| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
|---|---|---|
| | 45D0507284 | 08/11/2021 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Childress Regional Medical Center | Highway 83 North, Childress, 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** | The laboratory was surveyed and found to be in compliance with the conditions of participation found in the CLIA regulations at 42 CFR 493 and recertification is recommended. |
| **D5469** | CONTROL PROCEDURES<br>CFR(s): 493.1256(d)(10)(g)<br><br>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of quality control instructions for use, quality control records, and interview with facility personnel, the laboratory failed to define the acceptability criteria accurately for 12 of 12 controls reviewed between July 11, 2021 and August 11, 2021. The findings included: 1. Based on review of the Bio-Rad Liquid Assayed Multiqual instructions for use, the instructions stated: "Liquid Assayed Multiqual is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in this package insert." And "ASSIGNMENT OF VALUES - The mean and corresponding plus/minus 3SD ranges in the Assignment of Values Data Charts (available separately) were derived from |

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| | replicate analyses and are specific for this lot of product." 2. Based on review of quality control charts for Phosphorus, ALT, Magnesium, and Acetaminophen (3 levels each - low, medium, and high), the stated baseline standard deviations were set as follows: Phosphorus Low: 0.185 Medium: 0.245 High: 0.330 ALT Low: 0.85 Medium: 3.45 High: 7.5 Magnesium Low: 0.114 Medium: 0.155 High: 0.195 Acetaminophen Low: 0.85 Medium: 2.050 High: 5.00 Based on the Bio-Rad Liquid Assayed Multiqual chart, the stated baseline standard deviations should have been calculated as follows: Phosphorus Low: 0.125 Medium: 0.16 High: 0.223 ALT Low: 0.56 Medium: 2.28 High: 5.16 Magnesium Low: 0.07 Medium: 0.105 High: 0.13 Acetaminophen Low: 0.56 Medium: 1.38 High: 3.16 3. In an interview on 8/11/2021 at 16:15 hours in the office, the laboratory manager confirmed the acceptability ranges had been calculated as plus/minus 2 SD ranges rather than the plus/minus 3SD ranges as stated in the instructions for use. |