

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 52D2091821	(X3) Date Survey Completed 12/19/2018
Name of Provider or Supplier Numale Wisconsin Gb, Sc	Street Address, City, State 1525 Park Place, Ashwaubenon, WI	
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
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of proficiency testing (PT) records from 2017 and interview with the Director of Operations (staff A), the laboratory did not perform proficiency testing using the laboratory's routine methods for testing patient samples. Findings include: 1. PT records from event one in 2017 include a "Performance Review and Corrective Action" form signed by the laboratory director on June 23, 2017 that identifies a change in procedure for testing proficiency samples. The form states: "Going forward, the analyte results shall be entered accurately, and will have three-person verification as the analytes are put onto the TOSOH". 2. Interview with staff A on December 19, 2018 at 10:30 AM confirmed that since June 23, 2017, three persons verify the accurate placement of proficiency samples on the TOSOH chemistry analyzer, while patient samples are placed on the analyzer by one person and not verified by anyone else. Therefore, the laboratory does not test PT samples using the laboratory's routine methods for patient testing.</p>