| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 37D0472824 | 03/14/2025 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Memorial Hospital Of Texas County Authority | 520 Medical Drive, Guymon, OK | |

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 |
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| **D0000** | The recertification survey was performed on 03/11,12,13,14/2025. The laboratory was found out of compliance with the following CLIA Conditions: 493.1215; D5024: Hematology 493.1217; D5026: Immunohematology 493.1403; D6000 Laboratory Director, Moderate Complexity 493.1441; D6076: Laboratory Director, High Complexity The findings were reviewed with the laboratory director, interim laboratory manager, chief executive officer, respiratory manager, and chief of staff during an exit conference performed at the conclusion of the survey. |
| **D5024** | HEMATOLOGY<br>CFR(s): 493.1215<br><br>If the laboratory provides services in the specialty of Hematology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1269, and 493. 1281 through 493.1299.<br><br>This CONDITION is not met as evidenced by:<br>Based on a review of records, manufacturer's instructions, and interview with the interim laboratory manager, the laboratory failed to ensure the requirements were met for the specialty of Hematology for Coagulation testing during the review period of July 2023 through the current date. Findings include: (1) The laboratory failed to follow the manufacturer's instructions for implementing one of one coagulation reagent. Refer to D5411; (2) The laboratory failed to ensure Dade Innovin reagents had not been used beyond the expiration date; and failed to ensure expired materials were not available for use. Refers to D5417; (3) The laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures. Refer to D5429. |
| **D5026** | IMMUNOHEMATOLOGY<br>CFR(s): 493.1217 |

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| | 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.<br><br>This CONDITION is not met as evidenced by:<br>Based on a review of records, policies and procedures, manufacturer's instructions, observation, and interview with the interim laboratory manager, the laboratory failed to ensure the requirements were met for the specialty of Immunohematology during the review period of April 2023 through the current date. Findings include: (1) The laboratory failed to follow their written policy for labeling blood bank specimens. Refer to D5401; (2) The laboratory failed to ensure expired Blood Bank quality control materials were not available for use. Refer to D5417; (3) The laboratory failed to define a function check protocol to ensure the blood bank pipettes were functioning properly. Refer to D5435; (3) The laboratory failed to perform a negative and positive control material each day of patient Immunohematology testing. Refer to D5449; (4) The laboratory failed to ensure one of one unit of expired fresh frozen plasma was not available for use; and failed to ensure units of blood and blood products were stored under appropriate conditions. Refer to D5555; (5) The laboratory failed to document testing on the blood bank work logbook. Refer to D5789; (6) The laboratory failed to have an ongoing mechanism for performing analytic quality assessment. Refer to D5791. |
| **D5209** | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, written policies, and interview with the interim laboratory manager, the laboratory failed to establish a written general supervisor competency assessment policy, based on the position responsibilities as listed in the Subpart M for one of one person. Findings include: (1) A review of written policies and interview with the interim laboratory manager on 03/12/2025 at 09:20 am identified no evidence of a policy for assessing the competency of the general supervisor; (2) A review of Form CMS-209 (Laboratory Personnel Report) and personnel records for competency assessments performed during the review period of April 2023 through the current date identified no documentation competency assessments had been performed based on position responsibilities for one of one person listed as general supervisor; (3) The findings were reviewed with the interim laboratory manager on 03/12/2025 at 09:30 am, who confirmed the laboratory failed to define and perform assessments based on the specific position responsibilities. |
| **D5311** | SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br>CFR(s): 493.1242(a)<br><br>(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (a)(1) Patient preparation. (a)(2) Specimen collection. (a)(3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (a)(4) Specimen storage and preservation. (a)(5) |

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| | Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, manufacturer's instructions, observation, and interview with the interim laboratory manager, the laboratory failed to follow the manufacturer's instructions for storing patient specimens prior to testing for six of six analytes reviewed. Findings include: (1) On 03/12/2025 at 11:50 am, the interim laboratory manager stated that thyroid stimulating hormone (TSH), Free T4 (FT4), prostate specific antigen (PSA), Vitamin B12, Ferritin, and Folate testing were performed using the Beckman Access 2 analyzer twice weekly and aliquoted serum samples (pending tests) were stored in the chemistry freezer; (2) A review of the manufacturer's product inserts, under the section "Specimen Storage" stated serum /plasma can be stored at 2 to 8 degrees Centigrade for a maximum 48 hours, if testing will be delayed, store at less than -20 C"; (3) Observation of the chemistry freezer on 03/12/2025 at 11:50 am identified patient specimens that had been collected and were awaiting testing being stored warmer than -20 C; (4) A review of temperature records for March 2025, identified that the freezer was warmer than -20 C for 12 of 12 days reviewed; (5) The findings were reviewed with the interim laboratory manager who stated on 03/12/2025 at 11:50 am, the laboratory had not followed the specimen storage requirements. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, policy, and interview with the interim laboratory manager, the laboratory failed to follow their written policy for labeling blood bank specimens during the review period from April 2023 through the current date. Findings include: (1) A review of the blood bank policies and procedure on 03/13 /2025 identified a policy titled, "Blood Bank Transfusion Policy" which stated the following: (a) "Label specimens with Patient Name, DOB, Medical Record Number, Physician, Collector's Initials, Date, and Time." (2) Observation of the contents of the blood bank refrigerator identified a sample collected on 02/19/2025 at 3:00 pm, without the collector's initials; (3) Interview with the interim laboratory manager on 03 /13/2025 at 10:30 am, confirmed that the blood bank specimen had not been labeled according to policy. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>(b) The procedure manual must include the following when applicable to the test procedure: (b)(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. (b)(2) Microscopic examination, including the detection of inadequately prepared slides. (b)(3) Step-by- |

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| | step performance of the procedure, including test calculations and interpretation of results. (b)(4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (b)(5) Calibration and calibration verification procedures. (b)(6) The reportable range for test results for the test system as established or verified in 493.1253. (b)(7) Control procedures. (b)(8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (b)(9) Limitations in the test methodology, including interfering substances. (b)(10) Reference intervals (normal values). (b)(11) Imminently life-threatening test results, or panic or alert values. (b)(12) Pertinent literature references. (b)(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. (b)(14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the hematology policy and procedure manuals, and interview with the interim laboratory manager, the laboratory failed to have a complete written procedure for two of two procedures reviewed. Findings include: (1) On 03/11/2025 at 09:00 am, the interim laboratory manager stated the following: (a) CBC (Complete Blood Count) testing was performed using two hematology analyzers, the Beckman Coulter DXH 600 (primary) and Beckman Coulter DXH 520 (backup); (b) Three levels of QC (quality control) materials were tested each day of patient testing; (c) The manufacturer's provided ranges were used to determine acceptability of QC results. (2) A review of the procedures titled, "Beckman Coulter DXH 600" and "DXH 520" identified the procedure did not include instructions for how the laboratory verified the stated values of new lot numbers of QC materials before they were put into use; (3) The findings were reviewed with the interim laboratory manager who stated on 03/13/2025 at 11:35 am, the CBC procedure had not included all of the required information. |
| **D5411** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(a)<br><br>(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, manufacturer's instructions, observation, and interview with the interim laboratory manager, the laboratory failed to follow the manufacturer's instructions for implementing one of one coagulation reagent reviewed. Findings include: (1) On 03/11/2025 at 09:00 am, the interim laboratory manager stated the following: (a) The laboratory performed PT (Prothrombin Time/International Normalized Ratio) testing using the Sysmex CA-600 Coagulation analyzer (the INR was calculated using the PT normal reference interval mean); (b) Dade Innovin was used as the reagent for the PT testing. (2) On 03/11/2025 at 10:55 am, with the assistance of the interim laboratory manager, the following were observed in the analyzer memory: (a) Dade Innovin lot #564615A was put into use around 09/10/2024 and was currently in use (actual date of implementation could not be determined); (b) The ISI (International Sensitivity Index) that had been programmed in the analyzer |

was 1.07; (c) The Normal Patient Mean that had been programmed in the analyzer was 10.1. (3) On 03/13/2025, a review of the manual titled, "Sysmex CA-600 Installation Guide" Section XIV "Reagent Lot Roll-Over Studies" stated the following procedures should be follow each year before new lots of reagents are put into use: (a) "I. Verification of Reference Range: (i) 20 Normal Individuals (aa) 10 males; 10 females spanning age range. 20 is the minimum requirement for a statistically valid study (bb) Fresh samples preferred but frozen platelet poor plasma may be used if prepared and thawed per CLSI Guidelines (cc) Note medication history. After review of data, history may be used for excluding questionable results that can be attributed to medications. (ii) Assay samples on current and new lot number reagents simultaneously or within 1 hour of each other. This data can be used in Section II. (iii) Calculate mean and 2 SD range. (iv) MNPT for INR calculation must be the geometric mean. (b) II. Method Correlation (i) 40 samples: 20 normal, 20 abnormal (aa) Normal samples (Section I.) may be used for the Method Correlation and Verification of Reference Range (bb) Abnormal samples should span the Reportable Range of assay (ii) Assay samples on current and new lot number reagents simultaneously or within 1 hour of each other. (iii) Calculate Linear Regression statistics. (c) III. Quality Control (i) Assay new lot number of QC material with the new lot of reagent in PTN and APTTN protocols (ii) Collect a minimum of 30 data points over multiple days and stability limits of control. (iii) Calculate the mean, 2 SD and 3 SD range (iv) QC data for PTN and APTTN will be entered under QC Settings for PT and APTT when new reagent lot goes live for QC files to reflect the lot numbers in use." (4) A review of records for lot changes and the manufacturer package inserts for the PT reagent identified the following: (a) The ISI value for the current lot number (#564615A) was 1.04 (inconsistent with the value of 1.07 programmed into the analyzer); (b) There was no evidence to support the "Verification of Reference Range" procedure had been performed; (c) There was no evidence to support the "Method Correlation" procedure had been performed; (d) There was no evidence to support the "Quality Control" procedure to calculate mean, 2 SD and 3 SD (standard deviation) range had been performed. (5) The findings were reviewed with the interim laboratory manager who stated on 03/13/2024 at 04:30 pm, the manufacturer's instructions had not been followed for the Reagent Lot Roll-Over Studies as specified above. EXAMPLES OF PATIENT TESTING (1) The following were examples of PT/INR testing performed when the manufacturer's instructions had not been followed for the Reagent Lot Roll-Over Studies: (a) Patient #44194 - testing performed on 06/11/2024 (b) Patient #44627 - testing performed on 06/16/2024 (c) Patient #45345 - testing performed on 06/23/2024 (d) Patient #45800 - testing performed on 06/27/2024 (e) Patient #46396 - testing performed on 07/05/2024 (f) Patient #47112 - testing performed on 07/12/2024 (g) Patient #47862 - testing performed on 07/19/2024 (h) Patient #48399 - testing performed on 07/25/2024 (i) Patient #48869 - testing performed on 07/31/2024 (j) Patient #48989 - testing performed on 08/01/2024 (k) Patient #49480 - testing performed on 08/06/2024 (l) Patient #50282 - testing performed on 08/13/2024 (m) Patient #51139 - testing performed on 08/20/2024 (n) Patient #52412 - testing performed on 08/30/2024 (o) Patient #52704 - testing performed on 09/02/2024 (p) Patient #53219 - testing performed on 09/06/2024 (q) Patient #54259 - testing performed on 09/13/2024 (r) Patient #55079 - testing performed on 09/20/2024 (s) Patient #55597 - testing performed on 09/27/2024 (t) Patient #56471 - testing performed on 10/05/2024 (u) Patient #56856 - testing performed on 10/08/2024 (v) Patient #57701 - testing performed on 10/16/2024 (w) Patient #58452 - testing performed on 10/26/2024 (x) Patient #58850 - testing performed on 10/31/2024 (y) Patient #59105 - testing performed on 11/03/2024 (z) Patient #59507 - testing performed on 11/07/2024 (aa) Patient #60375 - testing performed on 11/15/2024 (bb) Patient #60938 - testing

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| | performed on 11/21/2024 (cc) Patient #61116 - testing performed on 11/25/2024 (dd) Patient #61494 - testing performed on 12/02/2024 (ee) Patient #62070 - testing performed on 12/07/2024 (ff) Patient #62983 - testing performed on 12/15/2024 (gg) Patient #63666 - testing performed on 12/22/2024 (hh) Patient #64372 - testing performed on 12/31/2024 (ii) Patient #65024 - testing performed on 01/06/2025 (jj) Patient #65654 - testing performed on 01/12/2025 (kk) Patient #66587 - testing performed on 01/20/2025 (ll) Patient #67248 - testing performed on 01/27/2025 (mm) Patient #68082 - testing performed on 02/03/2025 (nn) Patient #69162 - testing performed on 02/11/2025 (oo) Patient #70204 - testing performed on 02/18/2025 (pp) Patient #70898 - testing performed on 02/24/2025 (qq) Patient #71635 - testing performed on 03/01/2025 (rr) Patient #72116 - testing performed on 03/04/2025 (ss) Patient #73135 - testing performed on 03/13/2025 |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>(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: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, observation, and interview with the interim laboratory manager, the laboratory failed to ensure one of one box of Bilirubin Calibrator was stored as required by the manufacturer; and failed to document temperature and humidity as required for 12 of 92 days reviewed. Findings include: BILIRUBIN CALIBRATOR (1) On 03/11/2025 at 02:00 pm, observation of the contents of the chemistry freezer identified the following: (a) One box of bilirubin calibrators, lot # M310580. (2) The storage requirement, as stated on the box for the calibrators was -15 degrees C (Celsius) to -20 degrees C; (3) Observation of the freezer temperature on 03/11/2025 at 2:00 pm identified the current temperature reading as -25 degrees C; (4) A review of the freezer temperature logs from May 1, 2024 to May 31, 2024 identified the following: (a) The temperatures were colder than -20 degrees C for four of 31 days reviewed. (5) The findings were reviewed with the interim laboratory manager who stated on 03/11/2025 at 2:00 pm, the freezer temperatures were not within the manufacturer's storage requirements. RT (ROOM TEMPERATURE) AND RH (RELATIVE HUMIDITY) (1) On 03/11/2025 at 02:00 pm, a review of laboratory temperature and humidity records from July 2024 through September 2024 identified the following; (a) The acceptable range for the temperature was 15-25 degrees Celsius and 20-80% for relative humidity; (b) For 12 of 92 days reviewed, temperature and humidity readings had not been documented as observed by the laboratory. (2) The findings were reviewed with the interim laboratory manager on 03/22/2025 at 2:00 pm, who stated that the temperature and humidity readings had not been documented. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>(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 a review of records, observation and interview with the interim laboratory manager, the laboratory failed to ensure Dade Innovin reagents had not been used beyond the expiration date for one of one lot number; failed to ensure Hematology control materials had not been used beyond the expiration date for two of nine lot numbers; and failed to ensure expired materials were not available for use. Findings include: EXPIRED DADE INNOVIN REAGENTS (1) On 03/11/2025 at 09:00 am, the interim laboratory manager stated the following: (a) The laboratory performed PT /INR (Prothrombin Time/International Normalized Ratio) testing using the Sysmex CA-600 analyzer; (b) Dade Innovin was used as the reagent for the testing. (2) Observation of the laboratory on 03/11/2025 at 09:48 am identified expired Dade Innovin PT reagents as follows: (a) One refrigerated bottle of reconstituted Dade Innovin - lot #564615A with a manufacturer expiration date of 03/03/2025 and no opened date shown on the bottle; (b) Nine bottles of refrigerated unopened Dade Innovin - lot #564615A with a manufacturer expiration date of 03/03/2025. (3) On 03 /13/2025, a review of patient records confirmed patient PT/INR test results had been reported between 03/04/2025 and 03/13/2025 when the laboratory had used the expired reagent as follows: (a) Patient #72039 - testing performed on 03/04/2025 (b) Patient #72116 - testing performed on 03/04/2025 (c) Patient #72311- testing performed on 03/06/2025 (d) Patient #72422 - testing performed on 03/07/2025 (e) Patient #72493 - testing performed on 03/08/2025 (f) Patient #72534 - testing performed on 03/08/2025 (g) Patient #72678 - testing performed on 03/10/2025 (h) Patient #72741 - testing performed on 03/11/2025 (i) Patient #73016 - testing performed on 03/12/2025 (j) Patient #73135 - testing performed on 03/13/2025 (4) The findings were reviewed with the interim laboratory manager who stated on 03/13 /2025 at 10:00 am, the reagent had been used beyond the expiration date. EXPIRED HEMATOLOGY CONTROLS (1) On 03/11/2025 at 09:00 am, the interim laboratory manager stated the following: (a) The laboratory performed CBC (Complete Blood Count) testing using the Beckman Coulter DXH 600 as the primary analyzer; (b) Three levels of QC (quality control) materials were performed each day of patient testing. (2) A review of records for nine lot numbers of QC materials used from 01/19 /2025 through 03/01/2025 identified controls had been used beyond the manufacturer's expiration date for two of nine lot numbers reviewed as follows: (a) Low control lot #123175770 was used from 01/19/2025 through 03/01/2025. The manufacturer's expiration date was 02/28/2025; (b) Normal control lot #133185770 was used from 01/19/2025 through 03/01/2025. The manufacturer's expiration date was 02/28/2025. (3) A review of patient records confirmed patient CBC results had been reported for six patients on 03/01/2025 when the laboratory had used expired QC materials to assess the acceptable performance of the analyzer: (a) Patient #71576 - testing performed on 03/01/2025 at 12:49 am (b) Patient #71582 - testing performed on 03/01/2025 at 09:20 am (c) Patient #71590 - testing performed on 03/01/2025 at 01: 59 pm (d) Patient #71596 - testing performed on 03/01/2025 at 02:00 pm (e) Patient #71609 - testing performed on 03/01/2025 at 05:09 pm (f) Patient #71622 - testing performed on 03/01/2025 at 08:46 pm (4) The findings were reviewed with the interim laboratory manager who stated on 03/13/2025 at 10:00 am, the controls had been used beyond the expiration date. EXPIRED SUPPLIES (1) Observation of the laboratory on 03/11/2025 at 10:23 am, identified the following expired reagents were available for use: (a) One bottle of Beckman Coulter Synchron Systems Antifoam, lot M401494, expired 12/31/2024; (b) Three 1-gallon bottles of 10% Buffered Formalin

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| | reagent (two bottles expired on 07/2023, and one bottle expired on 06/2024 - No lot numbers were listed); (2) Interview with the interim laboratory manager on 03/13 /2025 at 04:15 pm confirmed the expired reagents were available for use. 48517 Based on a review of records, observation and interview with the interim laboratory manager, the laboratory failed to ensure expired Blood Bank quality control materials were not available for use during the review period of April 2023 through the current date; and failed to ensure five of five expired Aptima collection kits were not available for use. Findings include: EXPIRED BLOOD BANK QUALITY CONTROL (1) On 03/13/2025, a review of quality control records for patients tested from 04/01/2024 through the current date identified the following; (i) 07/14/2024 - The Affirmagen reverse typing control cells, lot# 8A777 had expired on 07/09/2024 and were used to ensure the accuracy for the reverse typing of patient #79913, who received two units of packed red blood cells; (ii) 11/14/2024 - The Selectogen and Confidence System quality controls, lot#CNF363 had expired on 11/12/2024 and were used to ensure the accuracy for antibody screen testing performed on patient #8025590 who received two units of packed red blood cells. (2) The findings were reviewed with the interim laboratory manager who stated on 03/13/2025 at 10:00 am the blood bank reagents were expired and used for patient testing. EXPIRED SUPPLIES (1) Observation of the laboratory on 03/11/2025 at 02:00 pm, identified the following expired supplies that appeared to be available for use: (a) Five Aptima collection kits, lot #82192V, expired 10/31/20245. (2) Interview with the interim laboratory manager on 03/11/2025 at 02:00 pm confirmed the expired supplies were available for use. |
| **D5429** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(1)<br><br>(a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, manufacturer's instructions, and interview with the interim laboratory manager, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures for two of two analyzers reviewed from January 2024 through February 2025. Findings include: BECKMAN COULTER DXH 600 (1) On 03/11/2025 at 09:00 am, the interim laboratory manager stated CBC (Complete Blood Count) testing was performed using the Beckman Coulter DXH 600 as the primary method; (2) A review of the manufacturer's maintenance log showed the following required monthly maintenance procedure: (a) Weekly: (i) Restart System Manager (b) Monthly: (i) Clean the STM (Six month or PRN) (ii) Print and export history log. (3) A review of maintenance logs from January 2024 through February 2025 identified maintenance had not been documented as performed as follows: (a) Weekly: (i) Between 04/26/2024 and 05/17 /2024 (ii) Between 02/13/2025 and 02/27/2025 (b) Monthly: (i) Between 01/01/2024 and 03/26/2024 (ii) Between 03/26/2024 and 11/29/2024 (iii) Between 11/29/2025 and 01/28/2025 (iv) Between 01/28/2025 and 02/28/2025 (4) The records were reviewed with the interim laboratory manager who stated on 03/13/2025 at 11:05 am, the maintenance procedures had not been documented as performed as stated above. BECKMAN COULTER DXH 520 (1) On 03/11/2025 at 09:00 am, the interim laboratory manager stated CBC testing was performed using the Beckman Coulter DXH 520 as the backup method; (2) On 3/13/2025, a review of the manufacturer's maintenance checklist showed the following required monthly maintenance |

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| | procedure: (a) Clean the WBC Bath Filter (3) A review of maintenance checklists from January 2024 through February 2025 identified monthly maintenance had not been documented as performed as follows: (a) Between 02/01/2024 and 04/05/2024 (b) Between 05/11/2024 and 07/13/2024 (4) The records were reviewed with the interim laboratory manager who stated on 03/13/2025 at 11:00 am, the monthly maintenance procedure had not been documented as performed as stated above. 48517 Based on a review of records, manufacturer's maintenance checklist, and interview with the interim laboratory manager, the laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures during the review period of July 2023 through the current date. Findings include: (1) On 03/13/2025 at 11:15 am, the interim laboratory manager stated Protime and Activated Partial Prothrombin Time testing were performed using the Sysmex CA-600 series analyzer; (2) A review of the manufacturer's CA-600 maintenance Checklist required the following maintenance procedure: (a) Yearly - "Replace Rinse Filter". (3) A review of maintenance logs from July 2023 through the current date identified the yearly maintenance had not been documented as performed between 07/18/2023 and 03/13 /2025; (4) The findings were reviewed with the interim laboratory manager who stated on 03/13/2025 at 11:15 am the laboratory was unable to provide documentation of maintenance performed as stated above. |
| **D5431** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(a)(2)<br><br>(a)(2) Function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturers established limits before patient testing is conducted. (b) Equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer. The laboratory must do the following:<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, manufacturer's instructions, written policy, and interview with the interim laboratory manager, the laboratory failed to ensure system checks were within the manufacturer's acceptable limits for four of five weeks reviewed. Findings include: (1) On 03/12/2025 at 09:50 am, the interim laboratory manager stated the laboratory performed Ferritin, Folate, Troponin I, Vitamin B12, Vitamin D, Thyroid Stimulating Hormone, and Free T4 testing using the Beckman Access 2 test system: (2) A review of the Access 2 instructions for use stated, "Perform weekly system check, if results are not acceptable, Troubleshoot System Check Results, or contact Technical Support"; (3) A review of the maintenance logs from May 2024 through July 2024 identified the following weekly system check failures: (a) 05/31/2024 to 06/07/2024 - the weekly system check failed; (b) 06/14 /2024 to 06/21/2024 - the weekly system check failed; (c) 06/21/2024 to 06/28/2024 - the weekly system check failed; (d) 06/28/2024 to 07/05/2024 - the weekly system check failed. (4) On 03/12/2025 at 09:50 am, the laboratory interim manager confirmed that the laboratory failed to ensure the weekly system checks were within manufacturer's acceptable limits. |
| **D5435** | MAINTENANCE AND FUNCTION CHECKS<br>CFR(s): 493.1254(b)(2)<br><br>(b)(2)(i) Define a function check protocol that ensures equipment, instrument, and test |

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| | system performance that is necessary for accurate and reliable test results and test result reporting. (b)(2)(ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with the interim laboratory manager, the laboratory failed to have a written function check protocol to ensure the urine centrifuge was functioning properly during the review period of April 2023 through the current date. Findings include: (1) On 03/11/2025 at 09:27 am, the interim laboratory manager stated the laboratory performed urine microscopic testing and urine specimens were processed at a speed of 1500 rpm (revolutions per minute) for 5 minutes using the Ample Scientific centrifuge model F33D; (2) Although the speed and time function checks had been performed semiannually for the urine centrifuge, a function check protocol that defined the frequency of the speed and timer checks and limits of acceptability could not be located; (3) The findings were reviewed with the laboratory manager who confirmed on 03/12/2025 at 11:30 am, although the speed and time function checks had been performed semiannually for the urine centrifuge, there was no written procedure that defined the centrifuge speed and timer function check. 48517 Based on a review of records, policies and procedures, and interview with the interim laboratory manager, the laboratory failed to ensure the Blood Bank pipettes were functioning properly for one of one pipettes during the review period of April 2023 through the current date. Finding include: (1) On 03/13/2025 at 10:00 am, the laboratory manager stated the following: (a) Blood Bank testing, to include ABO /Rh, Antibody Screen, and Compatibility testing were performed using the Ortho ID-MTS gel system; (b) One ID Tipmaster pipette (Serial Number A20401531), a multidelivery pipette (delivering 12.5 microliters, 25 microliters, and 50 microliters), was used for the testing. (2) A review of records from April 2023 through the current date identified for one of one pipette, each volume setting had not been checked during the review period: (3) There was no policy found to address the frequency of pipette calibrations for the pipette; (4) The findings were reviewed with the interim laboratory manager who stated on 03/13/2025 at 10:00 am the laboratory did not have a policy for ensuring pipette functions and the pipette had not been checked during the review period. |
| **D5449** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(3)(ii)(g)<br><br>(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with the laboratory supervisor, the laboratory failed to perform a negative and positive control material each day of patient Immunohematology testing for one of five days reviewed. Findings include: (1) On 03/13/2025 at 1:00 pm, the interim laboratory manager stated that the laboratory performed the following Immunohematology testing: (a) Type and Crossmatch - consisted of ABO/Rh, Antibody Screen and Compatibility Testing. (2) A review of the Immunohematology and quality control records for testing performed in March of 2024 identified quality control testing had not been performed for one of five days when patient Type and Crossmatch testing had been performed as follows: |

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| | (a) Patient #795886 - A Type and Crossmatch had been performed on 03/21/2024; (3) On 03/13/2025 at 1:00 pm, the interim laboratory manager stated there was no evidence quality control testing had been performed as indicated above. |
| **D5479** | CONTROL PROCEDURES<br>CFR(s): 493.1256(e)(5)(g)<br><br>(e)(5) Follow the manufacturer's specifications for using reagents, media, and supplies and be responsible for results.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, manufacturer's instructions, observation, and interview with the interim laboratory manager, the laboratory failed to follow the manufacturer's specifications for storing two of two lot numbers of QC (quality control) materials; and five of five levels of Hemoglobin A1c calibrators. Findings include: BIO-RAD SPECIALTY IMMUNOASSAY CONTROLS (1) On 03/12/2025 at 10:50 am, the interim laboratory manager stated the following: (a) Procalcitonin testing was performed using the Beckman Coulter Access 2 analyzer; (b) Two levels of Bio-Rad Specialty Immunoassay control materials were performed each day of patient testing. (2) Observation of the laboratory freezer on 03/12/2025 at 09:20 am identified aliquots of QC level 1 lot #88761 and level 3 lot #88763 in plastic bullet tubes, without dates of preparation or expiration; (3) A review of the manufacturer's instructions (package insert) for the control materials under "Storage and Stability" stated the following: (a) "Once the control is reconstituted and stored in tightly capped aliquot vials at -20 to -70 C, this product will be stable as follows: (i) All analytes: 30 days." (4) The findings were reviewed with the interim laboratory manager, who stated on 03/23/2023 at 10:00 am, the aliquoted materials had not been dated with the 30 day expiration date. HEMOGLOBIN A1C CALIBRATORS (1) On 03/12/2025 at 10:50 am, the interim laboratory manager stated the following: (a) Hemoglobin A1C testing was performed using the Beckman Coulter DXC 600 analyzer; (b) Five levels of Beckman Coulter Hemoglobin A1C calibrators were routinely used to calibrate the analyzer. (2) Observation of the laboratory freezer on 03/12/2025 at 09:20 am identified aliquots of the five levels of calibrators in plastic bullet tubes, without dates of preparation, expiration, or lot numbers; (3) A review of the manufacturer's instructions (package insert) for the calibrators under "Storage and Stability" stated the following: (a) "Reconstituted calibrators that are aliquoted immediately after reconstitution and stored at -15 to -20 C are stable for 60 days". (4) The findings were reviewed with the interim laboratory manager, who stated on 03/23/2023 at 10:00 am, the aliquoted materials had not been dated with the 60 day expiration date. |
| **D5555** | IMMUNOHEMATOLOGY<br>CFR(s): 493.1271(c)(f)<br><br>(c) Blood shall be stored in a clean and orderly environment in a manner to prevent mix-ups. Expired blood must not be in the routine inventory. Unacceptable units must be segregated from routine inventory. (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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, observation, and interview with the interim laboratory |

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| | manager, the laboratory failed to ensure one of one unit of expired fresh frozen plasma was not available for use; and failed to ensure units of blood and blood products were stored under appropriate conditions during the review period of April 2023 through the current date. Findings include: EXPIRED FRESH FROZEN PLASMA (1) Observation of the blood bank freezer on 03/11/2025 at 02:00 pm identified the following expired material that appeared to be available for use: (a) One unit of AB Positive FP24 (frozen plasma within 24 hours after phlebotomy) Plasma, unit #W091024135072, expired 01/28/2025. (2) Interview with the interim laboratory manager on 03/11/2025 at 2:00 pm confirmed the expired plasma was available for use. REFRIGERATOR AND FREEZER ALARM CHECKS (1) On 03/11/2025 at 02: 00 pm, the interim laboratory manager stated the laboratory stored units of packed red blood cells in the blood bank refrigerator and units of fresh frozen plasma in the blood bank freezer. The units were to be used for patient transfusions; (2) A review of the blood bank policies and procedures on 03/13/2025, identified a policy titled, "Blood Bank Alarms" which stated the following: (a) "Refrigerators and freezers that are used to store blood products for transfusion must be equipped with alarms, which sound in the event of a temperature change which falls out of the acceptable range. These alarms must be tested quarterly to assure their proper function." (3) A review of records from April 2023 through the current date identified no record of refrigerator and freezer alarm checks performed prior to 03/26/2024; (4) Interview with the interim laboratory manager on 03/13/2025 at 10:00 am, confirmed that the alarm checks had not been documented as performed. |
| **D5775** | COMPARISON OF TEST RESULTS<br>CFR(s): 493.1281(a)(c)<br><br>(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with the interim laboratory manager, the laboratory failed to have a system that twice a year evaluated and defined the relationship between test results using different analyzers during the review period of April 2023 through the current date. Findings include: (1) On 03/11/2025 at 09:00 am, the interim laboratory manager stated the following: (a) CBC (Complete Blood Count) testing was performed using two hematology analyzers, the Beckman Coulter DXH 600 (primary) and Beckman Coulter DXH 520 (backup). (2) On 03/13/2025 a review of records from April 2023 through the current date identified no evidence the relationship between the different test methods had been evaluated; (3) The records were reviewed with the interim laboratory manager who stated on 03/13/2025 at 11:31 am, the relationship between the above test methods had not been evaluated at least twice annually during the review period. |
| **D5789** | TEST RECORDS<br>CFR(s): 493.1283(b)<br><br>(b) Records of patient testing including, if applicable, instrument printouts, must be retained. |

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| | This STANDARD is not met as evidenced by:<br>Based on a review of records, policy, and interview with the interim laboratory manager, the laboratory failed to document testing on the blood bank work logbook, during the review period from April 2023 through the current date. Findings include: (1) A review of the blood bank policies and procedure on 03/13/2025, identified a policy titled, "Blood Bank Transfusion Policy" which stated the following: (a) "Blood Bank Work Logbook - Complete the following for ABO/Rh and/or Compatibility testing documentation: (i) Date (ii) Patient label that includes all of the Patient ID information (iii) Blood Bank Band number tag (iv) ABO and Rh reactions and interpretations (v) Blood unit ID label (number) from the unit bag (vi) Compatibility testing reactions and interpretation (vii) Initial of the testing personnel who performed the testing" (2) A review of the Blood Bank Work Logbook identified the following; (a) 03/21/2024 - Patient #795886, there was no documentation of the ABO/Rh reactions for blood units #W091024177909 and #W091024112985; (b) 06/10/2024 - Patient #798223, there was no documentation of testing persons initials on the work book; (c) 06/18/2024 - Patient #798507, there was no documentation of the Rh type for units #W091024240136 and W091024245631; (d) 6/27/2024 - Patient #798696, there was no documentation of the blood bank armband number or the crossmatch interpretation for blood unit #W091024260049; (e) 06/27/2024 - Patient #798696, there was no evidence of ABO/Rh testing or compatibility testing performed for unit #W091024262208; (f) 07/06/2024 - Patient #798869, there was no documentation of AHG testing for blood units #W091024261358 and W091024259808; (g) 11/12/2024 - Patient #802531, there was no documentation of the blood bank armband number, no testing person initials, no documentation of anti-human globulin (AHG) testing, and no documentation of the ABO/Rh type for blood unit #W091024385776; (h) 12/12 /2024 - Patient #803281, there was no documentation of the crossmatch interpretations for blood units #W091024426534 and W091024412292. (3) Interview with the interim laboratory manager on 03/13/2025 at 10:30 am, confirmed that the laboratory failed to document items on the blood bank work logbook according to policy. |
| **D5791** | ANALYTIC SYSTEMS QUALITY ASSESSMENT<br>CFR(s): 493.1289(a)(c)<br><br>(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, manufacturer's instructions, and interview with the interim laboratory manager, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment during the review period of July 2023 through the current date. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified with Coagulation testing: (a) The laboratory failed to follow the manufacturer's instructions for implementing one of one coagulation reagent. Refer to D5411; (b) The laboratory failed to ensure Dade Innovin reagents had not been used beyond the expiration date; and failed to ensure expired materials were not available for use. Refers to D5417; (c) The laboratory failed to ensure the manufacturer's instructions were followed for performing maintenance procedures. Refer to D5429. 48517 Based on a review of written policies and procedures, records, manufacturer instructions, observation, and interview with the |

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| | interim laboratory manager, the laboratory failed to have an ongoing mechanism for performing effective analytic quality assessment during the review period of April 2023 through the current date. Findings include: (1) It was determined the laboratory did not have an effective mechanism for performing analytic quality assessment because of the following issues identified during the survey: (a) The laboratory failed to follow their written policy for labeling blood bank specimens. Refer to D5401; (b) The laboratory failed to ensure expired Blood Bank quality control materials were not available for use. Refer to D5417; (c) The laboratory failed to ensure the Blood Bank pipettes were functioning properly. Refer to D5435; (d) The laboratory failed to perform a negative and positive control material each day of patient Immunohematology testing.Refer to D5449; (e) The laboratory failed to ensure one of one unit of expired fresh frozen plasma was not available for use; and failed to ensure units of blood and blood products were stored under appropriate conditions Refer to D5555; (f) The laboratory failed to document testing on the blood bank work logbook. Refer to D5789. |
| **D5807** | TEST REPORT<br>CFR(s): 493.1291(d)<br><br>(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with the interim laboratory manager and respiratory manager, the laboratory failed to make appropriate reference ranges available for two of two patient reports. Findings include: (1) On 03/12/2025 at 09:27 am, the interim laboratory manager stated the laboratory performed arterial and venous blood gas (pH, pCO2, pO2) testing using the GEM Premiere 5000 analyzer; (2) On 03/12/2025 two patient blood gas reports were reviewed - the first report was for a patient tested on 03/12/2025 at 03:50 pm using arterial specimen; the second report was for a patient tested on 12/19/2024 at 01:19 pm using venous specimen. Both reports included the same reference ranges for the blood gas parameters; (3) The reports were reviewed with the interim laboratory manager and respiratory manager who stated on 03/12/2025 at 04:53 pm, the patient reports did not include specific reference ranges for arterial and venous specimens. |
| **D6000** | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on a review of records, manufacturer's instructions, and interview with the interim laboratory manager, the laboratory director failed to provide overall management and direction during the review period of July 2023 through the current date. Findings include: (1) The laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results. Refer to D6014. |

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| **D6014** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1407(e)(3)(iii)<br><br>(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, manufacturer's instructions, and interview with the interim laboratory manager the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results during the review period of July 2023 through the current date. Findings include: (1) The laboratory director failed to ensure the manufacturer's instructions were followed for implementing one of one coagulation reagent. Refer to D5411; (2) The laboratory director failed to ensure Dade Innovin reagents had not been used beyond the expiration date. Refer to D5417; (3) The laboratory director failed to ensure the manufacturer's instructions were followed for performing maintenance procedures on the coagulation analyzer. Refer to D5429. |
| **D6053** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with the interim laboratory manager, the technical consultant failed to ensure competency evaluations for moderate complexity testing had been performed semiannually during the first year of testing for one of one testing person. Findings include: (1) A review of personnel records for one person performing moderate complexity testing identified the following: (a) Testing Person #7 - The initial training was completed on 05/11/2023. There was no evidence an evaluation had been performed between 05/11/2023 and 04/12/2024. (2) The records were reviewed with the interim laboratory manager who stated on 03/11/2025 at 02:00 pm, a semiannual competency evaluation had not been performed. |
| **D6054** | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(9)<br><br>(b)(9) Thereafter, evaluations must be performed at least annually<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records and interview with the interim laboratory manager, the technical consultant failed to ensure personnel performing moderate complexity testing had been evaluated at least annually for one of ten testing persons during the review period of March 2023 through the current date. Findings include: (1) On 03/11 /2025, a review of personnel records for ten persons performing moderate complexity testing during 2023 and to date in 2025 identified no evidence an annual competency evaluation had been performed for one of ten testing persons as follows: (a) Testing Person #6 - Not performed between 03/27/2024 and 01/07/2025. (2) The records were |

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| | reviewed with the interim laboratory manager who stated on 03/11/2025 at 01:55 pm, the annual evaluations had not been documented as performed. |
| **D6076** | LABORATORY DIRECTOR<br>CFR(s): 493.1441<br><br>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.<br><br>This CONDITION is not met as evidenced by:<br>Based on a review of records, manufacturer's instructions, written policies and procedures and interview with the interim laboratory manager, the laboratory director failed to provide overall management and direction during the review period of April 2023 through the current date. Findings include: (1) The laboratory director failed to ensure that testing systems developed and performed in the laboratory provided quality laboratory services for all aspects of test performance to include the analytic and post analytic phases of testing. Refer to D6082; (2) The laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported. Refer to D6087; (3) The laboratory director failed to ensure quality control programs were established and maintained. Refer to D6093; (4) The laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system. Refer to D6095; (5) The laboratory director failed to ensure procedures were available and followed by personnel. Refer to D6106. |
| **D6082** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(1)<br><br>(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the policy and procedure and interview with the interim laboratory manager, the laboratory director failed to ensure that testing systems developed and performed in the laboratory provided quality laboratory services for all aspects of test performance to include the analytic and post analytic phases of testing during the review period from April 2023 through the current date. Findings include: (1) The laboratory director failed to ensure expired Blood Bank quality control materials were not available for use. Refer to D5789. |
| **D6087** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(3)(iii)<br><br>(e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results;<br><br>This STANDARD is not met as evidenced by: |

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| | Based on a review of records, policy and procedure manual, and interview with the interim laboratory manager, the laboratory director failed to ensure test methods were performed as required by the manufacturer to ensure accurate and reliable results were reported during the review period of January 2024 through the current date. Findings include: (1) The laboratory director failed to ensure expired Blood Bank quality control materials were not available for use. Refer to D5417. |
| **D6093** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(5)<br><br>(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of written policies and procedures, records, manufacturer instructions, observation, and interview with the interim laboratory manager, the laboratory director failed to ensure quality control programs were established and maintained during the review period of April 2023 through the current date. Findings Include: (1) The laboratory director failed to ensure a function check protocol had been defined to ensure the blood bank pipettes were functioning properly. Refer to D5435; (2) The laboratory director failed to ensure a negative and positive control material had been performed each day of patient Immunohematology testing. Refer to D5449; (3) The laboratory director failed to ensure there was an ongoing mechanism for performing analytic quality assessment. Refer to D5791. |
| **D6095** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(6)<br><br>(e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, manufacturer's instructions, and interview with the interim laboratory manager, the laboratory director failed to ensure the establishment and maintenance of acceptable levels of analytical performance for each test system during the review period of April 2023 through the current date. Findings include: (1) The laboratory director failed to ensure units of blood products were stored under appropriate conditions. Refer to D5555. |
| **D6106** | LABORATORY DIRECTOR RESPONSIBILITIES<br>CFR(s): 493.1445(e)(14)<br><br>(e)(14) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; and<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, policy, and interview with the interim laboratory manager, the laboratory director failed to ensure procedures were available and followed by personnel during the review period of April 2023 through March 2025. |

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| | Findings include: The laboratory director failed ensure that staff followed their written policy for labeling blood bank specimens. Refer to D5401. |