

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 24D0405550	(X3) Date Survey Completed 10/23/2020
Name of Provider or Supplier Avera Marshall Regional Medical Center	Street Address, City, State 300 South Bruce Street, Marshall, MN	
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
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the laboratory failed to ensure the reportable range obtained during performance verification of two new Chemistry analytes was adopted by the laboratory. Findings are as follows: 1. The laboratory performed Chemistry testing as confirmed by the General Supervisor (GS) during a tour of the laboratory on 10/23/20, at 8:15 a.m. 2. A Beckman Coulter Access 2 chemistry analyzer was observed as present and available for use during the tour of the laboratory. 3. The laboratory completed performance verification (PV) activities for Free Triiodothyronine (FT3) and Prostate-Specific Antigen (PSA) analytes and began testing patient specimens using this analyzer in July 2020 as indicated by the GS during the tour and confirmed via laboratory records. 3. The reportable ranges found in procedures located in the online procedure program Policystat did not reflect the actual reportable range values obtained by the laboratory during the PV. See below. Procedure titles Free T3 - Access 2 PSA - Hybridtech for Access 2 Analyte PV Procedure FT3 1.31-30.0 0.88-30 PSA 0.07-147.65 0.01-142.0 4. In an interview at 2:55 p.m. on 10/23/20, the GS confirmed the above finding and indicated the laboratory had adopted the manufacturer's analytical measurement range as the reportable range for the analytes.</p>