

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0183623	(X3) Date Survey Completed 06/04/2026
Name of Provider or Supplier Titusville Area Hospital	Street Address, City, State 406 West Oak St, Titusville, PA	
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>(b) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (b)(1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (b)(1)(i)(A) Accuracy. (b)(1)(i)(B) Precision. (b)(1)(i)(C) Reportable range of test results for the test system. (b)(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 record review, lack of documentation, and interview with the Laboratory Manger (LM), the laboratory failed to verify the required performance specifications for reference intervals (normal values) for Chemistry testing performed on 1 of 1 Roche Cobas Pro and 1 of 1 Cobas Pure before reporting patient results from 10/01/2024 to 6/3/26. Findings Include: 1. On the day of survey, 6/3/2026 at 1:30 pm, the laboratory could not provide documentation for the verification of the required performance specifications for reference intervals (normal values) for Chemistry testing performed on 1 of 1 Roche Cobas Pro and 1 of 1 Roche Cobas Pure before reporting patient results from 10/01/2024 to 6/3/2026. 2. The laboratory performed 432,114 chemistry tests in 2025 (CMS-116, estimated annual volume, dated 05/05/2026). 3. The LM confirmed the above findings on 06/03/2026 , at 3:00 pm.</p>