

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D0680918	(X3) Date Survey Completed 12/13/2022
Name of Provider or Supplier Avera Medical Group O'Neill	Street Address, City, State Clinical Laboratory, Oneill, NE	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the laboratory's procedure manual, review of the list of tests performed provided by the laboratory, and interview with the lab director the laboratory failed to have a procedure for the wet prep test performed. 1. Surveyor review of the laboratory's procedure manual revealed the procedure manual was missing the procedure for the wet prep test. 2. The list of tests performed provided by the laboratory revealed the laboratory had performed twenty nine wet prep tests in the last year. 3. Interview with the lab director on 12/13/2022 at 2:00 PM confirmed the laboratory did not have a procedure for the wet prep test and the laboratory had performed twenty nine tests in the last year.</p>