# Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number	(X3) Date Survey Completed
	45D0495521	04/05/2023
Name of Provider or Supplier	**Street Address, City, State**	
El Campo Memorial Hospital	303 Sandy Corner Road, El Campo, 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	The laboratory was found out of compliance with applicable CLIA regulations (42 CFR Part 493, Requirements for Laboratories). The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility was found in compliance with applicable CLIA conditions, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D3025	REQUIREMENTS FOR TRANSFUSION SERVICES CFR(s): 493.1103(d) Investigation of transfusion reactions. The facility must have procedures for preventing transfusion reactions and when necessary, promptly identify, investigate, and report blood and blood product transfusion reactions to the laboratory and, as appropriate, to Federal and State authorities. This STANDARD is not met as evidenced by: Based on a review of the nursing and laboratory's policies, patient transfusion records, and staff interview, it was revealed that the facility failed to identify and report two of two transfusion reactions (per their defined criteria) to the laboratory in 2023. Findings include: 1. A review of the nursing policy titled 'ECMH Transfusion of Blood and Blood Products" revealed the following: "Patients receiving a transfusion will be continuously assessed at the bedside for signs and symptoms of transfusion reactions and complications for the first 15 minutes and reassessed with each set of

	vital signs. Some signs and symptoms associated with transfusion reaction include: a. Fever (increase in temperature by 2F or 1C) b. Urticaria (hives) c. Hemoglobinuria (urine turns red or dark brown) d. Arthralgias e. Chills/rigors f. Shortness of breath g. Flank pain h. Hypotension or hypertension (Systolic increase of >50mmHg; or decrease of 30mmHg) If a suspected transfusion reaction occurs during the transfusion: - Stop the transfusion and maintain adequate vascular access. Change the IV set and KVO with a new bag of 0.9% NaCl. - Notify the patient's physician and the Blood Bank. - Obtain sample(s) for transfusion reaction investigation workup" 2. A review of the laboratory's policies revealed the laboratory did not have a system in place to identify unreported transfusion reactions (per the criteria above) for investigation and make recommendations to medical staff. Refer to D5559. 3. A review of patient transfusion records from December 2022 to March 2023 identified the following two transfusions where the patients' vital signs met the criteria for a transfusion reaction, however the transfusions were not stopped and the transfusion reactions were not reported to blood bank for investigation: a) Patient ID: 10214027 Transfusion date: 1/13/23 Pre-transfusion blood pressure: 137/34 1 hour blood pressure: 106/62 Decrease in Systolic blood pressure by 31 mmHg b) Patient ID: 10217027 Transfusion date: 2/10/23 Pre-transfusion blood pressure: 164/83 2 Hour blood pressure: 117/75 Decrease in Systolic blood pressure by 47 mmHg 4. An interview with the technical consultant on 4/4/23 at 10:50 a.m. in the conference room, after review of the records, confirmed the above findings.
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 the review of the laboratory's test menu, the laboratory's proficiency testing records, the laboratory's alternative proficiency testing records, and confirmed in an interview, the laboratory failed to verify the accuracy of non-regulated test, Troponin, at least twice annually on one of one Quidel Triage Meter. The findings were: 1. Review of the laboratory's test menu revealed the laboratory performed non-regulated analyte, Troponin, on one of one Quidel Triage Meter (SN: 00043009). 2. Review of the laboratory's proficiency testing records revealed the laboratory did not enroll Troponin for Quidel Triage Meter (SN: 00043009). 3. An interview with the general supervisor and the technical consultant on 4/5/2023 at 11:50 am in the conference room confirmed the above findings.
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:

	A. Based on review of manufacturer's instructions, laboratory's order logs, specimen receipt logs, patient test records and staff interview, the laboratory failed to ensure manufacturer instructions were followed for processing of 2 of 350 lactic acid samples tested between January and April of 2023. Note: This is a repeat deficiency from the follow-up unannounced survey conducted on 3/22/2022. Findings included: 1. Review of manufacturer's instructions for use for Siemens Dimension Flex reagent cartridge for testing of lactic acid (REF: DF16, issued 2019-04-01) revealed: "Collection of a satisfactory specimen for lactate analysis requires special procedures to prevent changes in lactate while and after the specimen is drawn... Blood is best collected without stasis in a container of sodium fluoride/potassium oxalate, followed by immediate chilling of the specimen and separation of the cells within 15 minutes." 2. Review of laboratory's lactic acid order logs, specimen receipt logs and patient test records for January to April of 2023 revealed 2 of 350 patient lactic acid samples did not follow manufacturer instructions for sample processing prior to testing. These were: Patient Account: 10217278 Collected: 02/12/2023 at 12:03 Received: 02/12 /2023 at 12:05 Spin time: 12:05 Manufacturer instructions not met: Sample was received at room temperature. Result: 2.2 mmol/L (millimole/liter) - High Critical (normal range: 0.4-1.9) Patient Account: 10220470 Collected: 03/14/2023 at 05:19 Received: 03/14/2023 at 05:21 Spin time: 05:41 Manufacturer instructions not met: Separation of cells exceeded 15 minutes. Result: 4.7 mmol/L - High Critical (normal range: 0.4-1.9 mmol/L) 3. In an interview on 04/04/2023 at 1535 hours in the conference room, the laboratory's General Supervisor number 2 (as described on submitted Form 209), after review of the data, confirmed the findings. B. Based on review of manufacturer's instructions, laboratory's patient test records and staff interview, the laboratory failed to ensure manufacturer instructions were followed for sample stability of 1 of 67 ammonia samples tested between January and April of 2023. Note: This is a repeat deficiency from the follow-up unannounced survey conducted on 3/22/2022. Findings included: 1. Review of manufacturer's instructions for use for Siemens Dimension Flex reagent cartridge for testing of Ammonia (REF. DF119, issued 2019-04-08) revealed: "Separated samples are stable for 2 hours at 2-8C (Celsius)". 2. Review of patient test records for January to April of 2023 revealed 1 of 67 ammonia samples tested within this interval exceeded the manufacturer required sample stability timeframe as follows: Patient Account: 10218672 Collected: 02/24/2023 at 03:46 Received: 02/24/2023 at 03:49 Tested: 02/24/2023 at 06:25 Result: 104 umol/L (micromole/Liter) - High (normal range: 11.0-32.0 umol/L) Time elapsed: 2 hours 26 minutes 3. In an interview on 04/04/2023 at 1540 hours in the conference room, the laboratory's General Supervisor number 2 (as described on submitted Form 209), after review of the data, confirmed the findings.
D5393	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(b)(c) The preanalytic systems assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of preanalytic systems quality assessment reviews with appropriate staff. The laboratory must document all preanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory's specimen processing logs, patient test records, laboratory's quality assessment records for 2022 and staff interview, the laboratory failed to address effectiveness of corrective actions taken to resolve recurring

	problems in preanalytic systems. Findings included: 1. Review of laboratory's specimen processing logs and patient test records revealed recurring problems in ammonia and lactic acid specimen handling prior to testing. Cross-refer to D5311 A and B. 2. Review of the laboratory's quality assessment records for 2022 revealed the laboratory monitored and addressed individual outliers for ammonia and lactic acid specimen handling but did not address the overall effectiveness of corrective actions previously taken to resolve recurring problems. 3. In an interview on 04/05/2023 at 1545 hours in the conference room, the laboratory's General Supervisor number 2 (as described on submitted Form 209), after review of the data, 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 a review of the Questions for Normal Patient Population Study forms and staff interview, it was revealed that the laboratory failed to follow its policy two of forty times by ensuring patient's samples met the laboratory's criteria to be included in the normal patient study when starting a new lot number of PT-Fibrinogen coagulation reagent. Findings include: 1. A review of the laboratory's Questions for Normal Patient Population Study form revealed the following question was asked of patient volunteers: "Have you consumed alcohol in the past 24 hours?" 2. Further review of the laboratory's Questions for Normal Patient Population Study form revealed the following instructions for the laboratory personnel: "If yes- exclude- interferes with tests being validated." 3. A review of the laboratory's records revealed the following 2 patient samples were included in the study for the PT-Fibrinogen reagent (lot number: N0815183) after answering yes to consuming alcohol in the past 24 hours: Patient Sample Number M3 Patient Sample Number M6 4. An interview with the technical consultant on 4/5/23 at 9:30 a.m. in the conference room, after review of the records, confirmed the above findings.
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, laboratory's policies, quality control records, and staff interview, it was revealed that the laboratory failed to follow the manufacturer's instructions for new lot numbers of HemosIL coagulations reagents and control materials for the ACL Elite in 2022 and 2023, as follows: a) establish a new normal reference interval for a new lot of PT-Fibrinogen reagent b) establish a new assay control range for the Normal Control for use with PT-Fibrinogen and APTT-SP reagents c) establish a new normal reference interval for a new lot of APTT-

	SP reagent d) establish new assay control ranges for the Normal Control and Abnormal Control when the new lot of APTT-SP reagent was started. Findings include: 1. A review of the Hemostasis Performance Verification Manual (Revision A, 8/28/2012) revealed the following: " When changing to a new lot number of reagent or a new reagent, it is important to - establish a new normal reference interval for all tests - establish a new assay control range - verify the INR calculation - perform a comparison study for all tests - and to establish the heparin therapeutic range (APTT reagents). Establishing a control assay range is done under the following conditions: - at the installation of a new instrument or with major service repairs - With a change of the reagent lot number - With a change of the control lot number - At the request from IL representative - To follow the requirements of the appropriate regulatory agency." 2. A review of the laboratory's policies revealed the following: Policy titled: Laboratory Coagulation Normal Reference Range "Reference Intervals should be established or verified, as appropriate, whenever there is a change in: - lot number of reagent - At least once a year." Policy titled: Laboratory Coagulation Control Lot Change "Establishing a control assay range is done under the following conditions: - With a change of the reagent lot number - With a change of the control lot number" 3. A review of the laboratory's quality control records revealed the following dates when the laboratory started using the new lot numbers of reagent or quality control material on the ACL Elite coagulation analyzer: HemosIL PT-Fibrinogen Lot number: N0815183 Start date: 11/21/22 HemosIL Normal Control (Level 1) Lot number: N0421538 Start date: 12/22/22 HemosIL APTT-SP Lot number: N0622860 Start date: 1/31/23 4. A review of the laboratory's records revealed the laboratory failed to have documentation of the following 4 studies prior to using the HemosIL reagents and controls for patient testing: a) normal reference interval for PT-Fibrinogen reagent lot number: N0815183 b) assay control range for Normal Control lot number: N0421538 for the PT-Fibrinogen and APTT-SP reagents c) normal reference interval for APTT-SP reagent lot number: N0622860 d) assay control ranges for the Normal Control and Abnormal when the lot of APTT-SP reagent (N0622860) was started. 5. A review of the laboratory's patient test records revealed the laboratory reports an estimated 9,000 coagulation tests annually. 6. An interview with the technical consultant on 4/4/23 at 3:20 p.m. in the conference room, after review of the records, confirmed that the studies were not done. Key: PT = Prothrombin Time APTT = Activated Partial Thromboplastin Time
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: A. Based on a review of the laboratory's policies, surveyor observation of the controls currently in use for the Horiba Pentra 80 hematology analyzer, and staff interview, it was revealed that the laboratory failed to document the revised expiration dates on three of three Difftrol control vials used on the Horiba Pentra 80 hematology analyzer. Findings include: 1. A review of the laboratory's policy titled 'Horiba Difftrol' revealed the following: "Opened tubes are stable for 15 days provided they are handled properly, and provided the instructions in section "instructions for use" are

	followed. - When first opening a vial for use, the open date and the expiration date must be placed on the side of the vials." 2. Surveyor observation of the laboratory on 4/5/23 at 1:35 p.m. revealed the following 3 Difftrol controls currently in use for the Horiba Pentra 80 hematology analyzer with no documentation of a revised expiration date: Difftrol Level 1 Lot number: PX440L Open date: 4/1/23 Difftrol Level 2 Lot number: PX440N Open date: 3/27/23 Difftrol Level 3 Lot number: PX440H Open date: 3/27/23 3. An interview with the technical consultant on 4/5/23 at 1:35 p.m. in the conference room, after review of the records, confirmed the above findings. 44697 B. Based on the surveyor's direct observation, the sedimentation rate control package insert, and confirmed in an interview, the laboratory failed to label two of two in use reagent vials with new expiration dates for one of one QC lot number in use on Alcor miniiSED for the test of sed rate. The findings were: 1. Review of Alcor SEDITROL Erythrocyte Sedimentation Rate Control Package insert (315-09-011, Rev. 0) under STORAGE & STABILITY revealed, "*Note:The 60 days stability has been validated for use on the iSED and the miniiSED only and has not been validated for any other method or usage." 2. Surveyor's direct observation on 4/5/2023 at 1:50 pm in the laboratory revealed no revised expiration dates documented on the opened quality controls for one of one QC lot number in use. Alcor SEDITROL Erythrocyte Sedimentation Rate Controls Level 1 Lot: C141 Opened date: 3/17/23 Original expiration date: 2024-03-23 Level 2 Lot: C241 Opened date: 3/17/23 Original expiration date: 2024-03-23 3. An interview with the technical consultant on 4/5/2023 at 2:00 pm in the lab confirmed the above finding. Key: Sed rate=Sedimentation rate QC=Quality Control
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 the review of the laboratory's records from 7/17/2022 to 3/20/2023, patient results, and confirmed in an interview, the laboratory failed to perform two quantitative QC materials with different concentrations prior to patient testing on Quidel Triage Meter for the analytes: CKMB and Troponin for 26 of 80 days reviewed. The findings were: 1. Reviewed of the laboratory's records from 7/17/2022 to 3/20/2023 revealed the following dates did not have documentation of two quantitative QC materials with different concentrations prior to patient testing on Quidel Triage Meter for the analytes: CKMB and Troponin. 7/19/2022 7/20/2022 7/28/2022 7/29/2022 7/31/2022 8/1/2022 8/3/2022 8/4/2022 8/5/2022 8/6/2022 8/7/2022 8/9/2022 9/5/2022 9/6/2022 9/7/2022 9/8/2022 9/9/2022 9/10/2022 9/16/2022 9/27/2022 10/5/2022 10/6/2022 10/7/2022 10/8/2022 10/9/2022 10/10/2022 2. Reviewed the the laboratory's patient results for the dates above revealed 114 patients had CKMB and Troponin testing performed on Quidel Triage Meter (SN:00043009). 7/19/2022 LAB#: 61044 7/19/2022 LAB#: 61122 7/19/2022 LAB#: 61040 7/19/2022 LAB#: 61160 7/19/2022 LAB#: 61201 7/19/2022 LAB#: 61195 7/19/2022 LAB#: 61212 7/19/2022 LAB#: 61261 7/20/2022 LAB#: 61384 7/20/2022 LAB#: 61385 7/20/2022 LAB#: 61499 7/20/2022 LAB#: 61783 7/20/2022 LAB#: 62068 7/20/2022 LAB#: 62081 7/20/2022 LAB#: 62070 7/20/2022 LAB#: 62069 7/28/2022 LAB#:

	66365 7/28/2022 LAB#: 66372 7/28/2022 LAB#: 66417 7/28/2022 LAB#: 66492 7/28 /2022 LAB#: 66614 7/28/2022 LAB#: 66593 7/28/2022 LAB#: 66584 7/28/2022 LAB#: 66713 7/28/2022 LAB#: 66751 7/28/2022 LAB#: 66775 7/28/2022 LAB#: 66885 7/28/2022 LAB#: 66884 7/28/2022 LAB#: 66896 7/28/2022 LAB#: 66925 7/28 /2022 LAB#: 67239 7/29/2022 LAB#: 67430 7/29/2022 LAB#: 67625 7/29/2022 LAB#: 67640 7/31/2022 LAB#: 67847 7/31/2022 LAB#: 67890 7/31/2022 LAB#: 67914 8/1/2022 LAB#: 68279 8/1/2022 LAB#: 68653 8/1/2022 LAB#: 68698 8/1 /2022 LAB#: 68713 8/3/2022 LAB#: 69581 8/3/2022 LAB#: 69569 8/3/2022 LAB#: 69805 8/3/2022 LAB#: 69809 8/3/2022 LAB#: 69855 8/3/2022 LAB#: 69877 8/3 /2022 LAB#: 69939 8/3/2022 LAB#: 70067 8/4/2022 LAB#: 70126 8/4/2022 LAB#: 70310 8/4/2022 LAB#: 70656 8/4/2022 LAB#: 70659 8/5/2022 LAB#: 70944 8/5 /2022 LAB#: 70977 8/5/2022 LAB#: 70610 8/5/2022 LAB#: 71039 8/5/2022 LAB#: 71110 8/5/2022 LAB#: 71166 8/5/2022 LAB#: 71225 8/6/2022 LAB#: 71302 8/6 /2022 LAB#: 71212 8/6/2022 LAB#: 71338 8/6/2022 LAB#: 71381 8/6/2022 LAB#: 71394 8/6/2022 LAB#: 71397 8/7/2022 LAB#: 71437 8/7/2022 LAB#: 71465 8/7 /2022 LAB#: 71498 8/7/2022 LAB#: 71506 8/9/2022 LAB#: 72502 8/9/2022 LAB#: 72618 8/9/2022 LAB#: 72658 8/9/2022 LAB#: 72775 8/9/2022 LAB#: 72765 8/9 /2022 LAB#: 72810 8/9/2022 LAB#: 72818 8/9/2022 LAB#: 72837 8/9/2022 LAB#: 72855 9/5/2022 LAB#: 86759 9/5/2022 LAB#: 86764 9/5/2022 LAB#: 86802 9/5 /2022 LAB#: 86813 9/5/2022 LAB#: 86824 9/5/2022 LAB#: 86839 9/8/2022 LAB#: 88539 9/8/2022 LAB#: 89005 9/8/2022 LAB#: 89024 9/8/2022 LAB#: 89247 9/9 /2022 LAB#: 89351 9/9/2022 LAB#: 89772 9/10/2022 LAB#: 90437 9/16/2022 LAB#: 93473 9/16/2022 LAB#: 93805 9/16/2022 LAB#: 93833 9/16/2022 LAB#: 93936 9/16/2022 LAB#: 93833 9/27/2022 LAB#: 99457 10/5/2022 LAB#: 4339 10/5 /2022 LAB#: 4403 10/5/2022 LAB#: 4418 10/5/2022 LAB#: 4629 10/5/2022 LAB#: 4717 10/6/2022 LAB: 5495 10/7/2022 LAB#: 5823 10/7/2022 LAB#: 5831 10/7/2022 LAB#: 5842 10/7/2022 LAB#: 6096 10/8/2022 LAB#: 6361 10/9/2022 LAB#: 6600 10/10/2022 LAB#: 6646 10/10/2022 LAB#: 7071 10/10/2022 LAB#: 7191 10/10 /2022 LAB#: 7139 3. An interview with the technical consultant on 4/5/2023 at 1:40 pm in a conference room confirmed the above findings. Key: QC=Quality Control
D5461	CONTROL PROCEDURES CFR(s): 493.1256(d)(6)(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-- Perform control material testing as specified in this paragraph before resuming patient testing when a complete change of reagents is introduced; major preventive maintenance is performed; or any critical part that may influence test performance is replaced. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the Pentra 80 User Manual, the Pentra 80 Reagent Log from March 2023, the laboratory's quality control records, and staff interview, revealed the laboratory failed to have documentation of running a blank cycle and quality control materials after changing reagents for ten of fifteen times reagents were changed in March 2023. Findings include: 1. A review of the Pentra 80 User Manual (RAB131HEN) revealed the following: "Make sure that a blank cycle and Control run will be carried out after the change of a reagent in the course of day." 2. A review of the Pentra 80 Reagent Log for March 2023 revealed the laboratory changed the following ten reagents on the following days: Reagent: ABX Eosinofix Lot number: 220927G1 expiration: 6/27/23 Date: 3/1/23 8:50 a.m. Reagent: ABX Lyse Lot

	number: 220411Y2 expiration: 4/11/23 Date: 3/1/23 8:30 p.m. Reagent: ABX Diluent Lot number: 220819H1 expiration: 8/19/23 Date: 3/10/23 9:15 a.m. Reagent: ABX Basolyse 2 Lot number: 220801I2 expiration: 8/1/23 Date: 3/14/23 8:58 a.m. Reagent: ABX Lyse Lot number: 220411Y2 expiration: 4/11/23 Date: 3/14/23 9:01 a.m. Reagent: ABX Cleaner Lot number: 220517I1 expiration: 5/17/23 Date: 3/16/23 8:03 p.m. Reagent: ABX Eosinofix Lot number: 220927G1 expiration: 6/27/23 Date: 3/16 /23 8:43 p.m. Reagent: ABX Lyse Lot number: 22100Y2 expiration: 10/5/23 Date: 3 /28/23 9:45 a.m. Reagent: ABX Basolyse 2 Lot number: 220801I2 expiration: 8/1/23 Date: 3/29/23 8:35 a.m. Reagent: ABX Cleaner Lot number: 220517I1 expiration: 5/17 /23 Date: 3/29/23 8:44 a.m. 3. A review of the laboratory's quality control records for March 2023 revealed the laboratory failed to have documentation of running a blank cycle and quality control materials after changing the reagents listed above. 4. An interview with technical consultant on 4/5/23 at 1:40 p.m. in the laboratory, after review of the records, confirmed the above findings.
D5559	IMMUNOHEMATOLOGY CFR(s): 493.1271(e)(f) (e) Investigation of transfusion reactions. (e)(1) According to its established procedures, the laboratory that performs compatibility testing, or issues blood or blood products, must promptly investigate all transfusion reactions occurring in facilities for which it has investigational responsibility and make recommendations to the medical staff regarding improvements in transfusion procedures. (e)(2) The laboratory must document, as applicable, that all necessary remedial actions are taken to prevent recurrences of transfusion reactions and that all policies and procedures are reviewed to assure they are adequate to ensure the safety of individuals being transfused. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, patient transfusion records, and staff interview, it was revealed that the laboratory failed to have documentation of reviewing and investigating transfusion reactions (per the facility's defined criteria) for two of two patients in 2023. Findings include: 1. A review of the laboratory's policies revealed the laboratory did not have a system in place to identify unreported transfusion reactions (per the facility's criteria) for investigation and make recommendations to medical staff. 2. A review of patient transfusion records from December 2022 to March 2023 identified the following two transfusions where the patients' vital signs met the criteria for a transfusion reaction, however the transfusions were not stopped and the transfusion reactions were not investigated by the laboratory: a) Patient ID: 10214027 Transfusion date: 1/13/23 Pre-transfusion blood pressure: 137/34 1 hour blood pressure: 106/62 Decrease in Systolic blood pressure by 31 mmHg b) Patient ID: 10217027 Transfusion date: 2/10/23 Pre-transfusion blood pressure: 164/83 2 Hour blood pressure: 117/75 Decrease in Systolic blood pressure by 47 mmHg 3. An interview with the technical consultant on 4/4/23 at 10:50 a.m. in the conference room, after review of the records, confirmed the above findings.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c) (a) If a laboratory performs the same test using different methodologies or

	instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: A. Based on a review of the laboratory's records and staff interview, it was revealed that the laboratory failed to ensure that one of two comparison studies were performed as required in 2022 on the following systems that perform the same tests: a) Horiba Pentra 60 hematology analyzer for CBC (Complete Blood Count) testing b) Horiba Pentra 80 hematology analyzer for CBC testing. Findings included: 1. A review of the laboratory's records revealed the laboratory performed a comparison of CBC results between the Pentra 60 (Serial number: 111PCP16171) and the Pentra 80 (Serial number: 111PXL9352) on 3/30/22. 2. Further review of the laboratory's records revealed the laboratory failed to have documentation of a second comparison study in 2022. 3. An interview with the technical consultant on 4/5/23 at 1:50 p.m. in the conference room, after review of the records, confirmed that a second comparison study was not completed in 2022. 44697 B. Based on the review of the laboratory's test menu, the laboratory's records in 2022, and confirmed in an interview, the laboratory failed to have documentation of two instrument comparisons being performed in 2022 between Siemens Dimension EXL analyzer and Quidel Triage Meter for one of one analyte: CKMB. The findings were: 1. Review of the laboratory's test menu revealed the laboratory performs the analyte, CKMB, on Siemens Dimension EXL analyzer (SN: DR252052) and Quidel Triage Meter (00043009). 2. Review of the laboratory's records in 2022 revealed the laboratory failed to have documentation of performing 2 comparisons annually for the analyte, CKMB, tested on both on Siemens Dimension EXL analyzer and Quidel Triage Meter instruments. 3. An interview with the general supervisor and the technical consultant on 4/5/2023 at 2:58 pm in the conference room confirmed the above 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 facility's QA program, patient transfusion records, and staff interview, it was revealed that the laboratory failed to have an effective QA (quality assessment) system in place to review and identify unreported transfusion reactions in 2023. Findings include: 1. A review of the facility's QA program titled 'Blood Administration Audit' revealed the Quality Manager reviewed the following data for patient transfusions: - Time of Pre-Transfusion Vital Signs - Infusion Start Time - Time of 15 min Vital Signs - Infusion End Time - Time of Post Transfusion Vital Signs - Variation in Blood Pressure - Increase in Temp by 2F - Other Signs or Symptoms of Adverse Reaction 2. A review of patient transfusion records from December 2022 to March 2023 identified the following two transfusions where the patients' vital signs met the criteria for a transfusion reaction, however the QA system

	failed to identify the unreported transfusion reactions: a) Patient ID: 10214027 Transfusion date: 1/13/23 Pre-transfusion blood pressure: 137/34 1 hour blood pressure: 106/62 Decrease in Systolic blood pressure by 31 mmHg b) Patient ID: 10217027 Transfusion date: 2/10/23 Pre-transfusion blood pressure: 164/83 2 Hour blood pressure: 117/75 Decrease in Systolic blood pressure by 47 mmHg 3. Further review of the Blood Administration Audit revealed, for the transfusions listed above, the Quality Manager indicated "no change" in the Variation in Blood Pressure column. 4. An interview with the Quality Manager on 4/4/23 at 11:00 a.m. in her office, after review of the records, confirmed the above findings.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for use, sample processing logs and patient test records, review of laboratory's policies and procedures and staff interview, the Laboratory Director failed to ensure the laboratory provided quality services in the preanalytic aspects of test performance. Refer to D5311 A, B.
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 laboratory's specimen processing logs, patient test records, laboratory's quality assessment (QA) records for 2022 and staff interview it was determined the Laboratory Director failed to ensure laboratory's quality assessment was maintained. Refer to D5393.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing.

	This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, patient transfusion records, and staff interview, it was revealed that the laboratory director failed to ensure testing systems provided quality laboratory services for Immunohematology. Findings include: 1. The laboratory failed to have documentation of reviewing and investigating transfusion reactions (per the facility's defined criteria) for two of two patients in 2023. Refer to D5559.