Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D0660553	**(X3) Date Survey Completed** 02/15/2023
Name of Provider or Supplier Starr County Memorial Hospital	**Street Address, City, State** 128 N Fm 3167, Rio Grande City, TX	
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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found to be in compliance with applicable Conditions in the CLIA program, and recertification is recommended.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on a review of the laboratory's test records and staff interview, it was revealed that the laboratory failed to have documentation of performing twice annual accuracy assessments in 2022 for three unregulated analytes tested on the Dimension EXL chemistry analyzer. Findings include: 1. A review of the laboratory's test records revealed the laboratory tested for the following 3 analytes on the Dimension EXL chemistry analyzer: Vitamin B12 Folate C-Reactive Protein 2. The laboratory was asked to provide documentation of assessing the accuracy, twice annually, for Vitamin B12, Folate, and C-Reactive Protein. No documentation was provided. 3. Further review of the laboratory's test records revealed the laboratory performed 24 Vitamin B12 tests, 5 Folate tests, and 715 C-Reactive protein tests in 2022. 4. An interview with the technical consultant on 2/14/23 at 2:43 p.m. in the conference room, after review of the records, confirmed that the laboratory overlooked these three tests when re-enrolling for proficiency testing samples in 2022.
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: Based on review of the manufacturer's instructions for the Dimension Lactic Acid assay, a random sampling of patient lactic acid results from September 2022, and staff interview it was revealed the laboratory failed to centrifuge 1 of 10 specimens within 15 minutes of collection as required by the manufacturer. The findings include: 1. A review of the manufacturer's instructions for the Dimension Lactic Acid assay (issue date: 2019-04-01) under the section titled "Specimen Collection and Handling" revealed: "Blood is best collected without statis in a container of sodium fluoride /potassium oxalate, followed by immediate chilling of the specimen and separation of the cells within 15 minutes." 2. A random sampling of patient test records from September 2022 identified 1 of 10 patient samples for which the time from collection to receipt exceeded 15 minutes and thus, the sample could not have been centrifuged within 15 minutes. It was: Date: 09/18/2022 Patient ID: 10455979 Collected: 09/19 /2022 0415 Received: 09/19/2022 0458 Elapsed time: 43 minutes 3. An interview with the technical consultant on 02/15/2023 at 1350 hours in the conference room - after her review of the records- confirmed the findings.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, review of the laboratory's incoming specimens logs from February 1, 2023 to February 13, 2023, and staff interview, it was revealed the laboratory's quality assessment failed to identify that sample temperatures were not being monitored to ensure they were transported and received a the required temperatures. The findings include: 1. Based on review of the manufacturer's instructions for the Siemens Dimension ECO2 assay (issue date: 2019-04-01) under the section titled "Specimen Collection and Handling" revealed: "Unopened, separated samples may be stored for 8 hours at room temperature, 2 days at 2-8C." 2. A review of the manufacturer's instructions for the Siemens Dimension CA assay (issue date: 2019-05-21) under the section titled "Specimen Collection and Handling" revealed: "Specimens are stable for 8 hours at room temperature, 2 days at 2-8C." 3. A review of the manufacturer's instructions for the Siemens Dimension ALB assay (issue date: 2019-04-22) under the section titled "Specimen Collection and Handling" revealed: "Specimens are stable for 8 hours at room temperature, 2 days at 2-8C." 4. A review of the manufacturer's instructions for the Siemens Dimension TP assay (issue date: 2019-05-21) under the section titled "Specimen Collection and Handling" revealed:"Separated specimens are stable for 8 hours at room temperature, 72 hours at 2-8C." 5. A review of the laboratory's Incoming specimens logs from February 1, 2023 to February 13, 2023 revealed the laboratory failed to have documentation of monitoring the temperature of samples from 140 patients received from another facility. Thus, the laboratory could not ensure samples were received at

	the required temperature for testing. 6. An interview with the technical consultant on 02/14/2023 at 1500 hours in the conference room revealed the laboratory had monitored the temperature of samples in the past, but someone had updated the logs and the laboratory no longer documented the temperature of specimens. This confirmed the findings.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure for platelet poor studies, review of the laboratory's procedure for determining patient normal means, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to follow its policies for: A) performing platelet poor studies annually in 2022, and B) ensuring 5 of 20 volunteers for patient normal mean studies were healthy. The findings include: A) Platelet poor studies 1. A review of the laboratory's procedure titled "Platelet Poor Study" (approved 03/28/2019) revealed: "Platelet poor study must be performed once a year." 2. The laboratory was asked to provide documentation of the required platelet poor study being performed in 2022. No documentation was provided. 3. An interview with the technical consultant on 02/15/2023 at 1320 hours in the laboratory revealed the laboratory could not find any documentation to show the study had been performed. This confirmed the findings. B) Patient normal mean 1. A review of the laboratory's policy titled "Normal Patient Study for Coagulation" (approved 4/25 /2028) revealed: "A series of questions must be answered by the volunteer to determine eligibility to participate. Volunteer must have a clean records and be completely healthy." 2. A review of the laboratory's patient normal mean study performed in May 2022 revealed 5 of 20 volunteers failed to answer the question about their overall health, however, their samples were still included in the study. They were: Volunteer 1 Volunteer 3 Volunteer 11 Volunteer 18 Volunteer 19 3. An interview with the technical consultant on 02/15/2023 at 1330 hours in the conference room - after her review of the records- 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: I. Based on review of the manufacturer's instructions for the BD Macro-Vue RPR Card Tests, surveyor observation of equipment available in the laboratory, and staff interview, it was revealed the laboratory failed to have the required equipment for the interpretation of the test results. The findings include: 1. A review of the manufacturer's instructions for the BD Macro-Vue RPR Card Tests (0212013JAA

	(05), 2021-05) under the section titled "Procedures and Results" revealed: "Immediately read macroscopically in the "wet" state under a high intensity incandescent lamp or strong daylight." 2. Surveyor observation on 02/15/2023 at 1500 hours in the area where RPR testing was performed revealed the laboratory interpreted the Test Cards under regular room light. The facility did not utilize a high intensity incandescent lamp or strong daylight. 3. The laboratory reported performing 567 tests since May 2022 when the test kit was placed into use in laboratory. 4. An interview with the technical consultant on 02/15/2023 at 1500 hours in the conference room confirmed the findings. 41687 II. Based on a review of the Vidas D-Dimer Exclusion II Instructions for Use, surveyor observation, and staff interview, it was revealed that the laboratory failed to follow the manufacturer's instructions by not ensuring seven patient samples were centrifuged at the proper speed and then decanted into a plastic tube prior to testing. Findings include: 1. A review of the Vidas D-Dimer Exclusion II Instructions for Use (14219 B, 06/2011) revealed the following: "Centrifuge for 15 minutes at 3,000 rpm and decant plasma into a plastic tube. This separation should be carried out as soon as possible after collection." 2. Surveyor observation of the sample processing area on 2/15/23 at 3:00 p.m. revealed the laboratory's centrifuge had a pre-programmed setting for coagulation samples (setting number 4) that spun samples for 15 minutes at 1,500 rpm (not 3,000 rpm as required by the manufacturer). 3. Surveyor observation of the laboratory on 2/15/23 at 3:05 p.m. revealed the following 7 patient samples had been tested for D-Dimer using the Vidas analyzer and were not centrifuged at the proper speed and the plasma was not decanted into a plastic tube prior to testing: Patient ID: 10477512 Patient ID: 10477620 Patient ID: 10477679 Patient ID: 10477756 Patient ID: 10477738 Patient ID: 10477774 Patient ID: 10478034 4. An interview with the technical consultant on 2/15/23 at 3:15 p.m. in the conference room, after review of the records, confirmed the above findings. Key: rpm - revolutions per minute
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 review of the manufacturer's instructions for the BD Macro-Vue RPR Card Test, review of the laboratory's room temperature records from October 2022 to February 2023, review of patient test records from October 2022 to February 2023, and staff interview, it was revealed the laboratory failed to ensure the testing was performed within the manufacturer's acceptable temperature range for 30 of 155 test days. The findings include: 1. A review of the manufacturer's instructions for the BD Macro=Vue RPR Card Test (0212013JAA(05), 2021-05) under the section titled "Antigen" revealed: "upon removal from the refrigerator, allow the antigen to warm to room temperature (23 to 29C) before use." 2. A review of the laboratory's room temperature records from October 2022 to February 2023 (as of the day of the survey) revealed the laboratory's defined acceptable room temperature range was 20-30C. 3. Further review of the room temperature records revealed the following 30 of 155

	testing days when the documented room temperature was outside the manufacturer's acceptable range: Date Temperature 10/26 22.7C 10/30 22.5C 10/31 22.5C 11/14 22.3 C 11/17 22.3C 11/18 22.5C 11/19 22.1C 11/20 22.0C 11/21 22.2C 11/22 22.7C 11/24 22.5C 11/25 22.7C 11/26 22.9C 11/27 22.6C 11/28 22.7C 12/1 22.5C 12/2 22.5C 12 /23 22.5C 12/24 21.7C 12/25 21.4C 12/26 22.3C 12/27 22.5C 12/28 22.5C 2/1 22.9C 2 /3 22.9C 2/9 22.7C 2/10 22.5C 2/11 21.9C 2/12 21.1C 2/13 22.5C 3. A review of patient test records from October 2022 to February 2023 identified the following 64 patients whose samples were tested when the room temperature was documented outside the manufacturer's acceptable range: Date Patient ID 10/26 10463482 10462517 10462537 10462560 10/30 10463114 10/31 10463328 11/14 10465354 10465368 10465541 11/17 10465932 10466004 11/18 10466046 11/19 10466198 10466201 10466047 11/20 10466277 10466292 10466304 10466308 11/21 10466316 10466378 10466423 10466441 11/22 10466565 10466568 10466579 11/24 10466693 11/25 10466760 10466788 10466798 11/26 10466876 11/27 10466909 10466958 11 /28 10467038 10467020 10467057 12/1 10467677 10467689 12/2 10467806 10467855 12/24 10470763 10470768 12/25 10470810 12/26 10470874 10470888 10470905 10470958 12/27 10471119 12/28 10471133 10471233 2/1 10476059 10476091 2/3 10476364 2/9 10477147 10477201 10477228 2/10 10477042 2/11 10477168 2/12 10477582 2/13 10477681 4. An interview with the technical consultant on 02/15/2023 at 1515 hours in the conference room - after her review of the records- confirmed the findings.
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 review of the laboratory's test menu, review of the laboratory's records, and staff interview, it was revealed the laboratory failed to have documentation of performing verification studies for the BD Macro-Vue RPR Card Test. The findings include: 1. A review of the laboratory's test menu revealed the laboratory implemented the BD Macro-Vue RPR Card Test in May 2022. 2. A review of the laboratory's records revealed the laboratory failed to have documentation performing verification studies for the BD Macro-Vue RPR Card Test. 3. The laboratory was asked to provide documentation of performing the required studies. No documentation was provided. 4. The laboratory reported performing 583 tests utilizing the BD Macro-Vue RPR Card Test kit. 5. An interview with the laboratory manager on 02/15/2023 at 1515 hours in her office revealed verification studies had not been performed. This confirmed the findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at

	least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the laboratory's maintenance records for the Sysmex CA 2500 analyzer from January 2022 to January 2023 and staff interview, it was revealed the laboratory failed to have documentation of performing monthly maintenance for 8 of 13 months. The findings include: 1. A review of the laboratory's maintenance records for the Sysmex CA 2500 analyzer from January 2022 to January 2023 revealed the following maintenance was required to be performed monthly: Clean the Filter 2. Further review of the laboratory's Sysmex CA 2500 maintenance records from January 2022 to January 2023 revealed the laboratory failed to have documentation of performing the required monthly maintenance for 8 of 13 months. The months without documentation of monthly maintenance being performed were: January 2022 February 2022 March 2022 April 2022 May 2022 June 2022 July 2022 August 2022 3. The laboratory was asked to provide documentation of the maintenance being performed. No documentation was provided. 4. An interview with the technical consultant on 02/15/2023 at 1315 hours in the conference room - after her review of the records- confirmed the findings.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the maintenance records for the Sorvall Cell Washer from June 2022 to February 2023, and staff interview, it was revealed that the laboratory failed to ensure the cell washer: a) delivered the proper amount of saline to the blood bank tubes for 229 of 260 days between June 2022 to February 2023. b) was spinning at the appropriate RPMs for four of four times quarterly maintenance was performed between July 2022 to January 2023. Findings include: 1. A review of the laboratory's policy titled 'Cell Washer Preventative Maintenance' revealed the following: "Daily: Check saline fill volume - Using the CALIBRATE key and a graduated cylinder, make sure that the washer delivers 54 mls of saline to the 12x75 tubes. Every 3 months: Check motor speed - Set the power to ON and press the HOLD key. Allow the motor to accelerate to speed. Shine a stroboscope or tachometer through the viewport in the cover to verify the speed. RPM 3400 - 3600" 2. A review of the Maintenance for Sorvall Cell Washer records revealed the following: a) From June 2022 to February 2023 revealed the following 229 days where the saline volume check was documented below 54 mls: - 30 days in June 2022 - 31 days in August 2022 - 30 days in September 2022 - 31 days in October 2022 - 30 days in November 2022 - 31 days in December 2022 - 31 days in January 2023 - 15 days in February 2023 (2/1/23 - 2/15/23) b) From July 2022 to January 2023 revealed the following dates when the motor speed was checked and the RPMs were below

	3400: - 7/1/22 3000 RPM - 10/1/22 3000 RPM - 12/1/22 3000 RPM - 1/1/23 3000 RPM 3. An interview with the technical consultant on 2/15/23 at 3:15 p.m. in the conference room, after review of the records, confirmed the above findings. Key: mls - milliliters RPM - revolutions per minute
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on a review of the laboratory's policies, the laboratory's Media Quality Control forms, and staff interview, it was revealed that the laboratory failed to check each new lot number or new shipment of testing media for its ability to support growth for one of five lots of Chocolate agar in 2022. Findings include: 1. A review of the laboratory's policy titled 'Bacteriology Quality Control' revealed the following: "Quality controls for Chocolate or Thayer Martin should be performed with each new shipment or lot number." 2. A review of the laboratory's Media Quality Control forms for 2022 revealed the following lot number of Chocolate agar failed to have documentation of quality control being tested: Chocolate agar lot number: 429752 expire: 4/5/22 3. An interview with the technical consultant on 2/14/23 at 4:00 p.m. in the conference room, after review of the records, confirmed the above findings. II. Based on a review of the laboratory's Media Quality Control records from 2022 and staff interview, it was revealed the laboratory failed to provide documentation of checking each new lot number or shipment of media for sterility for six of ten lot numbers reviewed. Findings include: 1. A review of the Media Quality Control records for 2022 revealed the laboratory received 6 new lot numbers or shipments of the following media: - GN broth Lot number: 488021 expiration date: 5/5/23 - Thayer Martin agar Lot number: 593459 expiration date: 2/9/23 - Chocolate agar Lot number: 429752 expiration date: 4/5/22 - Blood agar (TSA w/Sheep Blood) Lot number: 491645 expiration date: 11/10/22 - Blood agar (TSA w/Sheep Blood) Lot number: 616315 expiration date: 3/29/23 - EMB agar (Levine) Lot number: 616299 expiration date: 4/5/23 2. An interview with the technical consultant on 2/14/23 at 4:00 p.m. in the conference room, after review of the records, confirmed the above findings. Key: GN - gram negative EMB - eosin methylene blue
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are

reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:
I. Based on a review of the nursing and laboratory's policies, patient transfusion records, and staff interview, it was revealed that the laboratory failed to have documentation of reviewing transfusion records to ensure potential transfusion reactions were identified in eight of nine patient's transfusion records reviewed between July 2022 to December 2022. Findings include: 1. A review of the nursing policy titled 'Blood/Blood Components- Transfusion: Deglycerized or Washed Red Blood Cells' revealed the following: "Observe for transfusion reactions up to one (1) hour after infusion of blood products: -Rash -Flushed feeling (hot) -Chills -Shortness of breath -Headache -Fever (>100.4) -Decreased blood pressure (>20 mm Hg Systolic and >10 mm Hg Diastolic) -Other reactions (see Blood/Blood Components - Transfusion Reaction policy) If a reaction occurs, stop the transfusion immediately!" 2. A review of the laboratory's policies revealed no policy that included the laboratory's role in investigating transfusion reactions. 3. A random review of patient transfusion records from July 2022 to December 2022 identified the following eight transfusions where the patients' vital signs met the criteria for a potential transfusion, however the transfusion was not stopped and a potential transfusion reaction was not investigated: a) Patient ID: 100480 Transfusion date: 7/1/22 Pre-transfusion blood pressure: 119/60 15 minute blood pressure: 108/42 Decrease in Diastolic blood pressure by 18 mm b) Patient ID: 126181 Transfusion date: 7/26/22 Pre-transfusion blood pressure: 136/69 1 Hour blood pressure: 117/56 Decrease in Diastolic blood pressure by 19 mm c) Patient ID: 022158 Transfusion date: 9/20/22 Pre-transfusion blood pressure: 124/82 15 minute blood pressure: 121/59 Decrease in Diastolic blood pressure by 23 mm 30 minute blood pressure: 118/61 Decrease in Diastolic blood pressure by 21 mm 1 Hour blood pressure: 107/59 Decrease in Diastolic blood pressure by 23 mm 2 Hour blood pressure: 118/66 Decrease in Diastolic blood pressure by 16 mm d) Patient ID: 119864 Transfusion date: 10/6/22 Pre-transfusion blood pressure: 144/58 30 minute blood pressure: 119/41 Decrease in Systolic blood pressure by 25 mm Decrease in Diastolic blood pressure by 17 mm 2 Hour blood pressure: 117/47 Decrease in Systolic blood pressure by 27 mm Decrease in Diastolic blood pressure by 11 mm e) Patient ID: 064101 Transfusion date: 11/20/22 (second unit) Pre-transfusion blood pressure: 141/66 15 minute blood pressure: 114/58 Decrease in Systolic blood pressure by 27 mm 30 minute blood pressure: 118/62 Decrease in Systolic blood pressure by 23 mm 1 Hour blood pressure: 114/64 Decrease in Systolic blood pressure by 27 mm f) Patient ID: 064101 Transfusion date: 11/20/22 (first unit) Pre-transfusion blood pressure: 147/71 1 Hour blood pressure: 116 /71 Decrease in Systolic blood pressure by 31 mm 2 Hour blood pressure: 101/71 Decrease in Systolic blood pressure by 46 mm g) Patient ID: 114138 Transfusion date: 12/2/22 Pre-transfusion blood pressure: 119/81 1 Hour blood pressure: 118/67 Decrease in Diastolic blood pressure by 14 mm h) Patient ID: 124292 Transfusion date: 12/13/22 Pre-transfusion blood pressure: 171/84 1 Hour blood pressure: 178/69 Decrease in Diastolic blood pressure by 15 mm 4. An interview with the technical consultant on 2/15/23 at 4:20 p.m. in the conference room, after review of the records, confirmed the above findings. II. Based on a review of the nursing and laboratory's policies, patient transfusion records, and staff interview, it was revealed that the laboratory failed to ensure blood products were released from the laboratory and transfused within fifteen minutes for two of nine pateint's transfusions reviewed from July 2022 to December 2022. Findings include: 1. A review of the nursing policy

	titled 'Blood/Blood Components- Transfusion: Deglycerized or Washed Red Blood Cells' revealed the following: "Blood product shall be used within 15 minutes from time it was signed out of the Blood Bank." 2. A review of the laboratory's policies revealed no policy that included instructed the laboratory to ensure blood products were transfused within 15 minutes from the time it was signed out of the Blood Bank. 3. A random review of patient test records from July 2022 to December 2022 revealed the following two blood products were transfused to patients beyond the 15 minute time frame: - Patient ID: 108617 Transfusion Date: 12/13/22 Time blood product was signed out of Blood Bank: 01:25 Time blood product transfused: 01:45 Elapsed time: 20 minutes - Patient ID: 124292 Transfusion Daate: 12/13/22 Time blood product was signed out of Blood Bank: 15:19 Time blood product transfused: 16:00 Elapsed time: 41 minutes 4. An interview with the technical consultant on 2/15/23 at 4:20 p.m. in the conference room, after review of the records, confirmed the above findings.
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: I. Based on review of the laboratory's Dimension EXL and Dimension EXL 200 chemistry analyzers' daily checks from January 2022 to February 2023, and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions when the documented cuvette temperature was outside the manufacturer's acceptable range for 24 of 24 occurrences. The findings include: 1. A review of the laboratory's Dimension EXL and Dimension EXL 200 chemistry analyzers' daily checks from January 2022 to February 2023 revealed the manufacturer required cuvette temperatures be 36.8 - 37.2 C. 2. Further review of the laboratory's daily checks from January 2022 to February 2023 identified the following times where the documented cuvette temperature was outside the manufacturer's required range and the laboratory failed to have documentation of performing corrective action for 24 of 24 occurrences. a) serial number 12252562 Date Temperature 4/10/2237.3C 4/17/2237.3C 5/25/2236.7C 6/3/22 36.7C 6/4/22 36.7C 6/5/22 36.7C 6/6/22 36.7C 6/8/22 36.7C 6/9/22 36.7C 6/11/2236.7C 6/17/2237.5C 6/18/2237.5C 7/4/22 37.4C 7/12/2237.3C 7/13/2237.3C 8/10/2236.6C 12/17/2237.3C 12/18/2237.3C 12/21/2237.3C 12/28/2237.3C 12/29/2237.3C 1/31/2336.7C b) serial number DR275089 Date Temperature 2/12/23 36.6C 2/14/23 36.7C 3. The laboratory was asked to provide documentation of performing corrective actions on the days identified. No documentation was provided. 4. An interview with the technical consultant on 02/15/2023 at 1030 hours in the conference room - after her review of the records- confirmed the findings. 41687 II. Based on a review of the Microbiology laboratory's Temperature and Humidity sheets for March 2022, and staff interview, it was revealed that the laboratory failed to have documentation of performing corrective actions when the laboratory's temperature was outside the acceptable range

	for six of thirty one days in March 2022. Findings include: 1. A review of the Microbiology laboratory's Temperature and Humidity sheets revealed the laboratory had a defined acceptability criteria of "Temperature: 20 -25C." 2. Further review of the Temperature and Humidity sheets for March 2022 revealed the following 6 days where the documented temperature was outside the laboratory's acceptability criteria and no corrective action was documented: 3/21/22 27C 3/22/22 27C 3/23/22 27C 3/24 /22 27C 3/25/22 27C 3/26/22 27C 3. An interview with the technical consultant on 2 /15/23 at 12:50 p.m. in the conference room, after review of the records, confirmed the above findings. Key: C = Degrees Celsius
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's Sysmex Insight quality control reports from March 2022 to January 2023, and staff interview, it was revealed the laboratory's quality assessment plan failed to ensure potential issues with quality control testing were investigated for 5 of 5 quality control lots monitored. The findings include: 1. A review of the laboratory's Sysmex Insight quality control reports from March 2022 to January 2023 revealed the manufacturer provided the following notes about how to assess the laboratory's quality control data: a) Accuracy Bias Codes "W Your Mean on this level is approaching a statistical bias in accuracy. Please follow you SOP for troubleshooting" b) QC Data Parameter SDI Ranges If you CV is 1.5 times greater than the Group CV, your result is presented in bold type and an investigation is warranted." 2. Further review of Sysmex Insight quality control reports from March 2022 to January 2023 revealed 5 of 5 lots had either accuracy bias codes or QC data parameter SDI ranges flags identified. They were: a) Lot: 2067 RBC Level 3 Code: W HCT Level 2 Code: W HCT Level 3 Code: W b) Lot: 2123 RBC Level 3 Code: W HCT Level 2 Code: W HCT Level 3 Code: W c) Lot: 2179 HCT Level 2 Code: W HCT Level 3 Code: W MCHC Level 3 Code: W d) Lot: 2235 HCT: Level 2 Code: W HCT: Level 3 Code: W e) Lot: 2291 HCT: Level 3 Code: W Lymph% Level 3 CV: 3.3 Mono% Level 2 CV: 10.2 Mono% Level 3 CV: 14.5 Lymph# Level 3 CV: 4.0 Mono# Level 3 CV: 14.2 3. The laboratory was asked to provide documentation of a procedure for troubleshooting Bias Codes or for investigating SDI ranges violations. No documentation was provided. 4. The laboratory was asked to provide documentation of performing corrective actions or investigations for the identified issues. No documentation was provided. 5. An interview with the technical consultant on 02/14/2023 at 1330 hours in the conference room confirmed the findings.
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 a review of the nursing policies and the Blood Products Flowchart, and staff interview, it was revealed that the laboratory failed to ensure the nursing policy for blood transfusions and the Blood Products Flowchart used by the nursing staff when transfusing blood products were adequate and included the same signs and symptoms for detecting transfusion reactions. Findings include: 1. A review of the nursing policy titled 'Blood/Blood Components- Transfusion: Deglycerized or Washed Red Blood Cells' revealed the following: "Observe for transfusion reactions up to one (1) hour after infusion of blood products: -Rash -Flushed feeling (hot) -Chills -Shortness of breath -Headache -Fever (>100.4) -Decreased blood pressure (>20 mm Hg Systolic and >10 mm Hg Diastolic) -Other reactions (see Blood/Blood Components - Transfusion Reaction policy)" 2. A review of the Blood Products Flowchart used by the nursing staff when transfusing blood products revealed one prompt for the nursing staff to answer when the transfusion begins: "Febrile Reaction ->2 Degrees Rise in T" (does not match the nursing policy of "fever (>100.4)". * There was no documentation that the Blood Products Flowchart contained any of the signs or symptoms that matched the nursing policy as listed above. 3. An interview with the technical consultant on 2/15/23 at 4:20 p.m. in the laboratory, after review of the records, confirmed the above findings.
D5813	TEST REPORT CFR(s): 493.1291(g) The laboratory must immediately alert the individual or entity requesting the test and, if applicable, the individual responsible for using the test results when any test result indicates an imminently life-threatening condition, or panic or alert values. This STANDARD is not met as evidenced by: Based on review of a sampling of patient critical values from January 28, 2023 to February 13, 2023, and staff interview, it was revealed the laboratory failed to have documentation of: a) notifying the provider of 3 of 5 critical values, and b) documenting the time of the notification for 3 of 5 critical values. The findings include: 1. A review of a sampling of critical values from January 28, 2023 to February 13, 2023 revealed the laboratory failed to have documentation of the notification of 3 of 5 critical values to the provider. They were: a) Date: 2/12/2023 Patient number: 10477595 Test: pCO2 Reported to respiratory tech b) Date: 2/12 /2023 Patient number: 10477595 Test: pO2 Reported to respiratory tech c) Date: 2/13 /2023 Patient number: 10477756 Test: pO2 Reported to respiratory tech 2. A review of a sampling of critical values from January 28, 2023 to February 13, 2023 revealed the laboratory failed to have documentation of the time of the notification of 3 of 5 critical values. They were: a) Date: 2/12/2023 Patient number: 10477595 Test: pCO2 b) Date: 2/12/2023 Patient number: 10477595 Test: pO2 c) Date: 1/28/2023 Patient number: 10475552 Test: pO2 3. An interview with the technical consultant on 02/15 /2023 at 1455 hours in the laboratory - after her review of the records- confirmed the findings.
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 review of the laboratory's records and staff interview, it was revealed the laboratory director failed to ensure verification studies were performed (refer to D5421).
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 review of the laboratory's records, and staff interview, it was revealed the laboratory director failed to ensure a quality assessment plan was developed and followed to identify and correct problems in pre-analytic systems (refer to D5391) and analytic systems (refer to D5791 and D5793).
D6040	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(2) The technical consultant is responsible for-- (b)(2) Verification of the test procedures performed and the establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and staff interview, it was revealed the technical consultant failed to ensure verification studies were performed (refer to D5421).