Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	19D0696771	11/17/2023
Name of Provider or Supplier	**Street Address, City, State**	
Northern Louisiana Medical Center	401 East Vaughn Street, Ruston, 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	An Initial survey was performed at Northern Louisiana Medical Center, CLIA ID 19D0696771 on November 14, 2023 through November 17, 2023. Northern Louisiana Medical Center was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250 CONDITION: Analytic systems 42 CFR 493.1403 CONDITION: Laboratories performing moderate complexity testing; Laboratory Director
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with personnel, the laboratory failed to retain proficiency testing records for at least two (2) years for one (1) of five (5) Critical Care Blood Gas with Chemistry events reviewed in 2022 and 2023. Findings: 1. Review of the laboratory's College of American Pathologists (CAP) proficiency testing records from 2022 and 2023 revealed the laboratory did not retain the original evaluation documents to include evaluation and comparative method statistics for results submitted for Arterial Blood Gas (ABG) testing for the following one (1) of five (5) testing events reviewed: a) AQ-C 2022 Critical Care Blood Gas w/ Chemistry (pH, pCO2, pO2) 3. In interview on November 15, 2023 at 12:56 pm, Testing Personnel 1 for the respiratory department stated the evaluation forms are printed from the computer and the wrong form was attached to the records for this event. Testing Personnel 1 from respiratory confirmed the laboratory did not have documentation for the identified proficiency testing event.
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250

	Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on observation by surveyors, review of laboratory policies and records as well as interview with personnel, the laboratory failed to ensure the quality of testing within the analytic systems. Findings: 1. The laboratory failed to perform platelet poor plasma studies monthly as required by laboratory policy for 2022 and 2023. Refer to D5403. 2. The laboratory failed to analyze Ammonia patient samples within thirty (30) minutes of centrifugation as required by the manufacturer for twenty four (24) of forty eight (48) patients reviewed. Refer to D5411 I. 3. The laboratory failed to ensure patient samples for D Dimer testing are analyzed within four (4) hours of collection as required by the manufacturer for three (3) of one hundred eighty seven (187) patients reviewed from August 2023 through November 2023. Refer to D5411 II. 4. The laboratory failed to ensure patient samples for Activated Partial Thromboplastin Time (APTT) testing are analyzed within four (4) hours of collection as required by the manufacturer for one (1) of one hundred forty seven (147) patients reviewed from July 2023 and November 2023. Refer to D5411 III. 5. The laboratory failed to ensure supplies did not exceed their expiration dates. Refer to D5417. 6. The laboratory failed to ensure verification of performance studies for Activated Clotting Time (ACT) on the i-Stat analyzer were complete. Refer to D5421. 7. The laboratory failed to have in house data to support the reduction of frequency of quality control for Activated Clotting Time (ACT) testing. Refer to D5445. 8. The laboratory failed to perform two (2) levels of quality controls (QC) prior to patient testing for D Dimer for one (1) of ninety two (92) days reviewed. Refer to D5447. 9. The laboratory failed to perform external reactive, weakly reactive, and non reactive quality controls for Rapid Plasma Reagent (RPR) each batch of patient testing for eight (8) of one hundred two (102) patients reviewed. Refer to D5449. 10. The laboratory failed to ensure the high /low temperature alarm spike was visible on the blood bank freezer circular chart in 2023. Refer to D5555. 11. The laboratory failed to perform corrective action when cuvette temperatures on the Siemens Dimension EXL exceeded the acceptable range for twenty six (26) of three hundred four (304) days reviewed in 2023. Refer to D5781. 12. The laboratory failed to take corrective action when quality control (QC) values were unacceptable for Activated Partial Thromboplastin Time (APTT) testing for one (1) of ninety two (92) days reviewed in 2023. Refer to D5783. 13. The laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Refer to D5793.
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 laboratory policy, platelet poor plasma records and inteview with personnel, the laboratory failed to perform platelet poor plasma studies monthly as required by laboratory policy for 2022 and 2023. Findings: 1. Review of the laboratory's "Platelet Poor Plasma Procedure" policy revealed the laboratory performs platelet poor plasma studies monthly. 2. Review of the platelet poor plasma records for 2022 and 2023 revealed the laboratory did not perform platelet poor plasma studies for the following four (4) of twenty two (22) months reviewed: a) September 2022 b) October 2022 c) December 2022 d) January 2023 3. In interview on November 15, 2023 at 10:32 am, General Supervisor 1 confirmed the laboratory did not perform platelet poor plasma studies monthly per laboratory policy.
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 observation by surveyors, review of manufacturer's package insert and patient test logs as well as interview with personnel, the laboratory failed to analyze Ammonia patient samples within thirty (30) minutes of centrifugation as required by the manufacturer for twenty four (24) of forty eight (48) patients reviewed. Findings: 1. Observation by surveyors during the laboratory tour on November 14, 2023 at 10: 00 am revealed the laboratory utilizes the Siemens Dimension EXL analyzer for Ammonia patient testing. 2. Review of the Siemens Dimension EXL package insert for Ammonia revealed "samples are to be analzyed within 30 minutes of centrifugation". 3. Review of the laboratory's patient test logs from May 16, 2023 through November 16, 2023 revealed the laboratory did not perform patient samples for Ammonia testing within thirty (30) minutes of centrifugation per manufacturer's requirements for the following twenty four (24) of forty eight (48) patients reviewed: a) PT 2133652: sample collected May 16, 2023 at 07:42 am and verified May 16, 2023 at 08:19 am (exceeding the manufacturer's requirements of 30 minutes by seven (7) minutes) b) PT 2133417: sample collected May 17, 2023 at 23:58 pm and verified May 18, 2023 at 00:30 am (exceeding the manufacturer's requirements of 30 minutes by eleven (11) minutes) c) PT 2134235: sample collected May 20, 2023 at 10:12 am and verified May 20, 2023 at 13:26 pm (exceeding the manufacturer's requirements of 30 minutes by one hundred sixty four (164) minutes) d) PT 2134235: sample collected

May 21, 2023 at 08:59 am and verified May 21, 2023 at 13:15 pm (exceeding the manufacturer's requirements of 30 minutes by two hundred twenty six (226) minutes) e) PT 2134779: sample collected May 25, 2023 at 10:29 am and verified May 25, 2023 at 11:15 am (exceeding the manufacturer's requirements of 30 minutes by sixteen (16) minutes) f) PT 2133417: sample collected May 31, 2023 at 12:56 pm and verified May 31, 2023 at 13:30 pm (exceeding the manufacturer's requirements of 30 minutes by four (4) minutes) g) PT 2136155: sample collected June 7, 2023 at 10:15 am and verified June 8, 2023 at 14:01 pm (exceeding the manufacturer's requirements of 30 minutes by twenty seven (27) sixteen (16) minutes) h) PT 2136598: sample collected June 10, 2023 at 16:40 pm and verified June 10, 2023 at 17:15 pm (exceeding the manufacturer's requirements of 30 minutes by five (5) minutes) i) PT 2136403: sample collected June 18, 2023 at 16:53 pm and verified June 18, 2023 at 17:29 pm (exceeding the manufacturer's requirements of 30 minutes by six (6) minutes) j) PT 2143341: sample collected August 9, 2023 at 09:50 am and verified August 9, 2023 at 10:25 am (exceeding the manufacturer's requirements of 30 minutes by five (5) minutes) k) PT 2143282: sample collected August 20, 2023 at 12:38 pm and verified August 20, 2023 at 13:51 am (exceeding the manufacturer's requirements of 30 minutes by forty three (43) minutes) l) PT 2145412: sample collected August 27, 2023 at 17:31 pm and verified August 27, 2023 at 18:09 pm (exceeding the manufacturer's requirements of 30 minutes by eight (8) minutes) m) PT 2145946: sample collected September 1, 2023 at 08:36 am and verified September 1, 2023 at 10: 23 am (exceeding the manufacturer's requirements of 30 minutes by seventy seven (77) minutes) n) PT 2146499: sample collected September 7, 2023 at 06:00 am and verified September 7, 2023 at 06:32 am (exceeding the manufacturer's requirements of 30 minutes by two (2) minutes) o) PT 2147377: sample collected September 13, 2023 at 16:33 pm and verified September 13, 2023 at 17:15 pm (exceeding the manufacturer's requirements of 30 minutes by twelve (12) minutes) p) PT 2147496: sample collected September 14, 2023 at 17:58 pm and verified September 14, 2023 at 18:32 pm (exceeding the manufacturer's requirements of 30 minutes by four (4) minutes) q) PT 2147875: sample collected September 18, 2023 at 10:51 am and verified September 18, 2023 at 11:27 am (exceeding the manufacturer's requirements of 30 minutes by six (6) minutes) r) PT 2149362: sample collected September 30, 2023 at 14:41 pm and verified September 30, 2023 at 15:18 pm (exceeding the manufacturer's requirements of 30 minutes by seven (7) minutes) s) PT 2152985: sample collected October 30, 2023 at 01:37 am and verified October 30, 2023 at 02:13 am (exceeding the manufacturer's requirements of 30 minutes by six (6) minutes) t) PT 2152914: sample collected October 31, 2023 at 18:38 pm and verified October 31, 2023 at 20:17 pm (exceeding the manufacturer's requirements of 30 minutes by sixty nine (69) minutes) u) PT 2154022: sample collected November 6, 2023 at 17:01 pm and verified November 6, 2023 at 17:43 pm (exceeding the manufacturer's requirements of 30 minutes by twelve (12) minutes) v) PT 2154056: sample collected November 6, 2023 at 16:22 pm and verified November 6, 2023 at 18:57 pm (exceeding the manufacturer's requirements of 30 minutes by one hundred twenty five (125) minutes) w) PT 2155020: sample collected November 13, 2023 at 21:50 pm and verified November 13, 2023 at 22:31 pm (exceeding the manufacturer's requirements of 30 minutes by eleven (11) minutes) x) PT 2154974: sample collected November 14, 2023 at 12:02 pm and verified November 14, 2023 at 12:45 pm (exceeding the manufacturer's requirements of 30 minutes by thirteen (13) minutes) 4. In interview on November 16, 2023 at 01:05 pm, General Supervisor 1 confirmed the laboratory did not perform the identified patient samples for Ammonia testing as required by the manufacturer. 5. Review of the task 1&3 form provided to surveyors revealed the laboratory performs 135 Ammonia tests annually. II. Based on observation by surveyors, review of manufacturer's instructions, and patient records as well as

	interview with personnel, the laboratory failed to ensure patient samples for D Dimer testing are analyzed within four (4) hours of collection as required by the manufacturer for three (3) of one hundred eighty seven (187) patients reviewed from August 2023 through November 2023. Findings: 1. Observation by surveyors during the laboratory tour on November 14, 2023 at 10:10 am revealed the laboratory utilizes the Sysmex CA-600 Series analyzer for D Dimer patient testing. 2. Review of the manufacturer requirements for the Sysmex CA-600 Series under "Handling Conditions" revealed "The whole blood specimen is checked for clot formation by gentle inversion and centrifuged and tested within 4 hours of specimen collection". 3. Review of patient records from August 2023 through November 2023 revealed the laboratory did not perform patient samples for D Dimer testing within the four (4) hours required by the manufacturer for the following three (3) of one hundred eighty seven (187) patients reviewed: a) PT 2145900: collected August 31, 2023 at 12:15 pm then resulted August 31, 2023 at 16:19 pm (exceeded the manufacturer's requirements of greater than four (4) hours by four (4) minutes) b) PT 2146943: collected September 9, 2023 at 23:49 pm then resulted September 10, 2023 at 04:06 am (exceeded the manufacturer's requirements of greater than four (4) hours by seventeen (17) minutes) c) PT 2153919: collected November 6, 2023 at 07:08 am then resulted November 6, 2023 at 13:46 pm (exceeded the manufacturer's requirements of greater than four (4) hours by two (2) hours thirty eight (38) minutes) 4. In interview on November 14, 2023 at 03:45 pm, General Supervisor 1 confirmed the identified patients were not analyzed within the four (4) hours per manufacturer. 5. Review of the task 1&3 form provided to surveyors revealed the laboratory performs 965 D Dimer tests annually. III. Based on observation by surveyors, review of manufacturer's instructions, and patient records as well as interview with personnel, the laboratory failed to ensure patient samples for Activated Partial Thromboplastin Time (APTT) testing are analyzed within four (4) hours of collection as required by the manufacturer for one (1) of one hundred forty seven (147) patients reviewed from July 2023 and November 2023. Findings: 1. Observation by surveyors during the laboratory tour on November 14, 2023 at 10:10 am revealed the laboratory utilizes the Sysmex CA-600 Series analyzer for Activated Partial Thromboplastin Time (APTT) patient testing. 2. Review of the manufacturer requirements for the Sysmex CA-600 Series under "Handling Conditions" revealed "The whole blood specimen is checked for clot formation by gentle inversion and centrifuged and tested within 4 hours of specimen collection". 3. Review of patient records from July 2023 and November 2023 revealed the laboratory did not perform patient samples for APTT testing within the four (4) hours required by the manufacturer for the following one (1) of one hundred forty seven (147) patients reviewed: a) PT 2141649: collected July 25, 2023 at 20:07 pm then resulted January 26, 2023 at 02:23 am (exceeding the manufacturer's requirements of greater than four (4) hours by two (2) hours sixteen (16) minutes) 4. In interview on November 14, 2023 at 03:45 pm, General Supervisor 1 confirmed the identified patients were not analyzed within the four (4) hours per manufacturer. 5. Review of the task 1&3 form provided to surveyors revealed the laboratory performs 1,855 APTT 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 observation by surveyors and interview with personnel, the laboratory failed to ensure supplies did not exceed their expiration dates. Findings: 1. Observation by surveyors during the laboratory tour on November 14, 2023 at 10:10 am revealed the following expired items: a) In House PCR Covid Collection Kits: Lot B202412, Expiration Date 10/31/23, Quantity - one (1) b) Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens: Lot 335703V, Expiration 9/30/23, Quantity - three (3) c) Aptima Unisex Swab Specimen Collection Kit for Endocervical and Male Urethral Swab Specimens: Lot 461933V, Expiration 10 /31/23, Quantity - three (3) 2. In interview on November 14, 2023 at 10:20 am, General Supervisor 4 confirmed the identified items were expired.
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 observaation by surveyor, review of laboratory policy, performance specification records, and test menu as well as interview with personnel, the laboratory failed to ensure verification of performance studies for Activated Clotting Time (ACT) on the i-Stat analyzer were complete. Findings: 1. Observation by surveyor during the laboratory tour on November 16, 2023 at 9:30 am revealed the laboratory performs Activated Clotting Time (ACT) patient testing on the i-Stat analyzer. 2. Review of the laboratory policy "Implementing New Methods and Equipment" revealed under Quantitative Methods (non-waived): Perform the following activities and summarize on the Validation Form: Accuracy, Precision, Linearity studies, Correlation Study, Reference Ranges (normal ranges), and Reportable Ranges. Retaining validation studies: validations studies should remain near the instrument/kit/equipment for the life of the instrument/kit/equipment. 3. Review of the laboratory's performance specification records for ACT testing revealed the laboratory did not have documentation of raw data to support the studies for accuracy (method correlation), precision (day to day, run to run, within run, operator variance), reportable range (linearity), and reference range. 4. In interview on November 15, 2023 at 4:00 pm, General Supervisor 1 stated all ACT validation data was documented directly from the i-Stat analyzer. General Supervisor 1 further stated the i-Stat analyzer does not have a process in place for documentation of raw data to support studies. 5. Review of the task 1&3 form provided to surveyors revealed the laboratory performs forty six (46) ACT tests annually.
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified

	in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory's Individualized Quality Control Plan (IQCP), quality control records, and interview with personnel, the laboratory failed to have in house data to support the reduction of frequency of quality control for Activated Clotting Time (ACT) testing. Findings: 1. Observation by surveyor during the laboratory tour on November 16, 2023 at 9:30 am revealed the laboratory utilizes the Abbott i-Stat analyzer for Activated Clotting Time (ACT) patient testing. 2. Review of the laboratory's Individualized Quality Control Plan (IQCP) revealed the laboratory recommends performing external quality control (QC) once every thirty (30) days and every new lot of cartridges. 3. Further review of the laboratory's IQCP records revealed the laboratory did not include the in-house quality control raw data to support the reduction of external controls to once every thirty (30) days. 4. In interview on November 16, 2023 at 10:00 am, General Supervisor 1 stated the ACT quality control data was documented directly from the i-Stat analyzer and the laboratory did not retain any data to support the QC reduction. General Supervisor 1 confirmed the laboratory did not have documentation to support the IQCP for ACT testing. 5. Review of the task 1&3 form provided to surveyors revealed the laboratory performs 46 ACT tests annually.
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(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 quantitative procedure, include two control materials of different concentrations; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of laboratory policy, quality control and patient records and interview with personnel, the laboratory failed to perform two (2) levels of quality controls (QC) prior to patient testing for D Dimer for one (1) of ninety two (92) days reviewed. Findings: 1. Observation by surveyors during the laboratory tour on November 14, 2023 at 10:10 am revealed the laboratory utilizes the Sysmex CA-600 Series analyzer for D Dimer patient testing. 2. Review of the laboratory policy "Hematology and Coagulation Quality Control" revealed "PT, PTT, and D Dimer QC are performed every eight hours. QC performed at scheduled times 00:00, 08:00, and 16:00". 3. Review of the D Dimer quality control (QC) and patient records from a random selection of months (March 2023, August 2023 and September 2023) revealed the laboratory did not perform two (2) levels of controls for one (1) of ninety two (92) days reviewed prior to patient testing: a) PT 2126914: testing performed on March 19, 2023 at 20:19 pm with no QC performed 4. In interview on November 15, 2023 at 3:45 pm, General Supervisor 1 confirmed the laboratory did not perform D Dimer QC prior to the above identified patient testing.

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: Based on observation by surveyors, review of laboratory procedure, test menu, quality control (QC) and patient records and interview with personnel, the laboratory failed to perform external reactive, weakly reactive, and non reactive quality controls for Rapid Plasma Reagent (RPR) each batch of patient testing for eight (8) of one hundred two (102) patients reviewed. Findings: 1. Direct observation by surveyors during the laboratory tour on November 14, 2023 at 10:10 am revealed the laboratory utilizes the Fisher Scientific Sure-Vue RPR test kit for Rapid Plasma Reagin (RPR) patient testing. 2. Review of the laboratory's "RPR Quality Control" policy revealed "Controls are to be run concurrently with patient specimens each time a batch of tests is performed. Reactive (R), Weakly-Reactive (WR), and Non-Reactive (NR) controls should be run each day of testing. All QC results are to be logged on the RPR QC Documentation Log". 3. Review of the quality control (QC) and patient records from January 2023 and September 2023 revealed the laboratory did not perform external QC with each batch of patient testing for the following eight (8) of one hundred two (102) patients reviewed: a) PT 2118394: performed on January 5, 2023 at 22:20 pm with no documentation of QC for this batch of testing b) PT 2119195: performed on January 12, 2023 at 23:44 pm with no documentation of QC for this batch of testing c) PT 2119104: performed on January 12, 2023 at 23:45 pm with no documentation of QC for this batch of testing d) PT 2120185: performed on January 21, 2023 at 17:56 pm with no documentation of QC for this batch of testing e) PT 2146765: performed on September 8, 2023 at 19:45 pm with no documentation of QC for this batch of testing f) PT 2146790: performed on September 8, 2023 at 19:45 pm with no documentation of QC for this batch of testing g) PT 2148691: performed on September 25, 2023 at 16:39 pm with no documentation of QC for this batch of testing h) PT 2148507: performed on September 25, 2023 at 20:40 pm with no documentation of QC for this batch of testing 4. In interview on November 16, 2023 at 11:08 am, General Supervisor 1 confirmed the identified patients were performed without QC for each batch of testing per the laboratory policy.
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 the laboratory policy, blood bank freezer circular charts, alarm

	check logs and interview with personnel, the laboratory failed to ensure the high/low temperature alarm spike was visible on the blood bank freezer circular chart in 2023. Findings: 1. Review of the laboratory's "Blood Bank Freezer Alarm Testing Procedure" revealed "To test the actual temperature of alarm activation (provides spike on continuous monitor graph). Use a thermometer verified by an NIST-traceable standard that will accurately indicate the temperature of alarm activation and note the temperature registered on the recorder. Warm the alarm probe and thermometer slowly. Pull the container and the cables outside the freezer chest for testing, leaving the door closed and the contents protected. Record this temperature at which alarm sounds on the Freezer Alarm Activation Form and note acceptability". 2. Review of the laboratory's freezer alarm check logs for 2023 revealed the laboratory documented quarterly alarm checks for the following dates: a) January 9, 2023 b) April 13, 2023 c) July 14, 2023 d) October 18, 2023 3. Review of the laboratory's blood bank freezer circular charts for 2023 revealed the high/low temperature alarm check spike was not visible on the July 2023 circular chart. 4. In interview on November 14, 2023 at 11:07 am, General Supervisor 2 confirmed the alarm check spike was not visible on the identified freezer circular chart in 2023.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of laboratory's maintenance logs and quality assurance records (QA) as well as interview with personnel, the laboratory failed to perform corrective action when cuvette temperatures on the Siemens Dimension EXL exceeded the acceptable range for twenty six (26) of three hundred four (304) days reviewed in 2023. Findings: 1. Observation by surveyors during the laboratory tour on November 14, 2023 at 10:20 am revealed the laboratory utilizes the following Siemens Dimension EXL analyzers for Chemistry testing: a) Siemens Dimension EXL "A" (serial number DR 251641) b) Siemens Dimension EXL "B" (serial number DR 251642) 2. Review of the laboratory's "Daily Maintenance Log" for the Siemens Dimension EXL analyzer revealed the acceptable range for the cuvette temperature is documented as 36.8 to 37.2 degrees celsius. 3. Review of the laboratory's "Daily Maintenance Log" for Siemens Dimension EXL "B" analyzer from January 1, 2023 through October 31, 2023 revealed the cuvette temperatures exceeded the acceptable limits (36.8 to 37.2 degrees celsius) for the following twenty six (26) of three hundred four (304) days reviewed with no corrective action documented: a) January 9, 2023: documented as 36.7 degrees celsius b) February 3, 2023: documented as 36.7 degrees celsius c) June 14, 2023: documented as 36.6 degrees celsius d) July 15, 2023: documented as 36.7 degrees celsius e) July 21, 2023: documented as 36.7 degrees celsius f) July 22, 2023: documented as 36.7 degrees celsius g) July 23, 2023: documented as 36.7 degrees celsius h) July 24, 2023:

	documented as 36.7 degrees celsius i) July 30, 2023: documented as 36.7 degrees celsius j) July 31, 2023: documented as 36.7 degrees celsius k) August 3, 2023: documented as 36.7 degrees celsius l) August 4, 2023: documented as 36.7 degrees celsius m) August 6, 2023: documented as 36.7 degrees celsius n) August 7, 2023: documented as 36.7 degrees celsius o) August 16, 2023: documented as 36.7 degrees celsius p) August 17, 2023: documented as 36.7 degrees celsius q) August 18, 2023: documented as 36.7 degrees celsius r) August 23, 2023: documented as 36.7 degrees celsius s) August 26, 2023: documented as 36.7 degrees celsius t) August 27, 2023: documented as 36.7 degrees celsius u) September 3, 2023: documented as 36.7 degrees celsius v) September 4, 2023: documented as 36.7 degrees celsius w) September 7, 2023: documented as 36.7 degrees celsius x) September 16, 2023: documented as 36.7 degrees celsius y) October 9, 2023: documented as 36.7 degrees celsius z) October 13, 2023: documented as 36.7 degrees celsius 4. Review of the laboratory's QA records for January 2023 through October 2023 revealed multiple email correspondance from the chemistry general supervisor requesting documentation from testing personnel for corrective actions performed for unacceptable cuvette temperature; however, the laboratory did not provide documentation of corrective action for unacceptable cuvette temperatures for the identified days. 5. In interview on November 16, 2023 at 9:15 am, General Supervisor 4 confirmed the laboratory did not document corrective action for cuvette temperatures that exceeded acceptable range on the above identified dates.
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: Based on observation by surveyors, review of laboratory policy, quality control records and interview with personnel, the laboratory failed to take corrective action when quality control (QC) values were unacceptable for Activated Partial Thromboplastin Time (APTT) testing for one (1) of ninety two (92) days reviewed in 2023. Findings: 1. Observation by surveyors during the laboratory tour on November 14, 2023 at 10:10 am revealed the laboratory utilizes the Sysmex CA-600 Series analyzer for Activated Partial Thromboplastin Time (APTT) patient testing. 2. Review of the laboratory's policy "Hematology and Coagulation QC" revealed "PT, PTT, and D Dimer QC is performed every eight hours. Troubleshooting out of range QC: If QC out of range, rerun test; If still out, acquire or reconstitute a new vial and rerun; If still out, contact appropriate technical support services for instructions on how to proceed". 3. Review of the laboratory's APTT quality control records from a random selection of months (March 2023, August 2023 and September 2023) revealed the laboratory did not perform coretive actions for unacceptable QC for the following one (1) of ninety two (92) days reviewed: a) On March 15, 2023 at 23:51 pm: APTT QC level 3 unacceptable at 1-2S with no documentation of corrective action 4. In

	interview on November 15, 2023 at 3:45 pm, General Supervisor 1 confirmed the laboratory did not take corrective actions for QC outside the acceptable range for the identifed date.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of laboratory policy, and interview with personnel, the laboratory's quality assessment monitors failed to correct issues identified with the analytic system. Findings: 1. The laboratory failed to perform platelet poor plasma studies monthly as required by laboratory policy for 2022 and 2023. Refer to D5403. 2. The laboratory failed to analyze Ammonia patient samples within thirty (30) minutes of centrifugation as required by the manufacturer for twenty four (24) of forty eight (48) patients reviewed. Refer to D5411 I. 3. The laboratory failed to ensure patient samples for D Dimer testing are analyzed within four (4) hours of collection as required by the manufacturer for three (3) of one hundred eighty seven (187) patients reviewed from August 2023 through November 2023. Refer to D5411 II. 4. The laboratory failed to ensure patient samples for Activated Partial Thromboplastin Time (APTT) testing are analyzed within four (4) hours of collection as required by the manufacturer for one (1) of one hundred forty seven (147) patients reviewed from July 2023 and November 2023. Refer to D5411 III. 5. The laboratory failed to ensure supplies did not exceed their expiration dates. Refer to D5417. 6. The laboratory failed to ensure verification of performance studies for Activated Clotting Time (ACT) on the i-Stat analyzer were complete. Refer to D5421. 7. The laboratory failed to have in house data to support the reduction of frequency of quality control for Activated Clotting Time (ACT) testing. Refer to D5445. 8. The laboratory failed to perform two (2) levels of quality controls (QC) prior to patient testing for D Dimer for one (1) of ninety two (92) days reviewed. Refer to D5447. 9. The laboratory failed to perform external reactive, weakly reactive, and non reactive quality controls for Rapid Plasma Reagent (RPR) each batch of patient testing for eight (8) of one hundred two (102) patients reviewed. Refer to D5449. 10. The laboratory failed to ensure the high/low temperature alarm spike was visible on the blood bank freezer circular chart in 2023. Refer to D5555. 11. The laboratory failed to perform corrective action when cuvette temperatures on the Siemens Dimension EXL exceeded the acceptable range for twenty six (26) of three hundred four (304) days reviewed in 2023. Refer to D5781. 12. The laboratory failed to take corrective action when quality control (QC) values were unacceptable for Activated Partial Thromboplastin Time (APTT) testing for one (1) of ninety two (92) days reviewed in 2023. Refer to D5783.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where

	the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on observation by surveyors, review of manufacturer's instructions, review of patient final test reports, and interview with personnel, the laboratory failed to report sickle cell test results as required by the manufacturer. Findings: 1. Observation by surveyors during the laboratory tour on November 14, 2023 at 10:14 am revealed the laboratory utilizes the Streck Sickedex test kit for sickle cell patient testing. 2. Review of the Streck Sickledex package insert under "Limitations" revealed "Sickledex is a qualitative screening procedure and does not differentiate between Sickle Cell Disease (S/S) and Sickle Cell Trait (A/S). All positive test results should be further evaluated by hemoglobin electrophoresis, when used for patient testing". 3. Review of one patient final test report (PT #2002112) revealed the laboratory did include the identified result comment. 4. In interview on November 15, 2023 at 15:15 pm, General Supervisor 1 confirmed the laboratory did not report sickle cell results as required by the manufacturer.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on observation by surveyors, review of laboratory policies and records as well as interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure performance verification studies were complete. Refer to D6013. 2. The Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Refer to D6014. 3. The Laboratory Director failed to ensure that a quality control program was established to assure the quality of laboratory testing. Refer to D6020. 4. The Laboratory Director failed to ensure that a quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D6021. 5. The Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Refer to D6024. 6. The Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D6026. 7. The Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D6031.
D6013	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(ii) 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)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; This STANDARD is not met as evidenced by: Based on observation by surveyor, review of laboratory policy, performance studies, and interview with personnel, the Laboratory Director failed to ensure performance verification studies were complete. Refer to D5421.
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 review of laboratory policy and records along with interview with personnel, the Laboratory Director failed to ensure the laboratory personnel performed test methods as required. Findings: 1. The laboratory failed to analyze Ammonia patient samples within thirty (30) minutes of centrifugation as required by the manufacturer for twenty four (24) of forty eight (48) patients reviewed. Refer to D5411 I. 2. The laboratory failed to ensure patient samples for D Dimer testing are analyzed within four (4) hours of collection as required by the manufacturer for three (3) of one hundred eighty seven (187) patients reviewed from August 2023 through November 2023. Refer to D5411 II. 3. The laboratory failed to ensure patient samples for Activated Partial Thromboplastin Time (APTT) testing are analyzed within four (4) hours of collection as required by the manufacturer for one (1) of one hundred forty seven (147) patients reviewed from July 2023 and November 2023. Refer to D5411 III. 4. The laboratory failed to ensure supplies did not exceed their expiration dates. Refer to D5417. 5. The laboratory failed to ensure the high/low temperature alarm spike was visible on the blood bank freezer circular chart in 2023. Refer to D5555.
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 review of the laboratory's quality control records and interview with

	personnel, the Laboratory Director failed to ensure that a quality control program was established to assure the quality of laboratory testing. Findings: 1. The laboratory failed to have in house data to support the reduction of frequency of quality control for Activated Clotting Time (ACT) testing. Refer to D5445. 2. The laboratory failed to perform two (2) levels of quality controls (QC) prior to patient testing for D Dimer for one (1) of ninety two (92) days reviewed. Refer to D5447. 3. The laboratory failed to perform external reactive, weakly reactive, and non reactive quality controls for Rapid Plasma Reagent (RPR) each batch of patient testing for eight (8) of one hundred two (102) patients reviewed. Refer to D5449.
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 record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was established to assure the quality of laboratory services provided. Refer to D5793.
D6024	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(7) 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)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratory's established performance specifications are identified, This STANDARD is not met as evidenced by: Based on review of laboratory policy, temperature records and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from laboratory's policies occurred. Findings: 1. The laboratory failed to perform corrective action when cuvette temperatures on the Siemens Dimension EXL exceeded the acceptable range for twenty six (26) of three hundred four (304) days reviewed in 2023. Refer to D5781. 2. The laboratory failed to take corrective action when quality control (QC) values were unacceptable for Activated Partial Thromboplastin Time (APTT) testing for one (1) of ninety two (92) days reviewed in 2023. Refer to D5783.
D6026	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(8) 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)(8) Ensure that reports of test results include pertinent information required for interpretation. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with personnel, the Laboratory Director failed to ensure patient final reports included required pertinent information. Refer to D5805.
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 policies and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5403.
D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must 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 the laboratory's CMS 209 form (Laboratory Personnel Report) and personnel records as well as interview with personnel, the Laboratory Director failed to ensure competency assessments for testing personnel were complete for all aspects of testing in specialty of coagulation. Refer to D6120.
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(7)(8) (7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly,

	accurately and proficiently. This STANDARD is not met as evidenced by: Based on review of the Laboratory Personnel Report (CMS 209), personnel records and interview with personnel, the Technical Supervisor failed to assess the competency for five (5) of thirteen (13) testing personnel for the specialty of Coagulation. Findings: 1. Review of the Laboratory Personnel Report (CMS 209) revealed the following: Laboratory Director serves as Technical Supervisor. 2. Review of the personnel records from 2023 revealed the laboratory did not have documentation of competency assessment to include mixing studies in the specialty of Coagulation for the following five (5) of thirteen (13) testing personnel: a) Personnel 1 b) Personnel 4 c) Personnel 6 d) Personnel 7 e) Personnel 15 3. In interview on November 15, 2023 at 2:40 pm, General Supervisor stated that she updated the competency assessment form in 2023 and did not include mixing studies as part of the assessment for coagulation. General Supervisor 1 confirmed that the above identified testing personnel did not have a complete competency assessment for the specialty of coagulation.
D6151	GENERAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1463(b)(3)(4) (3) The director or technical supervisor may delegate to the general supervisor the responsiblity for providing orientation to all testing personnel; and (4) Annually evaluating and documenting the performance of all testing personnel. This STANDARD is not met as evidenced by: Based on review of laboratory's policy, Laboratory Personnel Report (CMS 209), personnel records and interview with personnel, the general supervisor failed to perform competency assessments for all aspects of duties for five (5) of thirteen (13) testing personnel reviewed in 2023. Findings: 1. Review of the laboratory's "Employee Orientation and Competencies" policy revealed "all laboratory employees must undergo hospital wide orientation and department specific training and competency assessment as defined by CLIA/CMS standards. This training includes all aspects of their anticipated duties. Testing Personnel are allowed to perform patient testing only after they have been deemed competent by the Medical Director". 2. Review of the Laboratory Personnel Report (CMS 209) revealed the following employees and the role served for the laboratory: a) Personnel 1: serves as General Supervisor and Testing Personnel b) Personnel 4: serves as General Supervisor and Testing Personnel c) Personnel 6: serves as General Supervisor and Testing Personnel d) Personnel 7: serves as General Supervisor and Testing Personnel e) Personnle 15: serves as Testing Personnel 3. Review of personnel records for 2023 revealed the competency assessments for the following five (5) of thirteen (13) testing personnel did not include mixing studies as part of the duties assigned: a) Testing Personnel 1 b) Testing Personnel 4 c) Testing Personnel 6 d) Testing Personnel 7 e) Testing Personnel 15 4. In interview on November 15, 2023 at 2:40 pm, General Supervisor confirmed the above identified testing personnel did not have complete competency assessments for the duties served.