

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0484216	(X3) Date Survey Completed 11/08/2024
Name of Provider or Supplier Memorial Medical Center San Augustine	Street Address, City, State 511 E Hospital Street, San Augustine, 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
D0000	An onsite recertification survey completed on 11/8/2024 found the laboratory in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5891	<p>POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory test menu, patient test records, patient final reports, and confirmed in interview, the laboratory failed to have a system in place to ensure six of six patient test results were reported under the appropriate chemistry system for records reviewed on 6/29/2024 and 6/30/2024. The findings included: 1. Review of laboratory test menu included the following two chemistry systems performing sodium (Na), potassium (K), and chloride (Cl) testing: Chem 8+ cartridge on the iSTAT Abbott analyzer Dimension EXL chemistry analyzer In an interview on 11/7/2024 at 11:00 hours, in the conference room, technical consultant (TC) 1 stated the Chem 8+ cartridge on the iSTAT analyzer was used as a back up for the Dimension EXL chemistry analyzer. 2. Review of laboratory patient test records and patient final reports included the following six patients who had Na, K, and Cl testing performed on the Chem 8+ cartridge on the iSTAT on 6/29/2024 and 6/30/2024: Date: Patient ID 6/29/2024, C2241810006 6/29/2024, C2241810005 6/29/2024, C2241810003 6/30/2024, C2241820001 6/30/2024, C2241820013 6/30/2024, C2241820003 3. Review of the laboratories verified reference ranges for the iSTAT and the Dimension EXL Chemistry analyzer included the following verified reference ranges in place for patient testing: iSTAT verified normal patient reference ranges: Na 138 - 146 mmol/L K 3.5 - 4.9 mmol/L Cl 98 - 109 mmol/L Dimension EXL verified normal patient reference ranges: Na 137 - 145 mmol/L K 3.5 - 5.0 mmol/L Cl 98 - 107 mmol/L</p>

Review of the laboratory patient final reports did not differentiate the test performed on the iSTAT and the additional chemistries performed on the Dimension EXL. The final patient report for Na, K, and Cl (performed on the iSTAT) included the Dimension EXL normal patient reference range. Surveyor asked if the laboratory had a mechanism in place to differentiate the two different test systems, and none was provided. 4. In an interview on 11/7/2024 at 13:45, in the office, TC1 stated the laboratory previously had a specific test order for chemistry testing performed on the iSTAT but it was no longer available to the staff. TC 1 confirmed that the laboratory did not have a mechanism in place to differentiate test system for Na, K, and Cl for patient testing.