021; High: 5.6; Low: 1.4; Interpretation: S The HermerInc

	thermograph temperature monitoring wheel from 10/13/2021 through 10/20/2021 failed to capture a temperature peak of 5.6 C or a temperature trough of 1.4 C. b. Location of helicopter hanger: Rockwood LifeStar LifeStar Blood Bank Refrigerator and Temperature Chart entries: Alarm Check Date: 10/30/2021; High: 5.6; Low: 1.5; Interpretation: S The HermerInc thermograph temperature monitoring wheel from 10 /27/2021 through 11/03/2022 failed to capture a temperature peak of 5.6 C or a temperature trough of 1.5 C. c. Location of helicopter hanger: Morristown LifeStar LifeStar Blood Bank Refrigerator and Temperature Chart entries: Alarm Check Date: 01/28/2022; High: 6.9; Low: 1.4; Interpretation: S The high temperature documented (6.9 C) is outside of the acceptable range of 5.5 C to 6.0 C for high alarm activation. The HermerInc thermograph temperature monitoring wheel from 01/26/2022 through 02/02/2022 failed to capture a temperature peak of 6.9 C or a temperature trough of 1.4 C. The laboratory failed to inspect the alarm checks according to its established policy and failed to compare temperatures at which the alarm sounded to the temperature readings on the HermerInc thermograph recording chart. 4. In an interview on 04/28/2022 at 4:15 pm in the facility conference room, the Quality and Transfusion Manager, after review of the thermograph temperature monitoring wheels and Lifestar Blood Bank refrigerator forms, confirmed that temperature spikes or dips could not be identified. Word Key: NIST=National Institute of Standards and Technology C= degrees Celsius NaCl=Sodium Chloride (table salt)
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's quality control (QC) testing records, patient test reports, the lack of laboratory policy, and interview with the Chemistry lead tech, the laboratory failed to evaluate all patient test results after performing test system adjustments for QC flags since the last acceptable quality control test run to ensure accurate and reliable test results for 1 of 1 patients tested for Lactic Acid on 04-25-2022. 1. In review of the laboratory's quality control testing on Cobas lactic acids, the following quality control had to be calibrated to get the controls within acceptability limits. Review of the laboratory's lactic acid quality control testing records (04-25-2022) revealed the following: last successful QC 4/25/2022 08:27:49 am lactic acid results : 1.04 mmol/l a. 4/25/2022 5:02:42 pm QC lactic acid results: 1.09 mmol/l repeat QC b. 4/25/2022 5:02:48 pm QC lactic acid results 1.09 mmol/l repeat QC c. 4 /25/2022 5:44:06 pm 1.12 mmol/l cal. d. 4/25/2022 5:44:12 pm 1.11mmol/l cal e. 4/25 /2022 6:11:24 pm 1.03 mmol/l level one control Lot #92920 range of acceptability: 0.94 to 1.06 mmol/l 2. The laboratory could not provide documentation of a policy to evaluate all patients results obtained in an unacceptable QC test run that required test system adjustments (maintenance, calibration) to achieve results within acceptable limits and the last acceptable QC test run. 3. In review of 32 patients tested on 4-25-2022 none were evaluated between 0827 to 6:11:24 pm after the QC became acceptable after a major calibration. The following is a sample of patients ran during

	that time: a. accession#2022-115-001894 verified 4/25/2022 at 1040 b. accession#2022-115-002385 verified 4/25/2022 at 1059 c. accession#2022-115-002413 verified 4/25/2022 at 1059 d. accession#2022-115-002691 verified 4/25/2022 at 1147 e. accession#2022-115-002549 verified 4/25/2022 at 1148 f. accession#2022-115-002621 verified 4/25/2022 at 1218 g. accession#2022-115-002415 verified 4/25 /2022 at 1246 h. accession#2022-115-003193 verfied 4/25/2022 at 1341 4. In interview with the Chemistry lead tech at 1550 on 4-27-2022 he state that he was unaware if they had a policy for evaluating patients after multiple QC failures that subsequently required major maintenance or calibration to get the QC within the laboratory's acceptability limits. 41221 II. Based on quality control record review, laboratory corrective action record review and personnel interview, the laboratory failed to evaluate patient test results between the last successful quality control (QC) run and failed QC run for 1 out of 1 day reviewed. Findings: 1) Review of the instrument error log dated 4-2-22, time 0800 for instrument number 1463 (identified as XN-9100-1-L) stated that QC failed on all 3 levels. Instrument shutdown and auto-rinse were repeated but QC remained unsuccessful. The instrument was put out of use and technical service was called. 2) Quality control record review showed the first QC failure occurred at 0712 on 4/2/2022. The last successful QC run was at 0715 on 4/1 /2022. 3) Patient record review showed that 23 samples were analyzed on instrument XN-9100-1-L with the first sample 22091001683A run on 04/01/2022 at 09:16:43 and the last sample 22092000519B run on 04/02/2022 at 06:38:57. 4) Interview with the lab manager on 4/27/2022 at 1120 in her office and with the laboratory director on 4 /28/2022 at 1543 in the conference room confirmed that patient results were not evaluated to the last successful QC run and that there was not a policy in place. The laboratory performs approximately 393,924 hematology tests annually.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory competency assessment records and interview with the technical supervisor, the techical supervisor failed to evaluate and document the semi-annual competency for 2 of 46 Testing Personnel (TP). Findings include: 1. A review of Microbiology and Clinical Chemistry competency records revealed the Technical Supervisor failed to evaluate and document the semi-annual competency for 2 of 46 testing personnel. The technical supervisor stated they signed the forms once completed by staff. 2. The procedure titled, " Medical Director Designee Policy", revealed no delegation of the Technical Supervisor responsibility for evaluation and documentaton of the semi-annual competency assessment during the first year. 3. Review of the Microbiology, Hematology, Blood Bank, Clinical Chemistry and Cytology competency assessment procedures revealed each laboratory section had a separate Competency Assessment policy with the identical language under the section titled, "Competency " which stated, " 1. Competency assessment for each individual should be performed by an employee that has demonstrated competency in the duties being assessed". The laboratory failed to designate the Technical Supervisor is authorized to evaluate semi-annual training during the the first year of testing patients.

	3. During interview in the conference room with the technical supervisor on 5/28/22 at 10:00 am, the Technical Supervisor confirmed they did not evaluate and document the semi-annual competency assessment for new testing personnel during the first year.