| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 45D0659938 | 03/02/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Electra Memorial Hospital | 1207 S Bailey, Electra, 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 |
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| **D0000** | An onsite survey conducted 2/28/2023 through 3/2/2023 found the facility in substantial compliance with CLIA regulations (42 CFR Part 493). Standard level deficiencies were cited. |
| **D3025** | REQUIREMENTS FOR TRANSFUSION SERVICES<br>CFR(s): 493.1103(d)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of facility and laboratory blood product policies, patient blood transfusion records/electronic notes, blood transfusion review forms, and confirmed in staff interview, the facility failed to promptly identify, investigate and report blood transfusion reactions to the laboratory for 2 of 4 patients randomly reviewed from December 2022. Findings included: 1. Review of the facility policy "BLOOD PRODUCT TRANSFUSION" revealed: "Suspected Transfusion Reaction 1. If a reaction occurs, it usually manifests within the first 15 minutes of the transfusion. However, transfusion-related adverse events can occur hours after the transfusion is complete. 2. It is the responsibility of the transfusionist to recognize a possible transfusion reaction. Common signs and symptoms associated with a transfusion reaction are: Fever (increase in temperature by 2F or 1C from baseline) Chills/rigors, with or without fever Respiratory distress (Respiratory Rate >28, dyspnea, wheezing, coughing, hypoxemia) Blood pressure changes from baseline (acute hypertension or hypotension, 3OmmHg rise or fall in systolic) Abdominal, chest, flank or back pain Pain at the infusion site Skin manifestations (hives, rash, flushing, itching, or localized edema) Jaundice or darkened (red urine) Nausea with or without vomiting Abnormal bleeding Decreased/no urination Anaphylaxis Transfusion-Related Acute Lung Injury |

(TRALI) TRALI is an acute, often life-threatening clinical syndrome that consists of acute onset (usually within 6 hours after transfusion) of hypoxemia, severe bilateral pulmonary edema on frontal radiographic with no evidence of left atrial hypertension (i.e. circulatory overload). TRALI is indistinguishable from adult respiratory syndrome (ARDS) secondary to other causes (e.g. toxic inhalation, sepsis, or aspiration). These other medical conditions must be considered when evaluating patients for possible TRALI. 3. Immediately stop the transfusion and maintain adequate vascular access with a slow infusion of NS until additional orders are received from a provider. 4. Notify the patient's provider and/or the on-call provider and the Laboratory. 5. Perform an immediate bedside clerical check reviewing the blood product, patient identification information and medical record for correctness. 6. Change the IV set and start a new infusion of KVO with 0.9% normal saline. 7. Monitor and record post-transfusion vital signs and urinary output. 8. Collect first voided urine specimen for lab to examine macroscopically for blood. Place order for Urinalysis in the patient's EHR. 9. Take any measure(s) necessary to stabilize/support the patient throughout the event. 10. The responding provider should evaluate the patient to determine if a transfusion reaction is a possibility, what kind it might be and what immediate medical actions should be undertaken. 11. Circulatory overload or urticarial (hives) need not be evaluated as possible hemolytic transfusion reactions as determined by the physician. Post-transfusion specimens may not be required for evaluation, although the reaction is to be documented. 12. Complete sections 1-5 of the Investigation of Suspected Transfusion Reaction Form, OBI-CL-Form-255 and send to Laboratory. 13. Complete the post-transfusion data information located on the lower section of the Product ID tag (if the unit is permanently discontinued) and send to Laboratory. 14. Place remaining blood product involved in the suspected reaction, intravenous solution being transfused and infusion set in a biohazard bag and send to Laboratory. 15. Document reaction symptoms and actions taken in the patient's EHR. 16. Complete an incident report in the online incident reporting system ... QUALITY ASSURANCE A. Blood Transfusion Review 1. Nursing personnel will initiate a blood transfusion review as soon as possible following all transfusions to ensure all suspected transfusion reactions are identified, documented and addressed. 2. Nursing will refer the blood transfusion review to the Laboratory after the Nursing portion of the review is completed." 2. Review of the laboratory's policy titled "BLOOD PRODUCT TRANSFUSION GUIDELINES" stated: "Suspected Transfusion Reaction 1. Laboratory will be notified if the transfusionist suspects a transfusion reaction based on the following common signs and symptoms: Fever (increase in temperature by 2F or 1C from baseline) Chills/rigors, with or without fever Respiratory distress (Respiratory Rate 28, dyspnea, wheezing, coughing, hypoxemia) Blood pressure changes from baseline (hypertension, hypotension, 3OmmHg rise or fall in systolic) Abdominal chest, flank or back pain Pain at the Infusion site Skin manifestations (hives, rash, flushing, itching, or localized edema) Jaundice or darkened (red urine) Nausea/vomiting Abnormal bleeding Decreased/no urination Anaphylaxis Transfusion-Related Acute Lung Injury (TRALI) TRALI is an acute, often life-threatening clinical syndrome that consists of acute onset (usually within 6 hours after transfusion) of hypoxemia, severe bilateral pulmonary edema on frontal radiographic with no evidence of left atrial hypertension (i.e. circulatory overload). TRALI is indistinguishable from adult respiratory syndrome (ARDS) secondary to other causes (e.g. toxic inhalation, sepsis, or aspiration). These other medical conditions must be considered when evaluating patients for possible TRALI. 2. Report suspected transfusion reactions to the OBI Reference Laboratory at OKC immediately: 405-897-5654. 3. Collect the following post transfusion recipient specimens carefully to avoid hemolysis: 3m1 EDTA tube - purple top 10 ml clot (no additive) tube - red top 4. Ensure the post transfusion specimens are properly labeled

with extra Typenex labels and the following information: Patient's First and Last name Patient's Medical Record number which matches the label used on the requisition Date and time the specimen was collected Phlebotomist initials who performed the blood draw 5. Centrifuge the specimen and place into a biohazard bag. Specimens may be shipped at room temperature (20-24C). 6. Perform urinalysis on first voided urine. 7. Complete sections 6-7 of the Investigation of Suspected Transfusion Reaction Form, OBI-CL-Form-255 once received from Nursing Services. The attending provider will complete sections 8-9. 8. Fax the completed Investigation of Suspected Transfusion Reaction Form to OBI Reference Laboratory (405-297-5639) and then place in the outer pocket of the biohazard bag containing the post transfusion specimens. 9. Order a Transfusion Reaction workup through the OBI Blood Hub. 10. Send the following to the OBI Reference Laboratory: Remaining blood product involved in the suspected reaction, infusion set and intravenous solutions being transfused Post transfusion specimens Completed Investigation of Suspected Transfusion Reaction Form 11. Relay the following information to Laboratory Medical Director as soon as possible: Transfusion Reaction Report Form Transfusion Reaction Investigation Form Blood Transfusion Record (copy) or Blood Bank Flow Chart Any other pertinent lab results and records 12. The Laboratory Director will review OBI's final investigative report of the transfusion reaction and relay it to the Laboratory Manager who will then present it to Hospital Administration and Medical Staff. 13. Initiate an Event Report for the Hospital Quality Assurance /performance improvement Committee." The policy failed to state that the laboratory director and ordering physician should also be notified of a suspected transfusion reaction at the same time the reference laboratory was notified. 3. A random review of blood transfusion patient records and electronic nursing notes (December 2023) revealed the following 2 of 4 patients transfused in which the facility did not follow its own policy to ensure transfusion reactions were promptly identified, investigated and documented for all blood products: a. Patient Account: 4019978 Unit #W09102264633 (first transfused unit) Type: Red Blood Cells Transfusion initiated: 12/06/2022 at 07:05 hours Transfusion ended: 12/06/2022 at 09:35 hours Vital signs documented at baseline 07:05 hours: TEMPERATURE: 96.8 F BLOOD PRESSURE: 97/65 PULSE RATE: 70 RESPIRATORY RATE: 17 Vital signs at end of transfusion 09:35 hours were NOT documented on the transfusion record Vital signs documented in the electronic nursing record at 9:48 hours: TEMPERATURE: 96.5 F BLOOD PRESSURE: 111/71 PULSE RATE: 66 RESPIRATORY RATE: 22 A review of the electronic nursing notes on 12/06/2022 revealed: 07:05 hours: "BLOOD PRODUCTS ... Initiation of Blood Products ... Lung sounds diminished ... Nurses Notes ...LUNG DIMISHED B/L, UNCHANGED." 10:38 hours "BLOOD PRODUCTS ... One hour POST TRANSFUSION assessment ... Lungs sounds with crackles, bil. WILL NOTIFY PROVIDER OF LUNG SOUND CHANGES." 10:49 hours "DAILY ASSESSMENT Nurses Notes: PROVIDER [XX] NOTIFIED OF PT HAVING CRACKLES BILATERALLY IN HER LUNGS ONE HOUR POST ASSESSMENT OF HER FIRST UNIT OF BLOOD ...VORB [sic] FROM [XX] TO CONTINUE WITH INFUSING THE SECOND UNIT OF BLOOD AT A SLOWER INFUSION RATE." Unit #W091022354820 (second transfused unit) Type: Red Blood Cells Transfusion initiated: 12/06/2022 at 11:55 hours Transfusion ended: 12/06/2022 at 15: 20 hours Vital signs documented at baseline 11:55 hours: TEMPERATURE: 96.7 F BLOOD PRESSURE: 123/81 PULSE RATE: 76 RESPIRATORY RATE: 18 Vital signs documented at end of transfusion 15:20 hours: TEMPERATURE: 96.8 F BLOOD PRESSURE: 112/72 PULSE RATE: 63 RESPIRATORY RATE: 20 A review of the electronic nursing note on 12/06/2022 revealed: 11:55 hours "BLOOD PRODUCTS Initiation of Blood Products ... Lung sounds w/crackles bilaterally ... Nurses Notes ... PT HAS CRACKLES BILATERALLY IN LOWER LOBES." 12:10

hours "BLOOD PRODUCTS First 15 Minute Reassessment: No s/s transfusion reaction, Lung sounds w/crackles bilaterally. Nurses Notes ... PT HAS CRACKLES BILATERALLY THAT WAS PRESENT PRIOR TO THE SECOND TRANSFUSION." 12:25 hours "BLOOD PRODUCTS Second 15 Minute Reassessment: Lung sounds w/crackles bilaterally. Nurses Notes ... PT HAS CRACKLES BILATERALLY." 15:20 hours "BLOOD PRODUCTS ... Immediate Post-Transfusion Assessment: No S/S transfusion reaction, Lung sounds w/crackles bilaterally." 16:20 hours "BLOOD PRODUCTS ... One hour POST-TRANSFUSION assessment: No S/S transfusion reaction, Lung sounds with crackles, bil ... Nurses Notes ... pt has crackles bilaterally" During the first transfusion of blood products the patient's lung sounds changed from diminished to crackles bilatreally. The nurse documented "Lungs sounds with crackles, bil. WILL NOTIFY PROVIDER OF LUNG SOUND CHANGES" in the electronic note. She also documented "PROVIDER [XX] NOTIFIED OF PT HAVING CRACKLES BILATERALLY IN HER LUNGS ONE HOUR POST ASSESSMENT OF HER FIRST UNIT OF BLOOD ...VORB [sic] FROM [XX] TO CONTINUE WITH INFUSING THE SECOND UNIT OF BLOOD AT A SLOWER INFUSION RATE." Per facility and laboratory policies, respiratory distress was a sign/symptom of a possible transfusion reaction. The nurse failed to report the possible transfusion reaction to the laboratory. The provider failed to initiate the investigation of suspected transfusion reaction and failed to notify the laboratory director. The facility failed to follow its own policy for transfusion reaction identification. b. Patient Account: 40199714 Unit #W091022302170 (third transfused unit) Type: Red Blood Cells Transfusion initiated: 12/11/2022 at 11:25 hours Transfusion ended: 12/11/2022 at 14:15 hours Vital signs documented at baseline 11:25 hours: TEMPERATURE: 96.1 F BLOOD PRESSURE: 146/78 PULSE RATE: 68 RESPIRATORY RATE: 20 Vital signs documented at end of transfusion 14:15 hours: TEMPERATURE: 98.4 F BLOOD PRESSURE: 159/82 PULSE RATE: 74 RESPIRATORY RATE: 22 A review of the electronic nursing notes on 12/06/2022 revealed: 11:25 hours: "BLOOD PRODUCTS ... Initiation of Blood Products ... Lung sounds clear bilaterally" 11:40 hours "BLOOD PRODUCTS First 15 Minute Reassessment: No S/S transfusion reaction, [sic] Lung sounds diminished." 11:55 hours "BLOOD PRODUCTS Second 15 Minute Reassessment: Lung sounds slight weezes [sic] bilaterally ...No S/S transfusion reaction." 12:25 hours "BLOOD PRODUCTS ... 1 HOUR reassessment: No S/S transfusion reaction, [sic] Lung sounds w/wheezes ... Nurses Notes ... Patient tol well with no adverse effects noted." 14:15 hours "BLOOD PRODUCTS ... Immediate Post-Transfusion Assessment: No S/S transfusion reaction, [sic] Lung sounds diminished ... Nurses Notes ... no adverse reactions noted" 15:13 hours "BLOOD PRODUCTS One hour POST TRANSFUSION Assessment: No S/S of transfusion reaction, [sic] Lung sounds diminished, bil" During the third transfusion of blood products the patient's lung sounds changed from "clear bilaterally" to "diminished" and "wheezes". In the first 15-minute reassessment the nurse documented in the electronic note "No S/S transfusion reaction, [sic] Lung sounds diminished." In the second 15-minute reassessment the nurse documented in the electronic note "Lung sounds slight weezes [sic] bilaterally ...No S/S transfusion reaction." In the 1 hour reassessment "No S/S transfusion reaction, [sic] Lung sounds w/wheezes" was documented in the electronic note. One hour post transfusion assessment electronic note stated: "No S/S of transfusion reaction, [sic] Lung sounds diminished, bil". Per facility and laboratory policies, respiratory distress (wheezing) was a sign/symptom of a possible transfusion reaction. The facility failed to follow its own policy for transfusion reaction identification. 4. Review of the facility's "BLOOD TRANSFUSION REVIEW" audits performed by the facility and laboratory after the completion of blood transfusions for the above patients listed revealed: a. Patient Account: 4019978 "NURSING REVIEW

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| | Unit # 1 Donor ID#: W091022264833 ... Missed Transfusion Reaction identified" blank "Unit # 2 W091022354820 ... Missed Transfusion Reaction identified" blank "Suspected Transfusion Reaction (complete if applicable)" blank "LABORATORY REVIEW ... Transfusion Reaction Review ... Unit #1 ... Failed to Identify Suspected Transfusion Reaction" blank "Unit #2 ... Failed to Identify Suspected Transfusion Reaction" blank "Suspected Transfusion Reaction (if applicable) ... Comments: No suspected transfusion reaction noted." "Clinical Review ... Comments: 3 units were transfused without incident." b. Patient Account: 40199714 "NURSING REVIEW Unit # 3 Donor ID#: W091022302170 ... Missed Transfusion Reaction identified" blank "Suspected Transfusion Reaction (complete if applicable)" blank "LABORATORY REVIEW ... Transfusion Reaction Review ... Unit #3 ... Failed to Identify Suspected Transfusion Reaction" blank "Suspected Transfusion Reaction (if applicable) ... Comments: No suspected transfusion reaction noted." "Clinical Review ... Comments: 3 units transfused without incident." The audits performed by the facility and laboratory failed to identify a possible transfusion reaction. 5. During an interview on 03/02/2023 at 11:10 am, the Director of Nursing after review of the above findings, confirmed the facility failed to ensure transfusion reactions were promptly identified, investigated, documented. During an interview on 03/02/2023 at 11:35 am, the Laboratory Manager after review of the above findings, confirmed the facility failed to ensure transfusion reactions were promptly identified, investigated, documented. Word Key: S/S: signs and symptoms PT/pt: patient bil: bilateral w/: with tol: tolerate |
| **D5311** | SPECIMEN SUBMISSION, HANDLING, AND REFERRAL<br>CFR(s): 493.1242(a)<br><br>The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy, manufacturer's instructions, patient test records, and confirmed in interview, the laboratory failed to ensure patient complete blood count (CBC) specimens were not analyzed beyond the manufacturers stability requirements prior to testing on the Sysmex XN-L 550 hematology analyzer for 5 of 28 specimens in February and March 2023 (random sampling). The findings include: 1. Review of the laboratory policy titled "SYSMEX XN-L 550-revision of slide/diff criteria pg.8-9" revealed: "SPECIMEN ... B. Stored Specimen Stability 1. Specimen stability at room temperature (18-26C) is 24 hours 2. Specimen stability at 2 to 8 C is 48 hours except for the following parameters: -HCT and MCV parameter stability is 24 hours -Baso% parameter stability is 12 hours ..." 2. Review of the Sysmex Basic Operation guide revealed: "Chapter 4 Analyzing Samples ... 4.3 Preparing Samples ... Handling whole blood Mix the venous blood with an anticoagulant (EDTA-2K or EDTA-3K). Draw the amount of venous blood that is specified for the amount of EDTA anticoagulant. The sample should be analyzed within 4 hours after collection. If it is not possible to analyze the sample within 4 hours, store it in a refrigerator at 2 to 8C until it can be analyzed ..." 3. Review of the Sysmex Method Verification Manual revealed: "Section 3 Method Verification Protocols ... It is the customer's responsibility to perform additional studies, following the requirements of their |

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| | accrediting agency. The following protocols are provided: Correlation Studies (CAS assists) Sensitivity Studies (See Resource Manual) Reference Range Verification (See Resource Manual) Stability Study (See Resource Manual) Mixing Study (See Resource Manual) Typically, method verification studies are performed on new analyzers to verify and document satisfactory analyzer performance according to the manufacturer's specifications. It is up to the laboratory to perform more extensive studies if they deem it necessary to satisfy requirements over and above what is contained in these protocols." Review of the Stability Study section from the Method Verification Manual stated: "Stability Study (for Customer Reference Only) Stability studies may be performed to determine the readiness of a sample for CBC, differential and reticulocyte count analysis. Short term stability may be performed with fresh samples drawn and analyzed at intervals within one (1) hour. Long term stability is conducted under storage conditions and over a period of time defined by the laboratory as acceptable for specimen analysis. Typical long term studies include analysis of room temperature (18-26C) and refrigerated (4C) samples at intervals from zero to 48, 56 or 72 hours." 3. During an interview on 03/01/2023 at 12:18 p.m., the surveyor asked the Laboratory Manager if stability studies were performed for the Sysmex XN-L 550 hematology analyzer. The Laboratory Manager stated that the laboratory did not perform any stability studies. 4. A random review of patient test records from February and March 2023 revealed the following patients whose CBCs were performed beyond the manufacturer's 4-hour stability requirement: Patient ID: 40203489 Collection date/time: 02/10/2023 07:40 at hours Analysis date/time: 02/10 /2023 13:01 at hours Elapsed time from collection to analysis: 5 hours 21 minutes Patient ID: 40204264 Collection date/time: 02/23/2023 08:43 at hours Analysis date /time: 02/23/2023 13:17 at hours Elapsed time from collection to analysis: 4 hours 31 minutes Patient ID: 40204439 Collection date/time: 02/27/2023 at 08:05 hours Analysis date/time: 02/27/2023 at 13:03 hours Elapsed time from collection to analysis: 4 hours 58 minutes Patient ID: 40204516 Collection date/time: 02/28/2023 at 08:04 hours Analysis date/time: 02/28/2023 at 13:24 hours Elapsed time from collection to analysis: 5 hours 20 minutes Patient ID: 40204597 Collection date/time: 03/01/2023 at 08:28 hours Analysis date/time: 03/01/2023 at 13:22 hours Elapsed time from collection to analysis: 4 hours 54 minutes The laboratory did not ensure their written preanalytical requirements were consistent with manufacturer's preanalytical requirements. The laboratory extended the specimen stability beyond manufacturer's instructions for the above CBC specimens and could not provide studies to support the extended stability. 5. During an interview on 03/01/2023 at 04: 17 p.m., the Laboratory Manager confirmed the above findings. |
| **D5403** | PROCEDURE MANUAL<br>CFR(s): 493.1251(b)<br><br>The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals |

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| | (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy and confirmed in interview, the laboratory failed to ensure their policy for peripheral smear examinations included guidelines for grading and reporting red blood cell (RBC), white blood cell (WBC) and platelet (PLT) morphology and abnormalities in 2023. The findings include: 1. Review of the laboratory policy titled "EXAMINATION OF PERIPHERAL BLOOD SMEAR" revealed: "PURPOSE The examination of a peripheral blood smear is often performed as a part of the hematological evaluation, usual being done in conjunction with a complete blood count. Hematological findings from examination of a peripheral blood smear may include a differential white blood cell count, red blood cell morphology, and platelet estimates ... D. Manual Differential and Peripheral Smear Review ... 4. Switch microscope lens to oil immersion and examine RBCs, WBCs, and platelets for morphological characteristics and abnormalities. 5. Document findings on the instrument print out and transcribe in the laboratory information system (LIS) ..." The laboratory policy failed to include guidelines for grading and reporting red blood cell (RBC), white blood cell (WBC) and platelet (PLT) morphology and abnormalities. The surveyor requested documentation of guidelines for grading and reporting the above parameters. None was provided. 2. During an interview on 03/01/2023 at 04:41 p.m., the Laboratory Manager confirmed the above findings. |
| **D5421** | ESTABLISHMENT AND VERIFICATION OF PERFORMANCE<br>CFR(s): 493.1253(b)(1)<br><br>Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.<br><br>This STANDARD is not met as evidenced by:<br>I. Based on the review of laboratory policy, laboratory's CMS 116 form, and confirmed in interview, the laboratory failed to perform verification studies for the i-STAT analyzer prior to reporting 17 of 17 patient test results in 2022. Findings included: 1. Review of the laboratory's policy titled "METHOD VERIFICATION" revealed: "PURPOSE Method verification demonstrates that the Laboratory can obtain the performance specifications for accuracy, precision, reportable range of patient test results and reference range, comparable to those established by the manufacturer and verify that the manufacturer's reference range is appropriate for the laboratory's patient population prior to reporting patient test results. POLICY All Laboratory tests will be verified prior to reporting patient test results. Method verification is required for all new tests as well as any modification of existing procedures. Instrument verification is required for all new instruments, including replacement or loaned instruments, and instruments that have been moved. All |

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| | verifications will be performed according to manufacturer's recommendations and CLIA regulations and must be approved, signed, and dated by the Laboratory Director prior to reporting patient test results. The Laboratory will follow manufacturer's instructions for environmental requirements and operation and ensure that there is sufficient supply of reagents, controls, and calibrators, preferably of the same lot, prior to starting the verification study. PROCEDURE 1. Perform verification per manufacturer's instructions and CLIA regulations. 2. Retain verification documentation for the life of the instrument or use of the method plus 2 years ..." 2. Review of the laboratory's CMS 116 form submitted on the day of the survey revealed the i-STAT analyzer was used to test the Chem 8+ cartridge. Records further revealed the i-STAT analyzer was put in-use 03/2022. The laboratory was asked to provide verification studies on the i-STAT analyzer prior to reporting 17 patient test results that included: a. Accuracy b. Precision No verification studies were provided. 3. During an interview on 03/01/2023 at 3:15 pm, the Laboratory Manager after review of records, confirmed the above findings. Word key: CMS- Center for Medicare & Medicaid Services 46891 II. Based on review of the laboratory's implementation studies, laboratory records, and confirmed in interview, the laboratory failed to ensure verification studies were completed on the Diesse CUBE 30 Touch automated ESR (erythrocyte sedimentation rate) analyzer for accuracy, precision, and reportable range prior to analyzing and reporting patient specimens. The findings include: 1. Review of the laboratory's implementation studies for the Diesse CUBE 30 Touch automated ESR analyzer revealed the laboratory implemented the analyzer in July 2022. 2. Further review of the implementation studies revealed the laboratory did not document accuracy, precision, and reportable range as part of their studies. 3. Review of laboratory records revealed the laboratory performed 609 ESRs since implementation of the CUBE 30 Touch. 4. During an interview on 03/01/2023 at 03: 20 p.m., the Laboratory Manager confirmed the above findings. |