

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0507284	<b>(X3) Date Survey Completed</b>  08/21/2024
<b>Name of Provider or Supplier</b>  Childress Regional Medical Center	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An onsite recertification survey conducted 08/21/2024 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
<b>D5783</b>	<p><b>CORRECTIVE ACTIONS</b> CFR(s): 493.1282(b)(2)</p> <p>(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory policy, chemistry quality control (QC) records, patient test records, and confirmed in interview, the laboratory failed to evaluate 115 of 115 patient results obtained since the last acceptable QC, when QC results failed to meet the laboratory's established acceptability criteria for CO2 and AST testing on the Vitros chemistry analyzer, for records reviewed in August 2023. The findings included: 1. Review of the laboratory policy titled "Daily Quality Control Decisions" included the following instructions: "Accept Run-Report Results IF: All controls are within 2sd and no trends or shifts are detected. Only one control is greater than 2sd and is less than 3 sd and is less than 2sd on repeat with no trends or shifts detected. Reject Run IF: More than one control is greater than 2 sd from the mean. One control is greater than 3 sd from the mean. A control is greater than 2 sd but less than 3 sd and is greater than 2 sd on repeat. A control is greater than 2 sd but less than 2 sd on repeat but is part of a shift or trend. A shift or trend is detected. If a Run Is Rejected: Do not report patient results. Troubleshoot to identify systematic error in method. Document Corrective action. Repeat all controls and patient samples." Surveyor asked</p>

for the laboratory policy that included the evaluation of patient results to the last acceptable QC when QC failed to meet the laboratory's established acceptability criteria, and none was provided. 2. Review of the August 2023 laboratory QC records for AST and CO2 included the following three QC events where QC did not meet the laboratory acceptability criteria: Date, Time: Analyte, result [Expected 2 SD range], corrective action 8/16/2023, 01:45: CO2, 21.8 [14.534 - 21.466], "QC fluid was repeated" 8/16/2023, 02:20: CO2, 19.7 [14.534 - 21.466], "Recal / repeat acceptable" Review of patient testing included 45 patients with CO2 testing since the last acceptable QC on 8/15/2024 at 1:10 hours to include the following ten: 10424046, 10424408, 10424734, 10424820, 10424835, 10424871, 10424882, 10424816, 10424831, 10424790 Date, Time: Analyte, result [Expected 2 SD range], corrective action 8/24/2023, 02:26: CO2, 16.5 [16.934 - 23.866], "QC fluid was repeated" 8/24/2023, 02:43: CO2, 16.6 [16.934 - 23.866], "QC fluid was repeated" 8/24/2023, 02:53: CO2, 21.1 [16.934 - 23.866], "Changed reagent, Changed QC fluid" Review of patient testing included 40 patients with CO2 testing since the last acceptable QC on 8/23/2024 at 01:46 hours to include the following ten: 10425523, 10425710, 10425724, 10425733, 10425751, 10425788, 10425838, 10425771, 10425782, 10425822 Date, Time: Analyte, result [Expected 2 SD range], corrective action 8/30/2024, 00:34 - AST, 106.7 [108.4 - 128.4], "QC fluid was repeated" 8/30/2024, 00:58 - AST, 108.2 [108.4 - 128.4], "QC fluid was repeated" 8/30/2024, 02:52 - AST, 111.7 [108.4 - 128.4], "Recal / repeat acceptable" Review of patient testing included 30 patients with AST testing since the last acceptable QC on 8/29/2024 at 00:42 hours to include the following ten: 10426371, 10426331, 10426340, 10426342, 10426359, 10426377, 10426407, 10426434, 10426443, 10426469 Surveyor asked for documentation of the evaluation for the above 115 patients who had been tested prior to the failed QC run, to determine if patient test results had been adversely affected, and none was provided. 3. In an interview on 8/21/2024 at 15:40 hours, in the conference room, the general supervisor (GS) confirmed the laboratory did not evaluate all patient results obtained since last acceptable QC run when QC events failed to meet the laboratory's established criteria of acceptability. Key: AST - Aspartate aminotransferase CO2 - carbon dioxide SD - standard deviation