Department of Health & Human Services
Centers for Medicare & Medicaid Services

Form Approved
OMB No. 0938-0391

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0508933	(X3) Date Survey Completed 06/26/2025
Name of Provider or Supplier Medical Center Hospital Laboratory	Street Address, City, State 500 W 4th Street, Odessa, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	The laboratory was found to be in compliance with 42 CFR Part 493, Requirements for Laboratories as a result of a validation survey conducted June 24 through June 26, 2025.
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 laboratory policy, laboratory transfusion reaction workups, and confirmed in interview, the laboratory failed to ensure a culture work up for blood units transfused for six of six patients who met the work up criteria for records reviewed from February 2023 through May 2025. The findings included: 1. Review of the laboratory blood bank policy titled "Transfusion Reaction Investigation" included the following instructions: "II. Immediate blood bank workup on all investigations: ... B. Evaluate signs and symptoms: a. If the ONLY signs and symptoms noted include urticaria, hives, itching and/or local erythema (allergic reaction at infusion site) then no serologic testing is required. Stop the investigation here, call pathologist with findings, and report the transfusion reaction as "No evidence of hemolytic transfusion reaction". b. Presence of ANY other sign or symptom with or without the symptoms listed in "1" [sic] above will require serologic evaluation of the reaction. Call the findings to pathologist and continue with "C" below. III. Extended blood bank workup (when indicated): A. Evaluate type of component transfused: a. Red Blood Cells: An adverse reaction to a transfusion containing red cells is regarded as serious and steps will be taken to verify that a hemolytic reaction has not occurred. Continue with "F" below. ... F. Document all findings on transfusion reaction investigation worksheet. ...

	J. If the patient experienced a rise in temperature (greater that or equal to) 2 (degrees) F (1 (degrees) C) then order and set up culture (see Processing Culture on Blood Components policy)." Review of the laboratory blood bank policy titled "Processing Cultures on Blood Components" included the following statement: "Bacterial contamination remains a significant cause of transfusion morbidity and mortality. The blood/component unit will be cultured when the patient's transfusion reaction investigation shows a (greater than or equal to) 1 (degree) C increase in temperature or upon pathologist's request. " 2. Review of laboratory transfusion reaction workups included six patients with a temperature increase greater than or equal to 2 (degrees) F during transfusion initiating a transfusion reaction workup: 01/24/2025: MRN 000457549 Component Transfused: RBC Symptom Reported: Fever Temperature pre-transfusion: 98.1 (degrees)F Temperature post-transfusion: 100.6 (degrees)F Temperature increase: 2.5(degrees) F 02/08/2023: MRN 645877626 Component Transfused: RBC Symptom Reported: Chills, Fever Temperature pre-transfusion 99.3 (degrees)F Temperature post-transfusion: 102.0(degrees)F Temperature increase: 2.7 (degrees) F 05/18/2023: MRN 645835169 Component Transfused: RBC Symptom Reported: Fever, Dyspnea Temperature pre-transfusion: 100.5 (degrees)F Temperature post-transfusion: 102.9 (degrees)F Temperature increase: 2.4 (degrees) F 08/15/2023: MRN000494086 Component Transfused: RBC Symptom Reported: Chills, Fever Temperature pre-transfusion: 98.3 (degrees)F Temperature post-transfusion: 100.5 (degrees) Temperature increase: 2.2 (degrees) F 05/07/2025: MRN 646329001 Component Transfused: RBC Symptom Reported: Fever Temperature pre-transfusion: 98.2 (degrees)F Temperature post-transfusion: 101.2 (degrees) F Temperature increase: 3.0 (degrees) F 05/21/2025: MRN 646277851 Component Transfused: RBC Symptom Reported: Fever Temperature pre-transfusion: 97.8 (degrees)F Temperature post-transfusion: 99.8 (degrees) F Temperature increase: 2.0 (degrees) F Surveyor asked for documentation that the laboratory proceeded with a culture workup on the transfused blood component, to rule in or out bacterial contamination, and none could be provided. 3. In an interview on 6/25/2025 at 11:38 hours, in the office, the blood bank technical supervisor confirmed that a culture workup on the transfused RBC units for the patients whose transfusion reaction investigation showed a greater than or equal to 2 (degree) F increase in temperature. KEY F: Fahrenheit C: Celsius
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) (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) Conditions for specimen transportation. (a)(6) Specimen processing. (a)(7) Specimen acceptability and rejection. (a)(8) Specimen referral. This STANDARD is not met as evidenced by: A. Based on a review of the laboratory's policy, surveyor observation, review of the manufacturer's instructions, patient test records, and staff interview, the laboratory failed to ensure the temperature for two of two patient's blood specimens used for Prothrombin time (PT) testing were maintained during transport on June 26, 2025. Findings include: 1. A review of the laboratory's policy titled 'Specimen Transport' revealed the following: "MCH Laboratory's goal is to ensure that all medical specimens arrive at the testing facility: - At the correct temperature for testing - Intact

	in the container, without breakage or leakage - In the shortest possible time - In compliance with all applicable regulations" 2. Surveyor observation of the laboratory on 6/26/25 at 10:40 a.m. revealed a hospital courier arrived carrying a soft sided cooler with ice packs in the bottom. Four small biohazard bags were removed from the cooler, all containing patient's blood specimens. Two blue top (sodium citrate) tubes were at the bottom of one of the biohazard bags. When the surveyor grabbed the tubes to retrieve the patient's names, both tubes were cold to the touch. 3. An interview with the hospital courier on 6/26/25 at 10:43 a.m. revealed there were no temperature monitors in use to ensure proper temperatures for the specimens were being maintained. 4. A review of the STA- Neoplastine CI Plus Instructions for Use (REF 00606, December 2017) revealed the following: "Specimen Collection and Treatment Blood is collected in 0.109 M (3.2%) trisodium citrate anticoagulant. Centrifugation: 15 minutes at 2000 - 2500 g. Plasma storage: 8 hours at 20 +/- 5 degrees Celsius. Do not store plasma at 2 -8 degrees Celsius." 5. A review of patient test records revealed the following 2 specimens from the above listed shipment were tested for Prothrombin time and resulted on 6/26/25 and the laboratory failed to ensure the temperature of the specimens were maintained during transport: Patient ID: 000516898 Patient ID: 000035531 6. In an interview on 6/26/25 at 12:05 p.m. in the office, after review of the records, technical consultant #2 (as indicated on the CMS 209 form) confirmed the above findings. 49553 B. Based on review of the laboratory's policy, review of the manufacturer's package insert, review, review of the laboratory's instrument records, and confirmed in interview, the laboratory failed to ensure specimen stability for five of six lactic acid tests in 2025 (random review). Findings include: 1. Review of the laboratory's policy titled "Collection, Preservation, and Storage of Chemistry Samples" stated: "PROCEDURE: ...B. Lactic Acid (Lactate) a. To assure the integrity of lactic acid testing, collection must occur in a gray top tube and transported on ice to the lab, where it must be centrifuged within 15 minutes of collection." 2. Review of the manufacturer's package insert titled "cobas LACT2", version 2024-08, V4.0 English stated: "Specimen collection and preparation ... Centrifuge within 15 minutes of collecting the specimen." 3. Review of the laboratory's records determined the laboratory failed to ensure specimen stability for five of six lactic acid tests in 2025 (random review): a. Accession #: 25-175-0456 Collect date/time: 06/24/2025 09:00 AM Centrifuge date/time: 06/24/2025 09:18 AM Time elapsed: 18 minutes Result: 10.8 mmol/L b. Accession #: 25-175-0373 Collect date/time: 06/24/2025 03:10 AM Centrifuge date/time: 06/24/2025 03:58 AM Time elapsed: 48 minutes Result: 10.0 mmol/L c. Accession #: 25-175-0219 Collect date /time: 06/24/2025 02:31 AM Centrifuge date/time: 06/24/2025 03:21 AM Time elapsed: 50 minutes Result: 11.9 mmol/L d. Accession #: 25-175-1872 Collect date /time: 06/24/2025 07:40 PM Centrifuge date/time: 06/24/2025 08:20 PM Time elapsed: 40 minutes Result: 4.1 mmol/L e. Accession #: 25-175-0255 Collect date /time: 06/24/2025 12:29 AM Centrifuge date/time: 06/24/2025 12:54 AM Time elapsed: 25 minutes Result: 11.3 mmol/L 4. Technical consultant-2 (as listed on the CMS-209 form) confirmed the findings in an interview conducted on 06/25/2025 at 1612 hours in the office. Key: mmol/L - millimoles per liter CMS - Centers for Medicare and Medicaid Services
D5317	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(d) (d) If the laboratory accepts a referral specimen, written instructions must be available to the laboratory's clients and must include, as appropriate, the information specified in paragraphs (a)(1) through (a)(7) of this section.

	This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions for use, surveyor observation, the laboratory's records, and staff interview, the laboratory failed to ensure the instructions for outside clients included specimen storage and preservation procedures for prothrombin time (PT) testing for five of five patient specimens received in pour over tubes and tested in June 2025. Findings include: 1. A review of the STA-Neoplastine CI Plus Instructions for Use (REF 00606, December 2017) revealed the following: "Specimen Collection and Treatment Blood is collected in 0.109 M (3.2%) trisodium citrate anticoagulant. Centrifugation: 15 minutes at 2000 - 2500 g. Plasma storage: 8 hours at 20 +/- 5 degrees Celsius. Do not store plasma at 2 -8 degrees Celsius." 2. Surveyor observation of the laboratory on 6/25/25 at 4:00 p.m. revealed 5 patient's plasma specimens in pour over tubes in the Coagulation specimen storage racks. 3. A review of the laboratory's records revealed no documentation that the samples were properly centrifuged per the manufacturer's requirements and platelet poor plasma was produced. 4. Further review of the laboratory's records revealed the patient's specimens were run for PT testing and the results were reported: Patient ID: 000240272 Resulted: 6/23/25 Patient ID: 646332865 Resulted: 6/23/25 Patient ID: 645879886 Resulted: 6/24/25 Patient ID: 646334844 Resulted: 6/24/25 Patient ID: 645821218 Resulted: 6/24/25 5. In an interview on 6/25/25 at 4:07 p.m. in the office, after review of the records, technical consultant #2 (as indicated on the CMS 209 form) confirmed that the laboratory failed to provided instructions to outside clients that included the proper specimen storage and preservation as described by the manufacturer.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory quality control records, and confirmed in interview, the laboratory failed to ensure the documentation and expiration of external quality control (QC) used in for the detection of Chlamydia trachomatis (CT) and/or Neisseria gonorrhoeae (NG) testing on the Cephied GeneXpert RT-PCR system for records 16 of 16 QC records reviewed from January through March 2024 and October through January 2024. The findings included: 1. Review of the laboratory microbiology policy titled "Cepheid Xpert CT/NG Assay Procedure", section "Quality Control" included the following instructions: "Quality Control: A. Test appropriate manufacture recommended QC strains on each new lot /shipment of cartridges before or concurrently with placing materials into use for testing patient specimens using the Xpert CTNG Assay. B. Follow the Microbiologic External control procedure described below: ... f. See the following example for logging in the control into the computer: Sample ID: CTNG POSITIVE CONTROL or CTNG NEGATIVE CONTROL Notes: LOT # (Control Lot #), EXP. (Control Expiration Date)." 2. Review of the Cepheid Xpert CT/NG instrument print outs for 2024 quality control did not include the QC lot number and expiration date for the positive and negative QC reviewed from January 2024 through March 2024 and October 2024 through December 2024: January 2024: QC performed two times. 01/04

	/2024 01/12/2024 February 2024: QC performed three times. 02/07/2024 02/12/2024 02/20/2024 March 2024: QC performed three times. 03/05/2024 03/24/2024 03/25 /2024 October 2024: QC performed three times. 10/03/2024 10/18/2024 10/18/2024 November 2024: QC performed two times. 11/18/2024 11/25/2024 December 2024: QC Performed three times. 12/10/2024 12/17/2024 12/30/2024 Surveyor asked if the QC lot numbers, and expiration dates, were documented elsewhere and none could be provided. 3. In an interview on 6/26/2024 at 11:30 hours, in microbiology, the microbiology technical supervisor and microbiology lead tech confirmed the lot number and expiration date for the QC had not been documented for the records reviewed.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) (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-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. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's records, and staff interview, the laboratory failed to include acceptability criteria for patients utilized in the normal range geometric mean study for the assessment of Prothrombin Time (PT) for one of one new STA Neoplastine CL Plus lot assessments performed in 2024. Findings include: 1. A review of the laboratory's policy titled 'STA Prothrombin Time' revealed the following: "With each new lot of PT reagent, the Reference Time or geometric mean must be manually entered into the analyzer in order for the correct calculation of the INR. Validation of the normal range geometric mean must be confirmed onsite with each new lot of reagent." 2. Further review of the STA Prothrombin Time policy failed to include acceptability criteria for patients utilized to validate the normal range geometric mean study. 3. A review of the laboratory's records revealed the STA Neoplastine CL Plus reagent lot number 270678 normal range geometric mean study was performed on 12/12/24 utilizing the following patient's data: Patient IDs: 243470272, 24370507, 24370596, 243470663, 243470994, 243470794, 243470067, 243471658, 243471760, 243471639, 243471678, 243471001, 243472313, 243472233, 243472231, 243472299, 243472280,

	243472318, 243472637, 243472280 4. In an interview on 6/25/25 at 3:00 p.m. in the office, after review of the records, technical consultant #2 (as indicated on the CMS 209 form) confirmed the above findings.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) (d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based upon review of policies and procedures and interview of facility personnel, the laboratory failed to have documentation of approval of the policy titled QUALITY CONTROL (POCTQA 15). The Findings included: 1. Review of the policy titled Laboratory QA/QM Management Policy found on page 8 under the heading PROCEDURE MANUALS: "The laboratory Medical Director reviews and approves all new policies and procedures as well as substantial changes to existing documents, before implementation." 2. Review of the policy titled QUALITY CONTROL (POCTQA 15) found no documentation of approval by the laboratory director for the dates documented for the date written/ significant revisions dated 2/4/2019 and 1/19 /2021. 3. During interview of the point of care supervisor conducted June 25, 2025 at 2:12 PM, he confirmed the quality control procedure had not been approved by the laboratory director.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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: A. Based upon observations, review of policies and procedures, patient test records and interview of facility personnel, the laboratory failed to ensure 5% Chromic acid was not used for 25 days beyond it's expiration in staining of 10 patient tissue samples. The findings included: 1. Observations made in the Histology department on June 25, 2025 at 11:22 found the laboratory was currently using 5% Chromic acid lot 189463 expiration 2025-05-31. 2. Review of the policy titled Laboratory QA/QM Management Policy found on page 13 under the heading REAGENT USAGE: "Outdated reagents are not used." 3. Review of Special Stain Quality Control logs found The 5% Chromic Acid (used in GMS staining) was used in staining 10 patient tissue samples between June 1 and June 25 as follows: 06/02/2025 - Accession S25-2766 A and S25-2766-B 06/04/2025 - Accession S25-2802 and S25-2805 06/05/2025 - Accession S25-2784 06/06/2025 - Accession S25-2851 06/09/2025 - S25-2895 A and S25-2895-B 06/12/2025 - S25-2981 06/16/2025 - S25-3053 4. During interview of the histotechnician conducted June 25, 2025 at 11:22 AM, she confirmed that she was currently using the expired 5% Chromic Acid to stain tissue specimens. 41687 B. Based on surveyor's observation, a review of patient test records, and staff interview, the laboratory failed to ensure one of ten patient tubes had not exceeded its expiration date prior to using it for patient testing on June 25, 2025. Findings include: 1. Surveyor observation of the coagulation specimen storage racks on 6/25/25 at 11:35 a.

	m., after performing a random visual inspection of tubes, revealed 10 patient specimen tubes had been used for coagulation testing. 2. Further observation of the 10 patient specimen tubes revealed the following patient's tube had exceeded its expiration date: Patient ID: 000515836 Greiner Bio-One Coagulation Sodium Citrate Lot #: B2406336 Expiration date: 6/1/25 3. A review of patient test records confirmed the expired patient specimen tube was used for Prothrombin Time (PT), International Normalized Ratio (INR), and Partial Thromboplastin Time (PTT) testing and values were resulted on 6/25/25. 4. In an interview on 6/25/25 at 4:10 p.m. in the laboratory, after review of the records, technical consultant #2 (as indicated on the CMS 209 form) confirmed the above findings.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) (a)(1) Maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on surveyor direct observation, review of the laboratory's policy, review of the manufacturer's operator's guide, review of the laboratory's maintenance records, and confirmed in interview, the laboratory failed to have documentation of performing maintenance for the Roche Cobas Pro system in 2024. Findings include: 1. During a tour of the laboratory on 06/24/2025 at 0930 hours, the surveyor observed a Roche Cobas Pro system with two separate analytical units located in the laboratory. The units were identified as: Serial Number: 2105-10 Serial Number: 2106-01 2. Review of the laboratory's policy titled "Roche Cobas Pro Maintenance" stated: "Bi-Weekly Maintenance Cleaning Reagent Probes of c503 analytical unit: to ensure optimal condition of the reagent probes and accuracy of the analytical unit, the reagent probes must be manually cleaned at a regular interval ... Cleaning the wash nozzles of the c503 analytical unit: to ensure accurate results, clean the wash nozzles. Regular cleaning prevents contamination, crystal formation and clogging ... Cleaning the reaction cell covers and the ultrasonic mixer covers of the c503 analytical unit: to ensure accurate results, clean the reaction cell covers and the ultrasonic (US) mixer covers. Regular cleaning prevents contamination and crystal formation ... Cleaning the Rinse stations of the c503 analytical unit: to prevent clogging by bacterial growth and precipitation ... Cleaning the rinse stations of the ISE analytical unit: to prevent clogging by bacterial growth and precipitation .... Cleaning the rise and wash stations of the e801 analytical unit: To prevent contamination, clean and rinse the wash stations of the reagent probes, the microbeads mixer, and the ECL sipper nozzles ... Cleaning the ProCell aspiration pipes of the e801 analytical unit: to prevent incorrect results ... Cleaning the ProCell/CleanCell supply nozzles and replacing ProCell /CleanCell cups-e801: To prevent accumulation of crystals ... Cleaning the vortex mixers and separation stations-e801 - Spills on the vortex mixers or separation stations can cause a gripper movement alarm ... Cleaning the incubator disk-e801 - To prevent gripper movement alarms ... Cleaning the microbeads mixer-e801 - To prevent incorrect results ..." 3. Review of the manufacturer's operator guide for the Roche Cobas Pro system stated the following maintenance to be performed every two weeks: "Cleaning the incubator disk - e 801 Cleaning the microbeads mixer - e 801 Cleaning the ProCell aspiration pipes - e 801 Cleaning the ProCell/Clean Cell supply nozzles and replacing ProCell/CleanCell cups - e 801 Cleaning the reaction cell covers and the ultrasonic mixer covers - c 503 Cleaning the reagent probes - c 503 Cleaning the rinse and wash stations - e 801 Cleaning the rinse stations - c 503

	Cleaning the rinse stations - ISE Cleaning the vortex mixers and separation stations - e 801 Cleaning the wash nozzles - c 503" 4. Review of the laboratory's maintenance records determined the manufacturer's maintenance to be performed every two weeks was not documented in 2024: a. Serial Number: 2105-10 February 2024: 02/10/2024 02/24/2024 March 2024: 03/09/2024 03/23/2024 April 2024: 04/06/2024 04/20/2024 May 2024: 05/28/2024 July 2024: 07/20/2024 August 2024: 08/09/2024 September 2024: 09/20/2024 December 2024: 12/06/2024 b. Serial Number: 2106-01 February 2024: 02/25/2024 April 2024 04/07/2024 04/21/2024 May 2024: 05/05/2024 05/19/2024 July 2024: 07/13/2024 August 2024: 08/10/2024 5. Technical consultant-2 (as listed on the CMS-209 form) confirmed the findings during an interview on 06/26/2025 at 1133 hours in the office. Key: CMS - Centers for Medicare and Medicaid Services
D5447	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(i)(g) (d)(3)(i) Each quantitative procedure, include two control materials of different concentrations; This STANDARD is not met as evidenced by: Based on a review of the laboratory's quality control records, patient test records, and staff interview, the laboratory failed to have documentation of running two levels of quality control (QC) material each day of patient testing for the following: a) One of thirty one days reviewed in May 2024 for Complete Blood Count (CBC) testing on the Sysmex XN-10 and XN-20 hematology analyzers. b) One of thirty one days reviewed in December 2024 for Osmolality testing on the OsmoPRO MAX osmometer. Findings include: 1. A review of the laboratory's quality control records revealed the following: a) the laboratory ran 3 levels of XN-CHECK controls (low, normal, and high) every day of patient testing on the Sysmex XN-10 (serial number: 81391) and XN-20 (serial number: 80171) hematology analyzers. b) the laboratory ran 3 levels of Protinol Protein Based Serum Controls (low, normal and high) and 2 levels of Renol Urine Osmolality Controls (low and high) every day of patient testing on the OsmoPRO MAX (serial number: 24050488A) osmometer. 2. Further review of the laboratory's quality control records revealed the laboratory failed to have documentation of running 2 levels of QC material each day of patient testing for the following dates: a) May 26, 2024 for Complete Blood Count (CBC) testing on the Sysmex XN-10 and XN-20 hematology analyzers. b) December 15, 2024 for Osmolality testing (serum and urine) on the OsmoPRO MAX osmometer. 3. A review of patient test records revealed the following patients were tested on days when the laboratory failed to have documentation of running 2 levels of QC material: a) Date: 5/26/24 CBCs were run and resulted on the following 92 patients: 645832015, 646276934, 85986, 427717, 230461, 2823, 139489, 646278097, 646276919, 104423, 646268256, 431536, 456941, 434476, 418635, 513484, 460045, 646278101, 646244507, 430487, 248620, 646237250, 645822833, 517027, 646278113, 252406, 437663, 261991, 48252, 202076, 410522, 80542, 646208621, 433331, 646277239, 488228, 646248051, 743479, 646278105, 66701, 607110, 6286, 14159, 646250740, 646262779, 151497, 646278126, 646230557, 530344, 669110, 558688, 4212, 59695, 646278132, 645989715, 209301, 646261822, 173028, 646278134, 32634, 646278136, 52074, 646229864, 135104, 739968, 96920, 668170, 646253011, 7654, 492815, 124014, 39565, 95528, 60639, 480786, 26154, 646277239, 120071, 179515, 77063, 64682311, 489446, 646278149, 646278144, 421859, 229052, 63214, 100325, 175404, 646147765, 646278164, 646278165 b) Date: 12/15/24 Osmolalitys were run

	and resulted on the following 5 patients: 646310754, 646307841, 645922167, 646310726, 000404424 4. In an interview on 6/26/25 at 10:55 a.m. in the office, after review of the records, technical consultant #2 (as indicated on the CMS 209 form) confirmed the above findings.
D5555	IMMUNOHEMATOLOGY CFR(s): 493.1271(c)(f) (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. This STANDARD is not met as evidenced by: Based on a review of laboratory blood bank temperature records, weekly temperature wheel charts, laboratory policy, and interview, the laboratory failed to challenge the temperature probe connected to the temperature wheel chart as part of the blood banks continuous monitoring system for four of four temperature alarm checks performed in 2024. The findings included: 1. Review of the laboratory blood bank policy titled "Verifying Blood Bank Alarms" included the following statement: "The alarm on each blood/blood product storage refrigerator/freezer/rotator should be checked periodically to assure that it functions properly. If the equipment is new, monthly checks are appropriate until consistent behavior has been demonstrated. Thereafter, quarterly intervals are appropriate if there have been no special problems. The high and low temperature (high only on the plasma freezers) of activation must be checked and the results recorded." 2. The following available blood/blood product storage is as follows: Helmer Refrigerator A1 (EC21001) Helmer Refrigerator C1 (EC21003) Helmer Refrigerator D1 (SN2097937) Helmer Refrigerator E (71586) Helmer Plasma Freezer I Helmer Plasma Freezer J Helmer Plasma Freezer K 3. Review of the monthly laboratory maintenance records for 2024 included the following four months where a quarterly alarm check was initiated with no record of the temperature challenge on the continuous monitoring wheel chart: March 26, 2024 Helmer Refrigerator A1 (EC21001) High Alarm: 5.5 Low Alarm: 1.5 Helmer Refrigerator C1 (EC21003) High Alarm: 5.5 Low Alarm: 1.5 Helmer Refrigerator D1 (SN2097937) High Alarm: 5.5 Low Alarm: 1.5 Helmer Refrigerator E (71586) High Alarm: 5.5 Low Alarm: 1.5 Helmer Plasma Freezer I High Alarm: -19.9 Helmer Plasma Freezer J High Alarm: -19.9 Helmer Plasma Freezer K High Alarm: -19.9 Review of the continuous monitoring wheel charts from 3-25-2024 through 04-01-2024 did not include a temperature variant to match the above temperature alarms. June 23, 2024 Helmer Refrigerator A1 (EC21001) High Alarm: 5.5 Low Alarm: 1.5 Helmer Refrigerator C1 (EC21003) High Alarm: 5.5 Low Alarm: 1.5 Helmer Refrigerator D1 (SN2097937) High Alarm: 5.5 Low Alarm: 1.5 Helmer Refrigerator E (71586) High Alarm: 5.5 Low Alarm: 1.5 Helmer Plasma Freezer I High Alarm: -19.9 Helmer Plasma Freezer J High Alarm: -19.9 Helmer Plasma Freezer K High Alarm: -19.9 Review of the continuous monitoring wheel charts from 06-17-2024 through 06-24-2024 did not include a temperature variant to match the above temperature alarms. September 29, 2024 Helmer Refrigerator C1 (EC21003) High Alarm: 5.5 Low Alarm: 1.5 Helmer Refrigerator D1 (SN2097937) High Alarm: 5.5 Low Alarm: 1.5 Helmer Refrigerator E (71586) High Alarm: 5.5 Low Alarm: 1.5 Helmer Plasma Freezer I High Alarm: -19.9 Helmer Plasma Freezer J High Alarm: -19.9 Helmer Plasma Freezer K High Alarm: -19.9 Review of the continuous monitoring wheel charts from

	09-23-2024 through 09-30-2024 did not include record of the temperature variant to match the above temperature alarms. December 8, 2024 Helmer Refrigerator A1 (EC21001) High Alarm: 5.5 Low Alarm: 1.5 Helmer Refrigerator C1 (EC21003) High Alarm: 5.5 Low Alarm: 1.5 Helmer Refrigerator D1 (SN2097937) High Alarm: 5.5 Low Alarm: 1.5 Helmer Refrigerator E (71586) High Alarm: 5.5 Low Alarm: 1.5 Helmer Plasma Freezer I High Alarm: -19.9 Helmer Plasma Freezer J High Alarm: -19.9 Helmer Plasma Freezer K High Alarm: -19.9 Review of the continuous monitoring wheel charts from 12-2-2024 through 12-9-2024 did not include a temperature variant to match the above temperature alarms. 4. In an interview on 6/25/2025 at 10:32 am, in the office, the blood bank technical supervisor confirmed the laboratory had been performing audible alarm checks for one half of the blood bank storage system, and that the temperature probe used for the continuous monitoring wheel chart was separate from the primary monitor probe and had not been challenged to ensure the accuracy of each part of the alarm system during the alarm checks in 2024.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. This STANDARD is not met as evidenced by: Based upon observations, review of manufacturers instructions, quality control records and interview of facility personnel the laboratory failed to verify the temperature of iSTAT cartridges was acceptable upon receipt of each new shipment before being used for Chemistry and Hematology to test 72,298 specimens in 2024. The findings included: 1. Observations made during the tour of the laboratory found the laboratory maintained a supply of iSTAT cartridges for use by multiple departments throughout the hospital. The cartridges available for use were: Total B-HCG - available to ED Only Creatinine - available to WS- Radiology, CWI Radiology and MCH Radiology Chem8+ - available to ED, Cath lab, ICU2 and ICU4 cTnl (Troponin) - available to ED, ICU2, and ICU4 ACT - available to ICU2, ICU4 and Cath Lab G (Glucose) - available to all units EG7 (ionized Calcium) - available to ICU2 and ICU4 CG8 - available to Main OR and Cath Lab CG4+ (Lactate only)- available to ED, ICU2, ICU4 and Rapid Response 2. Review of the Abbott iSTAT users manual found on page 12-1 under the heading Manufacturer's Quality System instructions: Quality Control: Check Temperature Strip for a New Shipment of Cartridges Verify that the transit temperatures were satisfactory by reading the temperature strip included in each shipping container. 3. Review of Inventory Logs for September through November 2024 found the laboratory failed to verify the transit temperature of shipments was satisfactory for the cartridges received in the following shipments: August 21, 2024 - 100 ACT Celite lot R24192, 200 CG4+ lot D24206, 100 CG8+ lot W24194, 600 Chem8+ lot H24218, 100 Glucose lot K24191 and 200 Troponin lot S24175 September 25, 2024 - 200 CG4+ lot D24235, 200 Troponin lot S24204 September 26, 2024 - 1000 Chem 8+ lot H24258A October 2, 2024 - 100 ACT Celite lot R24237, 200 CG4+ lot D24241, 500 Chem 8+ lot H24263A, 100 G (Glucose) lot K24246, 200 Troponin lot S24226 October 15, 2024 - 300 Troponin lot S24235 October 17, 2024 - 300 Chem8+ lot H24275 November 12, 2024 - 200 ACT Celite lot R24276, 200 CG4+ lot D24274, 200 CG8+ lot W24270 November 15, 2024 - 500 Chem 8+ lot H24312A 4. During interview of the point of care technical

	consultant conducted June 25, 2025 at 3:16 PM she confirmed the temperature strips were not verified with each shipment of iSTAT cartridges.
D5805	TEST REPORT CFR(s): 493.1291(c) (c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of laboratory policy, laboratory documents, laboratory results, patient final reports, and confirmed in interview, the laboratory failed to ensure patient reports included the laboratory name and address for testing performed at a reference laboratory for four out of four random blood bank results reviewed from August 2024 through December 2024. The findings included: 1. Review of the laboratory blood bank policy titled "Referral of Specimens" included the following statement: "Testing, which is shipped out, includes, but is not limited to: Acid elutions, Lui freeze elutions, and Warm Auto antibodies ..." 2. Review of the laboratory blood bank "reference Laboratory Request Forms" included the following patients sent out for testing to be performed at a reference laboratory: Patient MRN: 646291675, sent 8/12/2024 for antibody ID, and DAT testing. Patient MRN: 000057066, sent 10/1/2024 for antibody ID Patient MRN: 646305509, sent 11/7/2024 for antibody ID, and DAT testing. Patient MRN: 000254170, sent 12/14/2024 for antibody ID Review of the laboratory patient final reports for the above patients did not indicate that the testing had been performed at a separate reference laboratory. 3. Review of the laboratory blood bank policy titled "Referral of Specimens" did not include instructions for the identification of those results which were provided by a reference laboratory. 4. In an interview on 6 /25/2025 at 13:50 hours, in the office, the blood bank technical supervisor confirmed the name and address of the laboratory performing the blood bank testing was not on the patient final report.
D5807	TEST REPORT CFR(s): 493.1291(d) (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. This STANDARD is not met as evidenced by: Based on a random review of patient test reports from January 2025 and staff interview, the laboratory failed to include the reference intervals for International Normalized Ratio (INR) on the final reports for 10 of 10 patient's reports reviewed. Findings include: 1. A random review of patient test reports from January 2025 revealed the following 10 patient's final test reports failed to include the reference intervals for INR: Patient ID: 23709 Resulted: 1/1/25 Patient ID: 646312704

	Resulted: 1/1/25 Patient ID: 487482 Resulted: 1/1/25 Patient ID: 646312709 Resulted: 1/1/25 Patient ID: 103506 Resulted: 1/1/25 Patient ID: 215916 Resulted: 1/1/25 Patient ID: 49024 Resulted: 1/1/25 Patient ID: 51237 Resulted: 1/1/25 Patient ID: 44878 Resulted: 1/2/25 Patient ID: 646312049 Resulted: 1/2/25 2. In an interview on 6 /26/25 at 12:30 p.m. in the office, after review of the records, technical consultant #2 (as indicated on the CMS 209 form) confirmed the above findings.
D6030	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12) (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills; This STANDARD is not met as evidenced by: Based upon review of the CMS 209 Laboratory Personnel Report, policies and procedures, personnel records and interview of facility personnel found the laboratory director failed to asses competency for 21 of 21 technical consultants involved in Chemistry and Hematology testing. The findings included: 1. Review of the CMS 209 Laboratory Personnel Report found the laboratory listed 21 individuals as technical consultants. 2. Review of the policy titled Laboratory QA/QM Management Policy (GEN 2020-2) found on page 8 under the heading Personnel Qualifications: "MCH Department of Pathology requires all personnel engaged in the pre-analytic, analytic and post-analytic phases of testing to meet applicable federal, state and local requirements. The laboratory collaborates with the Human Resources Department to hire qualified personnel and ensure that they have and can demonstrate the knowledge and skills to performed their duties." 3. Review of personnel files found no documentation of competency assessments for technical consultants. 4. During interview of the administrative director conducted June 24, 2025 at 11:17 AM, she confirmed that the laboratory director did not assess the competency of technical consultants listed on the CMS report 209.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) (e)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based upon review of the CMS report 209 Laboratory Personnel Report, policies and procedures, personnel records and interview of facility personnel, the laboratory director failed to specify in writing, the duties and responsibilities for 202 testing personnel and 21 technical consultants performing moderate complexity testing procedures in Hematology, Chemistry, Immunohematology and Bacteriology

	procedures. The findings included: 1. Review of the CMS Report 209 Laboratory Personnel Report found the laboratory listed 202 testing personnel and 21 technical consultants performing moderate complexity testing. 2. Review of the policy titled Laboratory QA/QM Management policy (Gen 2020-2) found on page 1 under the heading LABORATORY PERSONNEL AND HIERARCHY: "The Laboratory Medical Director and Administrative Directors and Departmental Supervisors oversee the management of quality and patient safety within the Department of Pathology. The clinical laboratory departments are organized into 7 administrative groups, each managed by a supervisor/coordinator who reports to the laboratory administrative and medical directors. The duties of the supervisors/coordinators are delineated by the laboratory administrative and medical directors. Administrative Groups: Core Lab, Transfusion Services, Microbiology, Phlebotomy, Regional Lab Services, Histology and POCT (Point of Care Testing)." Further review found on page 6 under the heading JOB DESCRIPTIONS: "All department of laboratory services personnel involved in the pre-analytic, analytic and post-analytic phases of testing have written job descriptions." 3. Review of personnel files found no written job descriptions for testing personnel or technical consultants which specifically defined their duties and responsibilities. 4. During interview of the administrative director conducted June 24, 2025 at 11:26, she confirmed the laboratory director did not specify the duties and responsibilities of each testing person and technical consultant. She went on to say they had a written job description for testing personnel, but it was not specific to each person or the specialties in which they performed testing.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) (e)(15) Specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based upon review of the CMS report 209 Laboratory Personnel Report, policies and procedures, personnel records and interview of facility personnel, the laboratory director failed to specify in writing, the duties and responsibilities for 39 testing personnel, 3 technical supervisors and 2 general supervisors performing high complexity testing procedures in Hematology, Chemistry, Immunology and Bacteriology procedures. The findings included: 1. Review of the CMS Report 209 Laboratory Personnel Report found the laboratory listed 39 testing personnel, 3 technical supervisors and 2 general supervisors performing high complexity testing 2. Review of the policy titled Laboratory QA/QM Management policy (Gen 2020-2) found on page 1 under the heading LABORATORY PERSONNEL AND HIERARCHY: "The Laboratory Medical Director and Administrative Directors and Departmental Supervisors oversee the management of quality and patient safety within the Department of Pathology. The clinical laboratory departments are organized into 7 administrative groups, each managed by a supervisor/coordinator who reports to the laboratory administrative and medical directors. The duties of the supervisors/coordinators are delineated by the laboratory administrative and medical directors. Administrative Groups: Core Lab, Transfusion Services, Microbiology, Phlebotomy, Regional Lab Services, Histology and POCT (Point of Care Testing)."

	Further review found on page 6 under the heading JOB DESCRIPTIONS: "All department of laboratory services personnel involved in the pre-analytic, analytic and post-analytic phases of testing have written job descriptions." 3. Review of personnel files found no written job descriptions for testing personnel or supervisors which specifically defined their duties and responsibilities. 4. During interview of the administrative director conducted June 24, 2025 at 11:26, she confirmed the laboratory director did not specify the duties and responsibilities of each testing person and supervisor . She went on to say they had a written job description for testing personnel, but it was not specific to each person or the specialties in which they performed testing.