Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0487467	10/28/2021
Name of Provider or Supplier	**Street Address, City, State**	
Nocona General Hospital	100 Park Rd, Nocona, 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	An entrance conference was held with the laboratory representatives. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be NOT in compliance with the CLIA conditions for specialties /subspecialties surveyed for 42 CFR 493.1100 Facility Administration 493.1217 Immunohematology 493.1250 Analytic Systems 493.1403 Laboratory Director, (moderate complexity) 493.1441 Laboratory Director (high complexity) 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 Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D2006	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b) The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing. This STANDARD is not met as evidenced by:

	Based on review of the Centers for Medicare and Medicaid (CMS)-209 form, American Proficiency Institute (API) Proficiency Testing (PT) records, and staff interview, the laboratory failed to test proficiency testing samples in the same manner as it tests patient specimens for 4 of 4 testing events in 2021 (Chemistry Core 1st and 2nd events and Hematology 1st and 2nd events). Findings included: 1. Review of the CMS 209 form revealed 12 Testing Persons (TP-1 through TP-12) performed moderate complexity chemistry and hematology testing. 2. Review of the API proficiency testing records from 2021 (Chemistry Core 1st and 2nd events and Hematology 1st and 2nd events) revealed TP-8, TP-9, TP-11, and TP-12 failed to participate in 4 of 4 proficiency testing events. The laboratory failed to ensure proficiency testing samples were tested in the same manner as patient samples and rotated amongst the routine testing personnel. 3. During an interview on 10/26/2021 at 02:26 pm in the conference room, the laboratory manager, after review of the proficiency testing records, confirmed the above findings.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the Centers for Medicare and Medicaid (CMS)-209 form, American Proficiency Institute (API) Proficiency Testing (PT) 2020 and 2021 records, and staff interview, the laboratory director and testing persons failed to attest to the routine integration of proficiency samples into the patient workload for 3 of 14 proficiency testing events. Findings Included: 1. Review of the CMS 209 form revealed 12 Testing Persons (TP-1 through TP-12) performing moderate complexity chemistry and hematology testing. 2. Review of API instructions stated the following: "ATTESTATION STATEMENT SIGNATURES REQUIRED- Testing personnel and the laboratory director must physically sign an attestation statement for all PT results and retain the signed statement (or a copy) for a minimum of 2 years. Either the attestation statement below or a printed copy of the form provided online can be used for this purpose." 3. Review of the laboratory's API proficiency testing 2020 records (Hematology 1st, 2nd, and 3 Events) and 2021 records (Hematology 1st and 2nd Events, Chemistry Core 1st and 2nd Events, Chemistry Miscellaneous 1st and 2nd Events, Immunology/Immunohematology 1st and 2nd Events, and Microbiology 1st, 2nd, and 3rd Events) revealed the laboratory director or designee failed to sign the attestation statement for the following: 2020 API Hematology 3rd Event The laboratory Director and Testing Person-2 failed to attest to the routine integration of proficiency samples into the patient workload. 2021 API Immunology /Immunohematology 2nd Event Testing Person-2 failed to attest to the routine integration of proficiency samples into the patient workload. 2021 Microbiology 3rd Event The laboratory Director failed to attest to the routine integration of proficiency samples into the patient workload. 4. During an interview on 10/26/2021 at 02:26 pm in the conference room, the laboratory manager, after review of the proficiency testing records, confirmed the above findings
D3000	FACILITY ADMINISTRATION CFR(s): 493.1100

	Each laboratory that performs nonwaived testing must meet the applicable requirements under 493.1101 through 493.1105, unless HHS approves a procedure that provides equivalent quality testing as specified in Appendix C of the State Operations Manual (CMS Pub. 7). (a) Reporting of SARS-CoV-2 test results During the Public Health Emergency, as defined in 400.200 of this chapter, each laboratory that performs a test that is intended to detect SARS-CoV-2 or to diagnose a possible case of COVID-19 (hereinafter referred to as a "SARS-CoV-2 test") must report SARS-CoV-2 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe. This CONDITION is not met as evidenced by: Based on review of the facility records and a review of patient transfusion records (09 /02/2021 - 10/25/2021), it was revealed the facility administration failed to meet the requirements specified in 493.1101 through 493.1105, as evidenced by: 1. The facility failed to ensure transfusion reaction policies promptly identified, investigated, and documented transfusion reactions for 6 of 8 patients that received blood products. Refer to D3025
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 review of the facility and laboratory blood/blood product transfusion policies, review of facility blood administration educational material, review of patient transfusion records (09/02/2021-10/25/2021), and staff interview, it was revealed the facility failed to ensure transfusion reaction policies promptly identified, investigated, and documented transfusion reactions for 6 of 8 patients that received blood products. Findings included: 1. The facility policy titled, "Blood and Blood Product Administration" (Reviewed/Revised 04/22/2013) stated the following: " ... POLICY: 1. General Instructions ...H. Prior to transfusion, blood and/or components are to be checked by two (2) licensed personnel as to the patient's name, blood type, and expiration date, and donor number. Both nurses must sign the Transfusion Flow Sheet in the appropriate blanks ...I. Obtain and document vital signs at fifteen (15), thirty (30), forty-five (45) minutes, and one (1) hours, then every hour on the Transfusion Flow Sheet. Use one Transfusion Flow Sheet per unit ...K. If there is a reaction, stop the blood transfusion and follow instructions on the Transfusion Reaction Investigative Report. Notify the lab tech and physician immediately." The facility policy failed to specify what patient vital signs were to be obtained at the specified times. The facility policy failed to define clinical criteria for a transfusion reaction. 2. The laboratory policy titled, "Administrative Policies" (Reviewed and signed by the laboratory director on 06/18/2021) stated the following: " ...3. Transfusion reactions: A. When any clinical findings listed on the transfusion report are present, the transfusion should be stopped immediately. A blood transfusion reaction investigation report must be completed and sent to the laboratory, along with required specimens. The laboratory personnel will then complete the investigation process following appropriate procedures ..." The laboratory policy failed to define

clinical criteria for a transfusion reaction. 3. Review of the facility's blood administration educational material titled, "Nocona General Hospital Blood Transfusion Annual Education" stated the following: "Blood Transfusion Process ...b. Patient Education ...2) Thoroughly inform the signs and symptoms of a reaction and ensure their understanding of such S/S and to call for help immediately. a) Rash b) Flushed feeling and/or chills c) Shortness of breath d) Fever e) Headache f) Back pain g) Hematuria h) chest tightness i) Delayed reactions up to 6 months following transfusion, patient should watch for the following: i. Jaundice ii. Fatigue iii. Loss of appetite iv. Darkened urine ...i. In the event of a Transfusion Reaction: 1) Follow the 'Blood Transfusion Reaction Workup Procedure' policy & procedure 2) Stop the transfusion immediately ..." The facility's blood administration educational material failed to communicate at what times vital signs should be documented during blood administration. The educational material failed to specify what changes in a patient's vital signs are indicative of a transfusion reaction. The educational material failed to provide signs and symptoms of a transfusion reaction for recognition by nursing personnel during the blood administration process. (The signs and symptoms listed in the policy were for patient awareness of a transfusion reaction.) The educational material failed to provide specific steps for the Blood Transfusion Workup procedure. 4. Review of the facility's patient transfusion records (09/02/2021 - 10/25/2021) revealed the following 6 of 8 patients in which the facility failed to ensure transfusion reactions were promptly identified, investigated, and documented for all blood products: a. Patient 245826 Date: 09/02/2021 1. Packed Red Cells; Unit Number W091021338704 Transfusion Start Time: 04:15 Vitals: O2 Sat-100%; Blood Pressure-144/64; Respiration-24; Pulse-102; Temperature-97.4 One Hour Reassessment; 05:15 Vitals: O2 Sat-97%; Blood Pressure-122/74; Respiration-24; Pulse-91; Temperature-98.4 Notation in "Patient Progress Notes": "No S/S of transfusion reaction. Vital signs stable." The patient had a decrease in systolic blood pressure of 22 from the transfusion start time (04:15) to the one-hour reassessment time (05:15). The facility failed to define specific transfusion reaction criteria for blood pressure changes. Nursing Physical Assessment; 07:00 Vitals: O2 Sat-99%; Blood Pressure-151/92; Respiration-22; Pulse-93; Temperature-98.3 Transfusion completed at 07:20. The patient had an increase in systolic blood pressure of 29 from the one-hour assessment time (05:15) to the nursing physical assessment time (07:00). The facility failed to define specific transfusion reaction criteria for blood pressure changes. 2. Packed Red Cells; Unit Number W091021155289 Transfusion Start Time: 13:50 Vitals: O2 Sat-98%; Blood Pressure-150/73; Respiration-28; Pulse-82; Temperature-97.8 The patient had a pulse rate decrease of 20 from the start of the first unit (04:15) to the start of the second unit (13:50). The facility failed to define specific transfusion reaction criteria for pulse rate changes. Second Hour Reassessment; 15:55 Vitals: O2 Sat-96%; Blood Pressure-125/52; Respiration-22; Pulse-83; Temperature-97.9 Notation in "Patient Progress Notes": "No change from previous assessment. No S/S of transfusion reaction. Vital signs stable ..." The patient had a decrease in systolic blood pressure of 25 from the start of the transfusion (13:50) to the second-hour reassessment time (15:55). The facility failed to define specific transfusion reaction criteria for blood pressure changes. Transfusion completed 16:30 Vitals: O2 Sat-96%; Blood Pressure-151/69; Respiration-20; Pulse-82; Temperature-98 Notation in "Patient Progress Notes": "Reassessment at time of completion: No change from previous assessment. No S/S of transfusion reaction. Vital signs stable ..." One-hour Post Transfusion 17:30 Vitals: O2 Sat-98%; Blood Pressure-168/84; Respiration-20; Pulse-86; Temperature-98 Notation in "Patient Progress Notes": "One Hour Post Transfusion: No S/S of transfusion reaction. Vital signs stable ..." The patient had an increase in systolic blood pressure of 43 from the second-hour assessment time (15:55) to the one-hour post transfusion time (17:30). The facility failed to define specific transfusion reaction

criteria for blood pressure changes. Vitals taken at 22:30 Vitals: O2 Sat-97%; Blood Pressure-180/86; Respiration-24; Pulse-93; Temperature-98.2 Notation in "Patient Progress Notes": "Reassessment at time of completion: No change from previous assessment." The patient had an increase in systolic blood pressure of 55 from the second-hour assessment time(15:55) to the vitals assessed at 22:30. The facility failed to define specific transfusion reaction criteria for blood pressure changes. b. Patient 239669 Date: 09/09/2021 1. Packed Red Cells; Unit Number W091021324861 Transfusion Start Time: 22:00 Vitals: O2 Sat-100%; Blood Pressure-179/89; Respiration-20; Pulse-88; Temperature-100.8 30-minute Reassessment; 22:30 Vitals: O2 Sat-99%; Blood Pressure-160/55; Respiration-20; Pulse-75; Temperature-99 One Hour Reassessment; 23:00 Vitals: O2 Sat-95%; Blood Pressure-188/53; Respiration-26; Pulse-76; Temperature-98.2 Notation in "Patient Progress Notes": "One Hour Reassessment: No change from previous assessment." The patient had an increase in systolic blood pressure of 28 from the 30-minute assessment (22:30) and a decrease in pulse rate of 12 from the start of the transfusion (22:00). The facility failed to define specific transfusion reaction criteria for blood pressure or pulse rate changes. Transfusion completed 09/10/2021; 01:55 Date: 09/10/2021 2. Packed Red Cells; Unit Number W091021315506 Transfusion Start Time: 13:00 Vitals: O2 Sat-95%; Blood Pressure-147/58; Respiration-16; Pulse-70; Temperature-97.9 Two Hour Reassessment; 15:05 Vitals: O2 Sat-99%; Blood Pressure-182/65; Respiration-17; Pulse-62; Temperature-97.8 Notation in "Patient Progress Notes": "Two Hour Reassessment: No S/S of transfusion reaction. No change from previous assessment" The patient had an increase in systolic blood pressure of 35 from the transfusion start time (13:00) to the two-hour reassessment time (15:05). The facility failed to define specific transfusion reaction criteria for blood pressure changes. c. Patient 235031 Date: 10/01/2021 1. Packed Red Cells; Unit Number W091021319519 Transfusion Start Time: 22:30 Vitals: O2 Sat-94%; Blood Pressure-143/44 Respiration-18; Pulse-78; Temperature-98.5 Two Hour Reassessment; 01:01 Vitals: O2 Sat-95%; Blood Pressure-100/46; Respiration-18; Pulse-78; Temperature-97.5 Notation in "Patient Progress Notes": "Second Hour Reassessment: No changes from previous assessment." The patient had a decrease in systolic blood pressure of 43 from the transfusion start time (22:30) to the two-hour reassessment time (01:01). The facility failed to define specific transfusion reaction criteria for blood pressure changes. Transfusion completed 10/02/2021; 01:45 Date: 10/02/2021 2. Notation in "Patient Progress Notes": "02:30 Blood Transfusion: Transfusion Started: 0230" The facility failed to provide documentation of Blood Bank Number (Unit Number), Blood Product Type, Patient Blood Type, Donor Unit Type, Blood Product Verification, and Patient Identification. Transfusion Start Time: 02:30 Vitals: O2 Sat-98%; Blood Pressure-144/41 Respiration-20; Pulse-71; Temperature-97.6 The patient had an increase in systolic blood pressure of 44 from the second-hour assessment time from the previous unit (01:01) to the transfusion start time of the current unit (02:30). The facility failed to define specific transfusion reaction criteria for blood pressure changes. d. Patient 240129 Date: 10/13/2021 1. Packed Red Cells; Unit Number W091021362705 Transfusion Start Time: 17:08 Vitals: O2 Sat-98%; Blood Pressure-158/72; Respiration-20; Pulse-103; Temperature-98.2 2. Packed Red Cells; Unit Number W091021364706 Transfusion Start Time: 20:50 Vitals: O2 Sat-95%; Blood Pressure-146/71; Respiration-18; Pulse-88; Temperature-97.5 The patient had a pulse rate decrease of 15 from the start of the first unit (17:08) to the start of the second unit (20:50). The facility failed to define specific transfusion reaction criteria for pulse rate changes. 15-Minute Assessment; 21:05 Vitals: O2 Sat-98%; Blood Pressure-170/71; Respiration-18; Pulse-81; Temperature-97.1 Notation in "Patient Progress Notes": "15 Minute Reassessment: No changes from previous assessment, Vital signs stable." The patient had an increase in systolic blood pressure of 24 from the transfusion start time

(10:50) to the 15-minute reassessment time (21:05). The facility failed to define specific transfusion reaction criteria for blood pressure changes. Transfusion completed at 22:45 One-hour Post Transfusion; 23:45 Vitals: O2 Sat-97%; Blood Pressure-134/65; Respiration-17; Pulse-79; Temperature-98 The patient had a decrease in systolic blood pressure of 36 from the transfusion completion time (22:45) to the one-hour post transfusion time (23:45). The facility failed to define specific transfusion reaction criteria for blood pressure changes e. Patient 241314 Date: 10/16 /2021 1. Packed Red Cells; Unit Number W091021332643 Transfusion Start Time: 10:35 Vitals: O2 Sat-96%; Blood Pressure-127/58; Respiration-18; Pulse-80; Temperature-98.1 45-Minute Assessment; 11:20 Vitals: O2 Sat-96%; Blood Pressure-115/60; Respiration-22; Pulse-97; Temperature-98.1 Notation in "Patient Progress Notes": "45 Minute Reassessment: No changes from previous assessment, No S/S of transfusion reaction. Vital signs stable." Second-Hour Reassessment; 12:35 Vitals: O2 Sat-96%; Blood Pressure-174/86; Respiration-20; Pulse-109; Temperature-97.4 Notation in "Patient Progress Notes": "Second Hour Reassessment: No changes from previous assessment, No S/S of transfusion reaction. Vital signs stable." The patient had an increase in systolic blood pressure of 59 from the 45-minute reassessment time (11:20) to the two-hour reassessment time (12:35). The facility failed to define specific transfusion reaction criteria for blood pressure changes. Transfusion completed at 13:35 Vitals: O2 Sat-97%; Blood Pressure-116/59; Respiration-20; Pulse-82; Temperature-98.8 The patient had a decrease in systolic blood pressure of 58 and a decrease in pulse rate of 27 from the second-hour assessment (12:35) to the transfusion completion time (13:35). The facility failed to define specific transfusion reaction criteria for blood pressure or pulse rate changes. 2. Packed Red Cells; Unit Number W091021380365 Transfusion Start Time: 14:00 Vitals: O2 Sat-97%; Blood Pressure-116/59; Respiration-20; Pulse-82; Temperature-98.8 15-minute Reassessment; 14:15 Vitals: O2 Sat-97%; Blood Pressure-140/62; Respiration-20; Pulse-103; Temperature-98.6 Notation in "Patient Progress Notes": "15 Minute Reassessment: No changes from previous assessment, No S/S of transfusion reaction. Vital signs stable." The patient had an increase in systolic blood pressure of 24 and an increase in pulse rate of 21 from the transfusion start time (14:00) to the 15-minute reassessment time (14:15). The facility failed to define specific transfusion reaction criteria for blood pressure or pulse rate changes 30-minute Reassessment; 14:30 Vitals: O2 Sat-97%; Blood Pressure-120/60; Respiration-22; Pulse-100; Temperature-98 Notation in "Patient Progress Notes": "30 Minute Reassessment: No changes from previous assessment, No S/S of transfusion reaction. Vital signs stable." The patient had a decrease in systolic blood pressure of 20 from the 15-minute reassessment time (14:15) to the 30-minute reassessment time (14;30). The facility failed to define specific transfusion reaction criteria for blood pressure changes. 3. Packed Red Cells; Unit Number W091021380365 Transfusion Start Time: 17:45 Vitals: O2 Sat-96%; Blood Pressure-168/85; Respiration-20; Pulse-101; Temperature-98.5 The patient had an increase in systolic blood pressure of 48 from the 30-minute reassessment time (14: 30) of the previous transfused unit to the transfusion start time of the current unit (17: 45). The facility failed to define specific transfusion reaction criteria for blood pressure changes. f. Patient 246101 Date: 10/25/2021 Packed Red Cells; Unit Number W091021389717 Transfusion Start Time: 16:34 Vitals: O2 Sat-98%; Blood Pressure-180/85; Respiration-16; Pulse-70; Temperature-98.4 Second Hour Reassessment; 18: 50 Vitals: O2 Sat-95%; Blood Pressure-150/68; Respiration-16; Pulse-70; Temperature-98.6 Notation in "Patient Progress Notes": "Second Hour Reassessment: No changes from previous assessment, No S/S of transfusion reaction. Vital signs stable." The patient had a decrease in systolic blood pressure of 30 from the transfusion start time (16:34) to the second hour reassessment time (18:50). The facility failed to define specific transfusion reaction criteria for blood pressure

	changes. 5. In an interview on 10/26/2021 at 04:00 pm in the conference room, the laboratory manager and chief nursing officer were asked to provide documentation of specific criteria for blood/blood component transfusion reactions that included interpretation of vital signs obtained during blood administration. No documentation was provided. The laboratory manager and chief nursing officer, after review of facility and laboratory policies, confirmed that the policies failed to include specific signs and symptoms of a transfusion reaction. The chief nursing officer was asked if the vital sign changes of the patients listed above were significant. She confirmed that the vital sign changes were significant. The laboratory manager was asked how many blood products were transfused annually. He stated about 120 blood products were transfused annually. The laboratory manager was asked to provide documentation of transfusion reaction workups performed from January 2020 to present. He stated the laboratory had zero transfusion reactions workups in that time period. This confirmed the above findings. WORD KEY: O2 Sat=Oxygen Saturation S/S=Signs and Symptoms
D5026	IMMUNOHEMATOLOGY CFR(s): 493.1217 If the laboratory provides services in the specialty of Immunohematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493. 1271, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the laboratory's immunohematology records, patient records, and staff interview, the laboratory failed to meet applicable requirements in the specialty of Immunohematology, as evidenced by: 1. The laboratory failed to ensure performance of the quarterly blood bank audible alarm system for 4 of 4 quarters. Refer to D5555 2. The laboratory failed to ensure transfusion reactions were promptly identified, investigated, documented, and recommendations were made to medical staff regarding transfusion procedure improvements for 6 of 8 patients that received blood products. Refer to D5559
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on review of theAmerican Proficiency Institute (API) Proficiency Testing (PT) 2020 and 2021 records, and staff interview, it was revealed the laboratory failed to have documentation of laboratory director review for 1 of 5 Hematology proficiency testing events. Findings included: 1. Review of the laboratory's API proficiency testing 2020 records (Hematology 1st, 2nd, and 3 Events) and 2021 records (Hematology 1st and 2nd Events) revealed the laboratory director failed to document review of the following proficiency testing events: 2021 API Hematology 2nd Event 2. During an interview on 10/26/2021 at 02:26 pm in the conference room, the laboratory manager, after review of the proficiency testing records, confirmed the above findings.

D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on direct observation, review of laboratory policy, laboratory records, and staff interview, it was revealed the laboratory failed to meet analytic systems requirements, as evidenced by: 1. The laboratory failed to include criteria for performing peripheral blood smears and a policy for documentation of slide reviews for 8 of 35 complete blood counts (CBC) with flagged results on the Beckman Coulter UniCel DxH 600 hematology analyzer. Refer to D5403 2. The laboratory failed to ensure relative humidity acceptable ranges were within manufacturer's specifications for the Ortho Clinical Diagnostics Vitros 350 chemistry analyzer and the Tosoh AIA-900 chemistry analyzer and failed to ensure room temperature acceptable ranges were within Alere Triage D-Dimer test device manufacturer's specifications for 10 of 10 months. Refer to D5413 3. The laboratory failed to have a system in place to monitor how many times hematology controls were used within 16 days. Refer to D5417 4. The laboratory failed to ensure daily maintenance was performed on each day of patient testing for 2 of 3 days in October 2020 and 1 of 8 days in February 2021 on the blood bank cell washer instrument. Refer to D5429, I. 5. The laboratory failed to ensure daily and as-needed maintenance was performed for 3 of 21 months on the Beckman Coulter UniCel DxH 600 Hematology analyzer. Refer to D5429, II. 6. The laboratory failed to have a system in place to detect immediate errors, monitor errors over time, and the accuracy and precision of the Ortho Clinical Diagnostics Vitros 350 performance with current and accurate statistical parameters for 26 of 26 analytes. Refer to D5441 7. The laboratory failed to provide data in the risk assessment to support its reduction in QC frequency to every 14 days for the Alere D-Dimer test on the Quidel Triage analyzer. Refer to D5445 8. The laboratory failed to ensure performance of the quarterly blood bank audible alarm system for 4 of 4 quarters. Refer to D5555 9. The laboratory failed to ensure transfusion reactions were promptly identified, investigated, documented, and recommendations were made to medical staff regarding transfusion procedure improvements for 6 of 8 patients that received blood products. Refer to D5559 10. The laboratory failed to evaluate all patient test results after performing test system adjustments for QC flags since the last acceptable test run to ensure accurate and reliable test results for 20 of 20 patients tested for ALKP on 08/18/2021 and 2 of 2 patients tested for AST on 08/29/2021. Refer to D5783
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 Beckman Coulter UniCel DxH 600 operator's manual, laboratory policy, patient records, and confirmed in staff interview, the laboratory failed to include criteria for performing peripheral blood smears and a policy for documentation of slide reviews for 8 of 35 complete blood counts (CBC) with flagged results on the Beckman Coulter UniCel DxH 600 hematology analyzer. Findings included: 1. The Beckman Coulter DxH 600 hematology analyzer operator's manual (B26647AF) stated the following: "Customization: You can customize Flags, Codes, and Messages to suit the needs of your laboratory ...You can also define Decision Rules to identify sample results that meet a set of criteria ...Flags: Flags appear to the right of the result. For some parameters, flagging occurs as a result of the flagging or editing of other parameters ...Several types of messages are generated on the DxH 800 /DxH 600 along with specimen results: Suspect, System, System status, Definitive and Exception ...All system messages are accompanied by R (Review) flags ...Lab Actions: Lab actions triggered by Decision Rules are listed in the Lab Actions area of the patient results screen." 2. Review of the laboratory policies titled, "Hematology" (Reviewed by the laboratory director 10/2021) and "Hematology Staining Procedure" revealed the laboratory failed to include criteria for performing peripheral blood smears for complete blood counts (CBC) with flagged results. . A random review of patient CBC records (01/04/2021 - 01/17/2021 and 10/27/2021 - 10/28/2021) revealed the following CBC results with system messages (flags): a. 01/04/2021; Patient 927842 System message: "Platelet Clumps" Action: "[1] Check for clots. No clots do PLT estimate. Unacceptable clumps, follow lab SOP [2]: slide review The patient's final CBC report failed to document a check for clots, a platelet estimate, or a slide review. b. 01/05/2021; Patient 927842 System message: "Platelet Clumps, Cellular inter" Action: "[1]: if first time of visit perform slide review, check patient history. Call critical and document. [2]: Check sample integrity and rerun. If flag persists, do slide review/manual diff. [3]: Check for clots. No clots do PLT estimate." The patient's final CBC report failed to document a check of the patient's history, a slide review/manual diff, a check for clots, or a PLT estimate. c. 01/05/2021; Patient 927914 System message: "RBC Frag/Micro Definitive: "Anisocytosis 1+, Thrombocytopenia, NRBC's present" Action: "[1]: If first time, Slide Review [2]: Slide Review [3]: Slide Review. If positive, enumerate NRBC. Correct WBC is appropriate" The patient's final CBC report failed to document slide review, an enumeration of NRBC's or a WBC correction. d. 01/09/2021; Patient 928108 System message: "Giant Platelets" Action: "[1]: If first time, Slide Review [2]: Slide Review The patient's final CBC report failed to document a slide review for giant platelets. e. 01/09/2021; Patient 928106 Definitive: "Anisocytosis 2+, Thrombocytopenia" The patient's final CBC report failed to document slide review for anisocytosis or

	thrombocytopenia. f. 01/17/2021; Patient 928338 Suspect message: "NE Blast" NOTE: NE Blast is defined in the Beckman Coulter DxH 600 hematology analyzer operator's manual as "Blasts in the Neutrophil region of the dataplot" The patient's final CBC report failed to document any abnormal white blood cells or blast cells. g. 10/27/2021; Patient 938398 System message: "Giant Platelets" Definitive: "Anisocytosis 1+" Action: "[1]: If first time, Slide Review [2]: Slide Review The patient's final CBC report failed to document a slide review for giant platelets or anisocytosis. h. 10/28/2021; Patient 938200 Definitive: "Hypochromia 1+, Microcytosis 1+, Anisocytosis 2+" The patient's final CBC report failed to document a slide review for hypochromia, microcytosis or anisocytosis. 4. In an interview on 10 /28/2021 at 08:45 am in the conference room, the laboratory manager was asked to provide a policy for performing peripheral blood smear reviews or manual differentials on flagged CBC specimens. No documentation was provided. He stated that whatever the laboratory does for a flagged specimen is programmed into the instrument. The laboratory manager was asked to provide documentation of peripheral blood smear reviews and documentation of the results of the smear (slide) review on the patient's final report. No documentation was provided. This confirmed the above findings. Word Key: PLT=Platelet SOP=Standard Operating Procedure Diff=Differential RBC=Red Blood Cell Frag=Fragment NRBC=Nucleated Red Blood Cells WBC=White Blood Cell
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on direct observation, review of manufacturer's instructions, laboratory environment records (12/2020 - 09/2021) and confirmed in interview, the laboratory failed to ensure relative humidity acceptable ranges were within manufacturer's specifications for the Ortho Clinical Diagnostics Vitros 350 chemistry analyzer and the Tosoh AIA-900 chemistry analyzer and failed to ensure room temperature acceptable ranges were within Alere Triage D-Dimer test device manufacturer's specifications for 10 of 10 months. Findings included: 1. During a tour of the laboratory area on 10/26/2021 at 09:13 am, the following instruments were observed to be use by the laboratory: a. Ortho Clinical Diagnostics Vitros 350 (Serial Number J25005160) b. Tosoh AIA-900 chemistry analyzer (Serial Number 11227408) c. Quidel Triage analyzer (Serial Number 88076) was observed. Triage D-Dimer test cartridges were observed stored at room temperature in a drawer below the instrument. 2. The manufacturer's instructions stated the following: a. Ortho Clinical Diagnostics Vitros 350 Operator's Manual (2016-03-01): "12 Specifications. Operating Environment: Temperature 15.6 C (60F) - 29.4 C (85F); Humidity 15% - 75%" b. Tosoh AIA-900 chemistry analyzer Operator's Manual (Rev. E): "Section 4 ... Installation Environment ...Temperature: 15 - 30C; Humidity: 40 - 80%" c. Triage D-Dimer test cartridge manufacturer's instructions: "Storage and Handling Requirements: ...Once removed from refrigeration, the pouched test device is stable

	for up to 14 days at room temperature, but not beyond the expiration date printed on the pouch ...Before using refrigerated test devices, allow individual foil pouches to reach operating temperature (20C to 24C or 68F to 75F)." 3. Review of the laboratory's environmental records from 12/2020 to 09/2021 revealed an acceptable relative humidity range of 20 - 85%. The laboratory's upper limit of relative humidity exceeded the upper limit of 75% for the Vitros 350 and exceeded the upper limit of 80% for the Tosoh AIA-900 chemistry analyzers. The laboratory failed to ensure relative humidity acceptable ranges were within manufacturer's specifications for the Ortho Clinical Diagnostics Vitros 350 chemistry analyzer and the Tosoh AIA-900 chemistry analyzer. Further review of the laboratory's environmental records revealed an acceptable room temperature range of 65 - 77 F (18 - 25 C). The laboratory's room temperature acceptable lower limit of 65F exceeded the lower limit for the Triage D-Dimer test device (68F) and the laboratory's room temperature upper limit of 77F exceeded the upper limit for the Triage D-Dimer test device (75F). The laboratory failed to ensure room temperature acceptable ranges were within Alere Triage D-Dimer test device manufacturer's specifications. 4. During an interview on 10/28/2021 at 01:50 pm in the conference room, the laboratory manager, after review of the records, confirmed the above findings.
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 surveyor's observations, review of the manufacturer's package insert and Table of Expected Results sheets for the Coulter 6C Controls, review of the laboratory's policies, review of the laboratory's quality control records for the Beckman Coulter DHX 600 hematology analyzer and staff interview it was determined the laboratory failed to have a system in place to monitor how many times hematology controls were used within 16 days. Findings included: 1. Surveyor's observations on 10/27/2021 at 1000 hours in the laboratory revealed the following opened/in use Coulter 6C hematology controls were stored in the refrigerator: Level 1 Lot #123173890, expiration 2021-10-30 Level 2 Lot #133183890, expiration 2021-10-30 Level 3 Lot #143193890, expiration 2021-10-31 2. Review of the manufacturer's package insert (Reference A59925, 628027) for the Coulter 6C Controls revealed: "For open vial stability, refer to the TABLE OF EXPECTED RESULTS for your system." 3.Review of the manufacturer's Table of Expected Results sheets for the Coulter 6C Controls revealed: "16* Open vial Days *Assumes that the Instruction for Use section of the package insert is performed a maximum of 18 times within 16 days." 4. Review of the laboratory's "Quality Control" policy (Date Implemented: 01 /2009; Revised Date: February 2020), under section IV, B. "DHX 600 Hematology" revealed: "Control material is tested and documented according to manufacturer instructions." 5. Review of the laboratory's quality control records for the Beckman Coulter DHX 600 hematology analyzer revealed the laboratory failed to have documentation of recording how many times opened control vials were used within 16 days. 6. In an interview on 10/27/2021 at 1030 hours in the laboratory Testing Person number five (as defined on CMS Form 209 signed by the laboratory director on 10/22 /2021) stated that the laboratory did not document number of uses per opened control vial. 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: I. Based on review of laboratory policy, laboratory blood bank testing records, laboratory maintenance records (01/01/2020-10/26/2021), and confirmed in interview, the laboratory failed to ensure daily maintenance was performed on each day of patient testing for 2 of 3 days in October 2020 and 1 of 8 days in February 2021 on the blood bank cell washer instrument. Findings included: 1. The untitled laboratory policy stated the following: " ...14. Maintenance is to be performed when required and logged in appropriate log sheets ..." 2. A random review of the laboratory's blood bank testing records from 01/01/2020 through 10/26/2021 revealed the following dates when blood bank testing was performed: a. 10/29/2020; Blood typing, Antibody screen, and Compatibility testing for Patient 925494 b. 10/31/2020; Compatibility testing for Patient 925494 c. 02/09/2021; Blood typing for Patient 928822 3. The laboratory maintenance record titled, "Cell Washer and Refrigerator maintenance" listed the following: "Daily Cell Washer: Check tubing and connections; Check interior bowl remove guard; Check saline fill vol [Volume] (32 ml 10%); Initials." Further review of the laboratory cell washer maintenance log from 01/01/2020 through 10/26/2021 revealed the following days the laboratory failed to document cell washer maintenance: 10/29/2020; 10/31/2020; 02/09/2021 The laboratory failed to ensure daily maintenance was performed on each day of patient testing on the blood bank cell washer instrument. 4. During an interview on 10/28/2021 at 10:28 am in the conference room, the laboratory manager, after review of the records, confirmed the above findings. II. Based on direct observation, review of laboratory policy, laboratory maintenance records (01/2020 through 09/2021), and confirmed in interview, the laboratory failed to ensure daily and as-needed maintenance was performed for 3 of 21 months on the Beckman Coulter UniCel DxH 600 Hematology analyzer. Findings included: 1. During a tour of the laboratory area on 10/26/2021 at 09:13 am, a Beckman Coulter UniCel DxH 600 hematology analyzer was observed to be in use. 2. The untitled laboratory policy stated the following: " ...14. Maintenance is to be performed when required and logged in appropriate log sheets ..." 3. The laboratory maintenance record titled, "UniCel DxH Series Cleaning Checklist" list the following: "Daily: Perform Shutdown; Perform Daily Checks-Verify that all results are within limits; Process Controls ...As Needed: Clean the BSV Externally; Clean (Bleach the Aperture); Clean the pneumatic supply module fan filter; Clean the (AMTC) module; Cleaning the STM (Specimen Transport Module); Cleaning the aspiration probe; Cleaning the STM optical sensors; Cleaning the vacuum trap; Cleaning the STM bar code scanner ...Tech Initials" Further review of the laboratory maintenance records revealed the following months in which the laboratory failed to document daily and as-needed maintenance on the Beckman Coulter UniCel DxH 600 Hematology analyzer: July 2020; September 2020; and October 2020 4. During an interview on 10/28/2021 at 08:45am in the conference room, the laboratory manager, after review of the records, confirmed the above findings.
D5441	CONTROL PROCEDURES CFR(s): 493.1256(a)(b)(c)(g)

(a) For each test system, the laboratory is responsible for having control procedures that monitor the accuracy and precision of the complete analytic process. (b) The laboratory must establish the number, type, and frequency of testing control materials using, if applicable, the performance specifications verified or established by the laboratory as specified in 493.1253(b)(3). (c) The control procedures must-- (c)(1) Detect immediate errors that occur due to test system failure, adverse environmental conditions, and operator performance. (c)(2) Monitor over time the accuracy and precision of test performance that may be influenced by changes in test system performance and environmental conditions, and variance in operator performance. (g) The laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:
Based on direct observation, review of laboratory policy, Ortho Clinical Diagnostics Vitros Operator's documentation, manufacturer's package inserts, Ortho Clinical Diagnostics Vitros 5600 chemistry analyzer quality control (QC) records (09/2021), and staff interview, the laboratory failed to have a system in place to detect immediate errors, monitor errors over time, and the accuracy and precision of the Ortho Clinical Diagnostics Vitros 350 performance with current and accurate statistical parameters for 26 of 26 analytes. Findings included: 1. During a tour of the laboratory area on 10 /26/2021 at 09:13 am, a Vitros 350 chemistry analyzer (Serial Number J25005160) was observed to be used for patient testing of following analytes: Albumin (ALB) Alkaline Phosphate (ALKP) Alanine Aminotransferase (ALT) Amylase (AMY) Aspartate Aminotransferase (AST) Blood Urea Nitrogen (BUN) Calcium (Ca) Cholesterol (Chol) Chloride (Cl) Carbon dioxide (CO2) Creatine Kinase (CK) Creatinine (Creat) Direct Bilirubin (DBili) Indirect Bilirubin Glucose (Glu) High Density Lipoprotein (HDL) Potassium (K) Lactate Lipase (Lip) Magnesium (Mg) Phosphorus (Phos) Sodium (Na) Total Bilirubin (TBil) Total Protein (TP) Triglycerides (Trig) Uric Acid 2. The laboratory policy titled, "Chemistry", stated the following: " ...Vitros 350: Two levels for control will be run as per chemistry section of this manual and no patient results will be reported until control values are found to be within the acceptable range ...When Q.C. values fall outside of acceptable range: Reanalyze the control, but do not report the patient results. If the second control results are: within acceptable limits, record control values and report patient results. Still outside acceptable limits, repeat the test using a fresh vial of control, but do not report the patient results. If third control results are: within acceptable limits, record control values and report patient results. Still outside acceptable limits, (indicating failure of the technician, the reagent, or the instrument), the following action should be taken: Check calibration and recalibrate if needed. Check reagent expiration date and any other possible problems with the reagent. Troubleshoot as per the Maintenance and Diagnostics Guide. If problem cannot be revolved, call Technical Service for assistance. Do not report or analyze patient specimens until Quality Control has been run and values are within acceptable limits." 3. The Vitros 350 operator's document titled, "Flags and Codes on Reports" (REF J12329EN), stated the following: " ...Flag: F2; Description QC is at least 2 but less than 3 Standard Deviations ...Condition: The control sample result is at least 2 but less than 3 standard deviations above the QC baseline mean; Suggested Actions: Review control and analyte results on the Quality Control Review and Edit QC. Repeat the test. Flag: F3; Description: QC is at least 3 Standard Deviations; Condition: The control sample result is at least 3 standard deviations above the baseline mean; Suggested Actions: Review control and analyte results on the Quality Control Review and Edit QC. Repeat the test." 4. Review of the package inserts for Vitros Performance Verifier control material Level I (Lot number R7909, expiration date 02/14/2022) and Level II

(Lot number 7911, expiration date 02/11/2022) revealed a "Range of Means" and a "Estimate of within-lab SD" was provided for each chemistry analyte. The package inserts stated the following: "Range of Means: The analyzer mean values should fall within this range ..." A random review of the package inserts revealed the following range of means and within-lab SD for the following analytes: Performance Verifier I AST; Range of Means 30-42; Estimate of within-lab SD= 1.5 ALT; Range of Means 21 - 31; Estimate of within-lab SD= 1.5 ALKP; Range of Means 76 - 127; Estimate of within-lab SD=3.5 Performance Verifier II Uric Acid; Range of Means 10.23 - 11.23; Estimate of within-lab SD= 0.220 CK; Range of Means 735 - 1081; Estimate of within-lab SD=41.7 5. A random review of the laboratory quality control records from 08/2021 revealed the following: a. 08/13/2021 Performance Verifier Level 1; Time performed: 07:58:58 Analyte: ALKP; Control Flag: F2; Result=97 Written on the quality control instrument printout: ALKP "IN 76 - 127" Review of the quality control statistics programmed into the Vitros 350 revealed: Level I ALKP mean= 97; SD=4.0 (Acceptable 2SD range of 89 - 105) The laboratory failed to document any corrective action for the flagged QC result. The laboratory failed to ensure quality control values were within the laboratory's established acceptable ranges (The laboratory based the QC result on the Performance Verifier "range of means" values). The laboratory failed to follow their own procedure for unacceptable QC results. b. 08/29/2021 Performance Verifier Level II; Time performed: 08:07:55 Analyte: Uric (Uric Acid); Control Flag: F2; Result=10.94 Written on the quality control instrument printout: Uric Acid "10.23 - 11.23" with a check mark Analyte: CK; Control Flag: F2; Result=738 Written on the quality control instrument printout: CK "735 - 1081" with a check mark Performance Verifier Level II Uric Acid and CK repeated at 08:22:17 Analyte: Uric; Control Flag: F2; Result=10.97 Analyte: CK; Result=837" Written on the quality control instrument printout: "Uric Acid "10.23 - 11.23" with a check mark Review of the quality control statistics programmed into the Vitros 350 revealed: Level II Uric Acid mean= 10.63; SD=0.300 (Acceptable 2SD range of 10.03 - 11.23) Level II CK mean= 785; SD=40.0 (Acceptable 2SD range of 705 - 865) The laboratory failed to document any corrective action for the second flagged Uric Acid QC result. The laboratory failed to ensure quality control values were within the laboratory's established acceptable ranges (The laboratory based the QC result on the Performance Verifier "range of means" values). The laboratory failed to follow their own procedure for unacceptable QC results. c. Date: 08/30/2021 Performance Verifier Level 1; Time Performed 07:36:11 Analyte: AST; Control Flag: F2; Result=38 Written on the quality control instrument printout: "Rerun" Performance Verifier Level I AST repeated at 08:10:01 Analyte: AST; Control Flag: F2; Result=37 Written on the quality control instrument printout: "30-42" with a check mark. Review of the quality control statistics programmed into the Vitros 350 revealed: Level I AST mean= 34; SD=0.9 (Acceptable 2SD range of 32.2 - 35.8) The laboratory failed to document any corrective action for the second flagged QC result. The laboratory failed to ensure quality control values were within the laboratory's established acceptable ranges (The laboratory based the QC result on the Performance Verifier "range of means" values). The laboratory failed to follow their own procedure for unacceptable QC results. d. Date: 08/31/2021 Performance Verifier Level 1; Time performed: 07:58:58 Analyte: AST; Control Flag: F2; Result=38 Analyte: ALT; Control Flag: F2: Result=29 Written on the quality control instrument printout: AST "30-42'; ALT "21-31" Review of the quality control statistics programmed into the Vitros 350 revealed: Level I AST mean= 34; SD=0.9 (Acceptable 2SD range of 32.2 - 35.8) Level I ALT mean=28; SD= 0.6 (Acceptable 2SD range of 26.8 - 29.2) The laboratory failed to document any corrective action for the flagged QC results. The laboratory failed to ensure quality control values were within the laboratory's established acceptable ranges (The laboratory based the QC result on the Performance

	Verifier "range of means" values). The laboratory failed to follow their own procedure for unacceptable QC results. Performance Verifier Level II; Time performed: 08:05: 14 Analyte: Uric (Uric Acid); Control Flag: F2; Result=10.80 Written on the quality control instrument printout: Uric Acid "10.23 - 11.23" Review of the quality control statistics programmed into the Vitros 350 revealed: Level II URIC Acid mean= 10.63; SD=0.300 (Acceptable 2SD range of 10.03 - 11.23) The laboratory failed to document any corrective action for the flagged QC result. The laboratory failed to ensure quality control values were within the laboratory's established acceptable ranges (The laboratory based the QC result on the Performance Verifier "range of means" values). The laboratory failed to follow their own procedure for unacceptable QC results. 6. In an interview on 10/28/2021 at 11:30 am in the laboratory manager's office, the laboratory manager was asked where the laboratory derived the ranges that were written on the instrument printouts. The laboratory manager stated that those were the ranges provided on the Performance Verifier packet insert and that the laboratory used these range of means as an acceptable QC result range. The laboratory manager was asked why the instrument was giving a control flag for some values that were within the laboratory's statistical parameters. He stated he did not know the reason the instrument flagged the result. The laboratory failed to have a system in place to detect immediate errors, monitor errors over time, and the accuracy and precision of the Ortho Clinical Diagnostics Vitros 350 performance with current and accurate statistical parameters. WORD KEY: SD=Standard Deviation
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 direct observation, review of manufacturer's instructions, laboratory's Individualized Quality Control Plan (IQCP), quality control (QC) records, patient records, and confirmed in interview, the laboratory failed to provide data in the risk assessment to support its reduction in QC frequency to every 14 days for the Alere D-Dimer test on the Quidel Triage analyzer. Findings included: 1. During a tour of the laboratory area on 10/26/2021 at 09:13 am, a Quidel Triage analyzer (Serial Number 88076) was observed. The laboratory used the Quidel Triage to test patient specimens for D-Dimer analyte. 2. The manufacturer's instructions for the Triage D-dimer test system stated the following: " ...Quality Control Considerations: ...Good Laboratory Practice suggests that external controls should be tested with each new lot or shipment of test materials, or every 30 days, and as otherwise required by your laboratory's standard quality control procedures ....Users should follow government guidelines (for examples, federal, state, and local) and/or accreditation requirements for quality control." 3. The laboratory's Individualized Quality Control Plan (IQCP) for the Alere D-Dimer test (signed by the laboratory director 110/26/2021) stated the following: "External QC shall be performed using two levels of control at least every 14 days; upon receipt of new shipments of reagent cartridges and upon lot switches." Further

	review of the laboratory's Individualized Quality Control Plan (IQCP) risk assessment showed that two levels of external controls were performed once daily for D-Dimer from 01/06/2021 to 01/19/2021. The laboratory failed to perform two levels of external QC material every 8 hours of operation for 14 consecutive days for the D-Dimer analyte on the Quidel Triage analyzer to support its reduction in QC frequency to every 14 days. 4. Review of Triage D-Dimer QC records from 09/03/2021 through 10/26/2021 revealed the laboratory performed external quality control once on the following dates: D-Dimer; External QC performed 09/03/2021; 09/17/2021; 10/01 /2021; 10/15/2021 The laboratory failed to perform two levels of external QC material each 8 hours of patient testing for the D-Dimer analyte on the Quidel Triage analyzer. 5. A random review of patient test records from 09/30/2021 through 10/26/2021 revealed the following patients tested for D-Dimer in which the laboratory failed to perform two levels of external quality control material at any time during the day of patient testing: Date of test 09/30/2021; Patient 937370 Date of test 09/30/2021; Patient 937363 Date of test 10/02/2021; Patient 937370 Date of test 10/04/2021; Patient 937542 Date of test 10/05/2021; Patient 937542 Date of test 10/06/2021; Patient 937676 Date of test 10/06/2021; Patient 937655 Date of test 10/07/2021; Patient 937655 Date of test 10/08/2021; Patient 937655 Date of test 10/10/2021; Patient 937804 Date of test 10/11/2021; Patient 937813 Date of test 10/21/2021; Patient 938200 Date of test 10/21/2021; Patient 938213 Date of test 10/23/2021; Patient 938200 Date of test 10/26/2021; Patient 938245 6. In an interview on 10/17 /2021 at 12:16 pm in the conference room, the laboratory manager stated that the laboratory did not perform two levels external quality control material every 8 hours for 14 days for the D-Dimer analyte to support its reduction in frequency to every 14 days for these analytes. This confirmed the above findings.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (c) Blood and blood products storage. Blood and Blood products must be stored under appropriate conditions that include an adequate temperature alarm system that is regularly inspected. (c)(1) An audible alarm system must monitor proper blood and blood product storage temperature over a 24-hour period. (c)(2) Inspections of the alarm system must be documented. (f) Documentation. The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory maintenance logs (01/2020 - 09 /2021) and staff interview it was revealed the laboratory failed to ensure performance of the quarterly blood bank audible alarm system for 4 of 4 quarters. Findings included: 1. Review of the policy titled, "Blood and Blood Product Administration" (Reviewed/Revised 04/22/2013), stated, " ...5. Blood Bank Alarm: A. Alarms within the Blood Bank refrigerators and thermoregulated. When the alarm sounds, it will simultaneously sound at the nurse's station. B. When the Blood Bank Alarm sounds: 1. If the lab tech is in the building, inform them that the alarm is sounding. 2. If the lab tech is not in the building, immediately check the Blood Bank doors to ensure they are closed, and then call the Lab Tech on call to tend to the alarm. 3. Never turn off the alarm off ...." This policy failed to provide a specific procedure to test the Blood Bank alarm system. 2. The laboratory maintenance log titled, "NGH Blood Bank Cell Washer and Refrigerator Maintenance" included a section for "Quarterly Refrigerator (Record Date/Initials) Due January, April, July and October. NOTE: If remote alarm is activated document who called and the time of call." This section of the

	maintenance log required the following to be documented: "Test High Temp. Alarm (Record Alarm Temp) Test High Temp Alarm (Record Alarm Temp) (Warm Water) Test Low Temp. Alarm (Record Alarm Temp) Test Low Temp Alarm (Record Alarm Temp) (Ice) Test the door alarm Test Power Failure alarm ... Check the backup battery for chart recorder Check the backup battery for remote alarm monitoring ..." 3. Further review of the laboratory maintenance logs from 01/2020 - 09/2021 revealed the laboratory failed to ensure performance of Blood Bank Alarm check for October 2020, January 2021, April 2021, and July 2021. 4. During an interview on 10/28/2021 at 08:55 am in the conference room, the laboratory manager was asked to provide documentation of quarterly alarm checks. He stated that the last couple of checks had been missed. This confirmed the above findings. WORD KEY: NGH=Nocona General Hospital
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 review of the laboratory and facility blood/blood product transfusion policies, patient transfusion records (09/02/2021 - 10/25/2021), and staff interview, the laboratory failed to ensure transfusion reactions were promptly identified, investigated, documented, and recommendations were made to medical staff regarding transfusion procedure improvements for 6 of 8 patients that received blood products. Findings included: 1. The laboratory policy titled, "Administrative Policies" (Reviewed and signed by the laboratory director on 06/18/2021) stated the following: " ...3. Transfusion reactions: A. When any clinical findings listed on the transfusion report are present, the transfusion should be stopped immediately. A blood transfusion reaction investigation report must be completed and sent to the laboratory, along with required specimens. The laboratory personnel will then complete the investigation process following appropriate procedures ..." The laboratory policy failed to define clinical criteria for a transfusion reaction. 2. The facility policy titled, "Blood and Blood Product Administration" (Reviewed/Revised 04/22/2013) stated the following: " ...POLICY: 1. General Instructions ...H. Prior to transfusion, blood and/or components are to be checked by two (2) licensed personnel as to the patient's name, blood type, and expiration date, and donor number. Both nurses must sign the Transfusion Flow Sheet in the appropriate blanks ...I. Obtain and document vital signs at fifteen (15), thirty (30), forty-five (45) minutes, and one (1) hours, then every hour on the Transfusion Flow Sheet. Use one Transfusion Flow Sheet per unit ...K. If there is a reaction, stop the blood transfusion and follow instructions on the Transfusion Reaction Investigative Report. Notify the lab tech and physician immediately. The facility policy failed to specify what patient vital signs were to be obtained at the specified times. The facility policy failed to define clinical criteria for a transfusion

	reaction. 3. Review of the facility's patient transfusion records (09/02/2021 - 10/25 /2021) revealed the following 6 of 8 patients in which the facility failed to ensure transfusion reactions were promptly identified, investigated, and documented for all blood products. Refer to D3025. 4. In an interview on 10/26/2021 at 04:00 pm in the conference room, the laboratory manager and chief nursing officer were asked to provide documentation of specific criteria for blood/blood component transfusion reactions that included interpretation of vital signs obtained during blood administration. No documentation was provided. The laboratory manager and chief nursing officer, after review of facility and laboratory policies, confirmed that the policies failed to include specific signs and symptoms of a transfusion reaction. The chief nursing officer was asked if the vital sign changes of the patients listed above were significant. She confirmed that the vital sign changes were significant. The laboratory manager was asked how many blood products were transfused annually. He stated about 120 blood products were transfused annually. The laboratory manager was asked to provide documentation of transfusion reaction workups performed from January 2020 to present. He stated the laboratory had zero transfusion reactions workups in that time period. This 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: Based on review of the laboratory's December 2020 and January 2021 quality control records for the Beckman Coulter DHX 600 hematology analyzer, review of the laboratory analyzer's corrective action documentation, review of the laboratory's Quality Assurance monthly report for January 2021, review of the laboratory's policies and staff interview it was determined the laboratory failed to provide documentation of corrective actions performed for 16 of 17 quality control failures. Findings included: 1. Review of the laboratory's December 2020 and January 2021 quality control records for the Beckman Coulter DHX 600 hematology analyzer revealed: Level 1 control failures occurred on: 12/21/2020 at 15:31 12/22/2020 at 08: 15 12/22/2020 at 15:04 12/31/2020 at 12:50 Level 2 control failures occurred on: 12 /25/2020 at 08:27 01/05/2021 at 08:12 01/06/2021 at 08:16 Level 3 control failures occurred on: 12/15/2020 at 07:59 12/15/2020 at 08:03-repeat failure 01/03/2021 at 13: 00 01/07/2021 at 08:25 01/07/2021 at 08:29-repeat failure 01/08/2021 at 14:31 01/09 /2021 at 16:04 01/10/2021 at 07:54 01/11/2021 at 15:22 2. Review of the laboratory Beckman Coulter DHX 600 hematology analyzer's corrective action documentation revealed no records of documentation of corrective action for any of the above control failures. 3. Review of the laboratory's Quality Assurance monthly report for January 2021 (signed electronically by the Laboratory Advisor on 01/21/2021) revealed: "Hematology - Coulter DXH600 Current Month QC Review All data is acceptable Previous Month QC Review All data is acceptable QAP Review Acceptable

	Maintenance Complete" Note: Quality Assurance monthly report did not address corrective actions for repeat control failures. 4. Review of the laboratory's "Quality Control" policy (Date Implemented: 01/2009; Revised Date: February 2020) revealed: a. Under section V. "Daily QC": "All corrective action is documented and provided with the results" b. Under section VII. "Documentation of corrective action": "All corrective action should be documented on the QC printout with the date and initials of the testing personnel that performed the QC. Repeated problems or errors should be noted and corrective action investigated, documented and followed up on the Quality assurance review." 5. In an interview on 10/27/2021 at 1500 hours in the laboratory the Technical Consultant (as defined on CMS Form 209 signed by the laboratory director on 10/22/2021) was asked to provide documentation of corrective actions for failed QC results. The Technical Consultant stated that corrective actions should have been documented in the instrument itself under comments. This confirmed the findings.
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 review of laboratory policy, a random review of Ortho Clinical Diagnostics Vitros 5600 chemistry analyzer quality control (QC) records (09/2021), patient test records, and confirmed in interview, the laboratory failed to evaluate all patient test results after performing test system adjustments for QC flags since the last acceptable test run to ensure accurate and reliable test results for 20 of 20 patients tested for ALKP on 08/18/2021 and 2 of 2 patients tested for AST on 08/29/2021. Findings included: 1. The laboratory policy titled, "Chemistry", stated the following: " ...Vitros 350: Two levels for control will be run as per chemistry section of this manual and no patient results will be reported until control values are found to be within the acceptable range ...When Q.C. values fall outside of acceptable range: Reanalyze the control, but do not report the patient results. If the second control results are: within acceptable limits, record control values and report patient results. Still outside acceptable limits, repeat the test using a fresh vial of control, but do not report the patient results. If third control results are: within acceptable limits, record control values and report patient results. Still outside acceptable limits, (indicating failure of the technician, the reagent, or the instrument), the following action should be taken: Check calibration and recalibrate if needed. Check reagent expiration date and any other possible problems with the reagent. Troubleshoot as per the Maintenance and Diagnostics Guide. If problem cannot be revolved, call Technical Service for assistance. Do not report or analyze patient specimens until Quality Control has been run and values are within acceptable limits." The laboratory policy titled, "Quality Control" (Revised date February 2020) stated the following: " ...VI. Unacceptable Controls: Testing personnel will troubleshoot controls for all test systems or test systems by referring to the test procedures or instrument manuals. Patient results may not be ran or reported until all controls are acceptable. Once analyzer or reagent issues

	are corrected and QC is in range patient testing can resume. Previously resulted patient samples will be retested to ensure reported results are correct. Begin with the most recently reported patients. If the results are the same/not significantly different, no more patient samples will need retested ..." 2. A random review of the laboratory quality control records and patient test records from 08/2021 revealed the following: a. 08/19/2021 Performance Verifier Level 1; Lot number R7909; Time performed: 07: 20:27 Analyte: ALKP; Control Flag: F2; Result=97 Written on the quality control instrument printout: "Recal'd" and a check mark. The following patients tested for ALKP were not evaluated to ensure accurate and reliable test results since the last acceptable QC run (08/18/2021) after test system adjustments performed on 08/19 /2021: Patient IDs: 11658, 11641, 11644, 11628, 11624, 11620, 11610, 11581, 11596, 11572, 11567, 11549, 11557, 11397, 11370, 11544, 11402, 11537, 11533, 11520 b. 08 /30/2021 Performance Verifier Level 1; Lot number R7909; Time performed: 07:36: 11 Analyte: AST; Control Flag: F2; Result=38 Written on the quality control instrument printout: "Rerun" and "Recal'd" The following patients were tested for AST were not evaluated to ensure accurate and reliable test results since the last acceptable QC run (08/28/2021) after test system adjustments performed on 08/30 /2021: Patient IDs: 12734, 12702 3. During an interview on 10/28/2021 at 11:30 am, the laboratory manager confirmed the laboratory failed to evaluate all patient test results after performing test system adjustments for QC failures and since the last acceptable test run to ensure accurate and reliable test results. WORD KEY: Recal'd=Recalibrated ALKP=Alkaline Phosphate AST=Aspartate Aminotransferase
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 review of laboratory procedures, laboratory quality control records, patient records, and confirmed in staff interview, the laboratory failed to have an effective QA (quality assessment) in place to identify and correct problems for the analytical phase of testing, as evidenced by: 1. The laboratory failed to ensure relative humidity acceptable ranges were within manufacturer's specifications for the Ortho Clinical Diagnostics Vitros 350 chemistry analyzer and the Tosoh AIA-900 chemistry analyzer and failed to ensure room temperature acceptable ranges were within Alere Triage D-Dimer test device manufacturer's specifications for 10 of 10 months. Refer to D5413 2. The laboratory failed to ensure daily maintenance was performed on each day of patient testing for 2 of 3 days in October 2020 and 1 of 8 days in February 2021 on the blood bank cell washer instrument. Refer to D5429, I. 3. The laboratory failed to ensure daily and as-needed maintenance was performed for 3 of 21 months on the Beckman Coulter UniCel DxH 600 Hematology analyzer. Refer to D5429, II. 4. The laboratory failed to have a system in place to detect immediate errors, monitor errors over time, and the accuracy and precision of the Ortho Clinical Diagnostics Vitros 350 performance with current and accurate statistical parameters for 26 of 26 analytes. Refer to D5441 5. The laboratory failed to provide data in the risk assessment to support its reduction in QC frequency to every 14 days for the Alere D-Dimer test on the Quidel Triage analyzer. Refer to D5445 6. The laboratory failed to ensure

	performance of the quarterly blood bank audible alarm system for 4 of 4 quarters. Refer to D5555 7. The laboratory failed to ensure transfusion reactions were promptly identified, investigated, documented, and recommendations were made to medical staff regarding transfusion procedure improvements for 6 of 8 patients that received blood products. Refer to D5559 8. The laboratory failed to provide documentation of corrective actions performed for 16 of 17 quality control failures. Refer to D5781 9. The laboratory failed to evaluate all patient test results after performing test system adjustments for QC flags since the last acceptable test run to ensure accurate and reliable test results for 20 of 20 patients tested for ALKP on 08/18/2021 and 2 of 2 patients tested for AST on 08/29/2021. Refer to D5783
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 direct observation, review of manufacturer's instructions, laboratory policies, patient final reports, and confirmed in interview, the laboratory director failed to provide overall management and direction, as evidenced by: 1. The Laboratory Director failed to ensure laboratory overall operations and test systems were in compliance with regulations. Refer to D6004 2. The Laboratory director failed to ensure that the quality control program was established and maintained to assure the quality of laboratory services provided. Refer to D6020 3. The laboratory director failed to ensure quality assessment programs were established and maintained. Refer to D6021
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) 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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies, laboratory records, patient test reports, and confirmed in staff interview, the Laboratory Director failed to ensure laboratory overall operations and test systems were in compliance with regulations as evidenced by: 1. The laboratory failed to include criteria for performing peripheral blood smears and a policy for documentation of slide reviews for 8 of 35 complete blood counts (CBC) with flagged results on the Beckman Coulter UniCel DxH 600 hematology analyzer. Refer to D5403 2. The laboratory failed to ensure relative humidity acceptable ranges were within manufacturer's specifications for the Ortho Clinical

	Diagnostics Vitros 350 chemistry analyzer and the Tosoh AIA-900 chemistry analyzer and failed to ensure room temperature acceptable ranges were within Alere Triage D-Dimer test device manufacturer's specifications for 10 of 10 months. Refer to D5413 3. The laboratory failed to ensure daily maintenance was performed on each day of patient testing for 2 of 3 days in October 2020 and 1 of 8 days in February 2021 on the blood bank cell washer instrument. Refer to D5429, I. 4. The laboratory failed to ensure daily and as-needed maintenance was performed for 3 of 21 months on the Beckman Coulter UniCel DxH 600 Hematology analyzer. Refer to D5429, II.
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 laboratory policies,laboratory records, patient test reports, and confirmed in staff interview, it was revealed the laboratory director failed to ensure that the quality control program was established and maintained to assure the quality of laboratory services provided, as evidenced by: 1. The laboratory failed to have a system in place to detect immediate errors, monitor errors over time, and the accuracy and precision of the Ortho Clinical Diagnostics Vitros 350 performance with current and accurate statistical parameters for 26 of 26 analytes. Refer to D5441 2. The laboratory failed to provide data in the risk assessment to support its reduction in QC frequency to every 14 days for the Alere D-Dimer test on the Quidel Triage analyzer. Refer to D5445
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 direct observation, review of manufacturer's instructions, laboratory policies, laboratory records, patient final test reports, and confirmed in staff interview, the laboratory director failed to ensure quality assessment programs were established and maintained. Refer to D5793.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) 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; This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Centers for Medicare and Medicaid (CMS -209) form, personnel records, and staff interview, it was revealed the technical consultant failed to ensure the laboratory had documentation of training for performing moderate complexity testing for 2 of 12 testing personnel. Refer to D6066.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(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 Centers for Medicare and Medicaid Services (CMS) -209 form, personnel records, and staff interview, the technical consultant failed to evaluate and document competency in 2020 and 2021 for 6 of 12 Testing Persons (TP-5, TP-6, TP-7, TP-9, TP-11, TP-12) who perform moderate complexity testing. Findings included 1. Review of CMS 209 form revealed laboratory testing was performed by Testing Person-1 through Testing person-12. TP-5 through TP-12 performed only moderate complexity testing. 2. Review of personnel records from 2020 through 10/25 /2021 revealed the following: a. Testing Person-5; Date of Hire 01/08/1990 Annual competency assessment 06/22/2020; conducted by Testing Person-7. Annual competency assessment 06/10/2021; conducted by Testing Person-7. The technical consultant failed to evaluate and document annual competency for TP-5. b. Testing Person-6; Date of Hire 01/29/1999 Annual competency assessment 06/22/2020; conducted by Testing Person-5. Annual competency assessment 06/10/2021; conducted by Testing Person-5. The technical consultant failed to evaluate and document annual competency for TP-6. c. Testing Person-7; Date of Hire 07/17/2005 Annual competency assessment 06/25/2020; conducted by Testing Person-5. Annual competency assessment 06/11/2021; conducted by Testing Person-5. The technical consultant failed to evaluate and document annual competency for TP-7. d. Testing Person-9; Date of Hire 05/01/2020 Annual competency assessment 02/11/2021; conducted by Testing Person-3. The technical consultant failed to evaluate and document annual competency for TP-9. e. Testing Person-11; Date of Hire 04/02 /2019 Annual competency assessment 02/24/2021; conducted by Testing Person-3. The technical consultant failed to evaluate and document annual competency for TP-11. f. Testing Person-12; Date of Hire 10/24/2018 No documentation of 2020 competency assessment provided. Annual competency assessment 09/29/2021; conducted by Testing Person-3. The technical consultant failed to evaluate and document annual competency for TP-12. 3. During an interview on 10/26/2021 at 10: 48 am in the conference room, technical consultant-1 was asked to provide documentation competency assessment performed by the technical consultant for the testing persons listed above. No documentation was provided. This confirmed the above findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES

	CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Centers for Medicare and Medicaid (CMS -209) form, review of laboratory personnel records, and in staff interview, the technical consultant failed to perform testing personnel competency assessments at least semiannually during the first year of patient testing for 2 of 12 testing persons listed on Form CMS-209 who perform moderate complexity testing. Findings included: 1. Review of CMS 209 form revealed laboratory testing was performed by Testing Person-1 through Testing person-12. TP-5 through TP-12 performed only moderate complexity testing. 2. Review of the laboratory's personnel records revealed the laboratory failed to have documentation of personnel competency assessments performed by the technical consultant at least twice the first year of patient testing for the following 2 of 12 testing personnel (as listed on Form CMS-209) who performed moderate complexity: a. Testing Person-9; Date of Hire 05/01/2020 No documentation of six-month competency assessment provided. The technical consultant failed to evaluate and document six-month assessment for TP-9. a. Testing Person-11; Date of Hire 04/02/2019 No documentation of six-month competency assessment provided. No documentation of annual competency assessment provided. The technical consultant failed to evaluate and document six-month and annual competency assessments for TP-11. 3. During an interview on 10/26/2021 at 10:48 am in the conference room, technical consultant-1 was asked to provide documentation semi-annual competency assessments performed by the technical consultant for the testing persons listed above. No documentation was provided. This confirmed the above findings.
D6066	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(4)(ii) Have documentation of training appropriate for the testing performed prior to analyzing patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Centers for Medicare and Medicaid (CMS -209) form, review of the laboratory's personnel records, and in interview with staff, it was revealed the laboratory failed to have documentation of training for the following 2 of 12 testing persons to qualify them to perform moderate complexity testing. Findings included: 1. Review of CMS 209 form revealed laboratory testing was performed by Testing Person-1 through Testing person-12. TP-5 through TP-12 performed only moderate complexity testing. 2. A review of the laboratory's personnel records revealed the laboratory failed to have documentation training for the following 2 of 12 testing personnel (as listed on Form CMS-209) who performed moderate complexity in the laboratory a. Testing Person-9; Date of Hire 05/01/2020 No documentation of training for moderate complexity testing. b. Testing Person-11; Date of Hire 04/02/2019 No documentation of training for moderate complexity testing. 3. During an interview on 10/26/2021 at 10:48 am in the conference room, technical consultant-1 was asked to provide documentation of personnel training for

	the testing persons listed above. No documentation was provided. This confirmed the above findings.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the facility and laboratory blood/blood product transfusion policies, review of facility blood administration educational material, review of patient transfusion records, the laboratory director failed to provide overall management and direction in accordance with 493.1445 of this subpart. The laboratory director failed to ensure testing systems provide quality laboratory services for immunohematology. Refer to D6082.
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 review of the laboratory blood/blood product transfusion policies, review of facility blood administration educational material, and review of patient transfusion records, it was revealed the laboratory director failed to ensure testing systems provide quality laboratory services for immunohematology, as evidenced by: The laboratory failed to ensure transfusion reactions were promptly identified, investigated, documented, and recommendations were made to medical staff regarding transfusion procedure improvements. Refer to D5559.
D6091	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iii) The laboratory director must ensure all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) laboratory's proficiency testing results, and staff interview, it was revealed the laboratory director failed to ensure all proficiency testing results were reviewed. Refer to D5211
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9)

	The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the submitted Center for Medicare & Medicaid Services (CMS) form 209, personnel records, and interview with staff, the Technical Supervisor (TS-1) failed to evaluate competency of 1 of 4 testing persons (TP-1) responsible for high complexity testing, at least semiannually during the first year of testing. Findings included: 1. Review of the CMS 209 form revealed TP-1 through TP-4 perform high complexity testing. 2. Review of the laboratory's personnel records revealed the laboratory failed to have documentation of personnel competency assessments performed by the technical supervisor at least twice the first year of patient testing for the following 1 of 4 testing personnel (as listed on Form CMS-209) who performed high complexity testing complexity: Testing Person-1; Date of Hire 08/21/2020 Documentation of Initial Training: 08/27/2020 Six-month competency assessment: 02 /25/2021 conducted by Testing Person-3 Annual competency assessment: 09/08/2021 conducted by Testing Person-3 The Technical Supervisor failed to evaluate and document semiannual competency assessments for all testing personnel performing high complexity testing. 3. During an interview on 10/26/2021 at 10:48 am in the conference room, the laboratory manager was asked to provide documentation of semiannual competency assessment performed by the Technical Supervisor. No documentation was provided. This confirmed the above findings