| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 37D0472320 | 11/16/2022 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Mangum Regional Medical Center | 1 Wickersham Drive, Mangum, 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 11/14,15,16/2022. The laboratory was found in compliance with standard-level deficiencies cited. The findings were reviewed with the administrator, chief clinical officer, technical consultant, and laboratory manager during an exit conference performed at the conclusion of the survey. |
| **D3021** | REQUIREMENTS FOR TRANSFUSION SERVICES<br>CFR(s): 493.1103(c)(1)<br><br>Blood and blood products storage and distribution. If a facility stores or maintains blood or blood products for transfusion outside of a monitored refrigerator, the facility must ensure the storage conditions, including temperature, are appropriate to prevent deterioration of the blood or blood product.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, policies and procedures, and interview with the technical consultant and laboratory manager, the laboratory failed to ensure an adequate alarm system was in place for the blood bank refrigerator for three of eight alarm checks. Findings include: (1) On 11/16/2022 at 09:20 am, the laboratory manager stated the laboratory routinely maintained 2 units of O negative and 2 units of O positive packed red blood cells in the blood bank refrigerator. The units were available for emergency patient transfusions; (2) A review of the policy titled "Blood Bank Alarm System" required the alarm checks be performed on a quarterly basis and stated the following: (a) "Blood units will be maintained between 2-6 Degrees C in a continuously monitored refrigerator (allowable storage is 1-6 degrees C.)"; (b) "The alarm points are set at 1.5 degrees C and 5.5 degrees C. This maintains the units between 1-6 degrees C". (3) A review of alarm check records from January 2021 through the current date in 2022 identified the high alarm checks sounded at temperatures beyond the acceptable range for storing blood products for three of eight alarm checks performed as follows: (a) 04/20/2021 - The documented high alarm |

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| | temperature was 6.2 (b) 10/25/2021 - The documented high alarm temperature was 6.1 (c) 04/19/2022 - The documented high alarm temperature was 6.6 (4) The findings were revived the the technical consultant and laboratory manager. Both stated on 11/16 /22 at 09:45 am the documented temperatures for the high alarm checks above were not acceptable. |
| **D5407** | PROCEDURE MANUAL<br>CFR(s): 493.1251(d)<br><br>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of policies and interview with the technical consultant and laboratory manager, the laboratory failed to ensure one of three policies had been approved, signed, and dated by the laboratory director. Findings include: (1) On 11/15 /2022 at 11;20 am, the laboratory manager stated the following: (a) The laboratory began performing pH, pCO2, pO2, and Lactate testing using the CG4+ cartridge and the iSTAT 1 analyzer on 10/25/2021; (b) An IQCP (Individualized Quality Control Plan) had been developed for the test system. (2) A review of the IQCP identified the QCP (Quality Control Plan) for the test system had not been approved, signed, and dated by the laboratory director; (3) The records were reviewed with the technical consultant and laboratory manager. Both stated on 11/15/22 at 11:25 am, the QCP for the above test system had not been approved, signed, and dated by the current laboratory director. |
| **D5409** | PROCEDURE MANUAL<br>CFR(s): 493.1251(e)<br><br>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of the procedure manual and interview with the technical consultant and laboratory manager, the laboratory failed to ensure that written procedures no longer in use had been discontinued for two of two procedures reviewed. Findings include: (1) On 11/14/2022 at 03:00 pm, the laboratory manager stated the laboratory discontinued ABO/Rh typing, Antibody Screen, and Compatibility testing on 08/18/2022; (2) A review of the manual titled, "Laboratory Policies and Procedures" identified the following procedures: (a) "Quality Control for the MTS Gel Test System" (b) "Immediate Spin Crossmatch Using MTS Buffered Gel Card" (3) The procedures were reviewed with the technical consultant and laboratory manager. Both stated on 11/14/2022 at 03:44 pm, the procedures should have been indicated as discontinued. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>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 |

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| | instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, observation, and interview with the technical consultant and laboratory manager, the laboratory failed to ensure materials were stored as required for ten of ten months. Findings include: (1) On 11/16/2022 at 09:54 am, observation of the contents of the Kenmore chest freezer identified the following materials with a manufacturer's storage requirement of -20 to -70 degrees C (Centigrade): (a) Bio-Rad Liquid Assayed Multiqual level 3 controls, lot #45893 - five boxes containing 12 bottles each and one box containing 7 bottles; (b) Bio-Rad Liquid Assayed Multiqual level 1 controls, lot #45891 - five boxes containing 12 bottles each and one box containing five bottles; (c) Bio-Rad Liquichek Immunoassay plus level 3 controls, lot #85283 - five boxes containing 12 bottles each and one box containing five bottles; (d) Bio-Rad Liquichek Immunoassay plus level 1 controls, lot# 85281 - five boxes containing 12 bottles each and one box containing six bottles. (2) A review of temperature records for ten months (January 2022 through October 2022) identified the documented temperatures were warmer than -20 degrees C (the warmest temperature allowed for the materials) during ten of ten months as follows: (a) January 2022 - 12 of 31 temperatures were documented as warmer than -20 degrees C (b) February 2022 - 19 of 28 temperatures were documented as warmer than -20 degrees C (c) March 2022 - 23 of 31 temperatures were documented as warmer than -20 degrees C (d) April 2022 - 18 of 30 temperatures were documented as warmer than -20 degrees C (e) May 2022 - 22 of 31 temperatures were documented as warmer than -20 degrees C (f) June 2022 - 16 of 30 temperatures were documented as warmer than -20 degrees C (g) July 2022 - 11 of 31 temperatures were documented as warmer than -20 degrees C (h) August 202 - 7 of 31 temperatures were documented as warmer than -20 degrees C (i) September 2022 - 14 of 30 temperatures were documented as warmer than -20 degrees C (j) October 2022 - 5 of 31 temperatures were documented as warmer than -20 degrees C (3) The records were reviewed with the technical consultant and laboratory manager. Both stated on 11/16/22 at 10:07 am, the materials were not being stored as required by the manufacturer. |
| **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>Based on a review of records and interview with the technical consultant and laboratory manager, the laboratory failed to utilize the demonstrated reportable ranges for one of one new test method. Findings include: (1) On 11/15/2022 at 11;20 am, the laboratory manager stated the laboratory began performing pH, pCO2, pO2, and |

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| | Lactate testing using the CG4+ cartridge and the iSTAT 1 analyzer on 10/25/2021; (2) A review of the performance specification records identified the laboratory had demonstrated the following reportable ranges: (a) pCO2 - 18.3-88 mm/Hg (b) pO2 - 62-427 mm/Hg (c) Lactate - 0.72-16.92 mmol/L (3) Interview with the technical consultant and laboratory manager on 11/15/2022 at 12:25 pm confirmed the laboratory was using the following manufacturer's reportable ranges instead of the reportable ranges that had been demonstrated by the laboratory: (a) pCO2 - 15-130 mm/Hg (b) pO2 - 15-530 mm/Hg (c) Lactate - 0.30-20.0 mmol/L |
| **D5805** | TEST REPORT<br>CFR(s): 493.1291(c)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on a review of records, MedTox Scan Drugs of Abuse test system package insert, and interview with the technical consultant and laboratory manager, the laboratory failed to ensure test reports for Urine Drug Screen testing included information required for interpretation for one of one patient report. Findings include: (1) On 11/15/2022 at 10:35 am, the laboratory manager stated Urine Drug Screen testing was performed using the Profile V Medtox Scan Drugs of Abuse test system; (2) On 11/16/2022, a review of the Profile V Medtox Scan Drugs of Abuse test package insert stated, "The Profile-V MedTox Scan Drugs of Abuse test system provides only a preliminary analytical test result. A more specific alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography /mass spectrometry (GC/MS), high performance liquid chromatography (HPLC) or liquid chromatography/tandem mass spectrometry (LC /MS/MS) are the preferred confirmatory methods. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained." (3) A review of one patient report with Urine Drug Screen test results reported on 11/02/2022 identified the report did not include a disclaimer with the manufacturer's statement that the results were preliminary and guidance on obtaining a confirmed analytical result; (4) The findings were discussed with the technical consultant and laboratory manager. Both stated on 11/16/2022 at 10:45 am the patient report did not include the disclaimer. |