| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 37D2112538 | 09/05/2023 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Community Hospital | 9800 Broadway Extension, Oklahoma City, 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 09/05/2023. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the laboratory director, quality assurance specialist, director of hospital laboratory operations, laboratory supervisor, hospital transfusion services manager, and chief operating officer during an exit conference performed at the conclusion of the survey. |
| **D1001** | CERTIFICATE OF WAIVER TESTS<br>CFR(s): 493.15(e)<br><br>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.<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 laboratory supervisor and technical consultant, the laboratory failed to follow the manufacturer's instructions for i-Stat creatinine testing. Findings include: (1) On 09/05/2023 at 0930 am, the technical consultant stated Creatinine testing was performed using the Abbott i-Stat analyzer; (2) Observation of the emergency room refrigerator on 09/05/2023 at 09:30 am identified one i-Stat Creatinine cartridge, lot #A220678, expired 09/04/2022; (3) The findings were discussed with the technical consultant who stated on 09/05/2023 at 09:30 am, the cartridge was being stored beyond the expiration date, and was available for use. |
| **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 |

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| | appropriate, to Federal and State authorities.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, nursing policy, and interview with the hospital transfusion services manager and laboratory director the facility failed to ensure written policies were followed for preventing transfusion reactions for four of five units transfused. Findings include: (1) On 9./5/2023 at 2:00 pm, the laboratory director stated that the laboratory performed Crossmatch Testing, which consisted of ABO/Rh, Antibody Screen, and Compatibility testing (performed between the patient and red blood cell donor unit(s)); (2) The policy "Blood and Blood Products Administration" defined the parameters of issuing blood products from the blood bank; (3) The surveyor reviewed the policy which stated: (a) "Blood/blood components must be infused over a time period not to exceed four (4) hours." (b) "PACKED RED BLOOD CELLS (PRBC)": (i) 5. "Document the date and time of initiation of administration of blood products and signature of RN who started the product on the Transfusion Record where indicated." (ii) 7. "Document completion date and time of blood product." (4) A review of transfusion records for five units of blood transfused with the hospital transfusion services director. For four or five units transfused, the policy was not followed by nursing personnel: (a) Unit #W091023198292 - The unit was checked out from the blood bank on 05/26/2023 at 02:38 pm and there was no documentation of when the transfusion was completed; (b) Unit #W091023202093 - The unit was checked out from the blood bank on 05/05 /2023 at 07:16 pm and there was no documentation of when the transfusion was completed; (c) Unit #W091023195646 - The unit was checked out from the blood bank on 05/08/2023 at 01:46 pm and there was no documentation of when the transfusion was completed; (d) Unit #W091023195163 - The unit was checked out from the blood bank on 05/08/2023 at 02:52 pm and there was no documentation of when the transfusion was completed; (5) Interview with the laboratory director 09/05 /2023 at 02:00 pm confirmed that the transfusion stop times had not been documented. |
| **D5417** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(d)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on observation and interview with the technical consultant, the laboratory failed to ensure expired supplies were not available for use. Findings include: (1) Observation of the emergency room on 09/05/2023 at 09:30 am, identified the following expired collection tubes that appeared to be available for use: (a) Six Bactec Lytic/10 Anaerobic /F blood culture bottles, lot #2290037, expiration date of 07/31 /2023 (b) Six Bactec Plus Aerobic F blood culture bottles, lot#2277247, expiration date of 07/31/2023 (c) Four Bactec Peds Plus /F blood culture bottles, lot#2277311, expiration date of 7/31/2023 (2) Interview with the technical consultant on 09/05/2023 at 09:30 am confirmed the Bactec bottles were available for use. |