

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 35D0041814	(X3) Date Survey Completed 07/28/2022
Name of Provider or Supplier Smp Health St Aloisius	Street Address, City, State 325 Brewster St E, Harvey, ND	
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
D5451	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Test procedures producing graded or titered results include a negative control material and a control material with graded or titered reactivity, respectively; 493.1256 (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on record review, staff interview, procedure review, and manufacturer's instructions review, the laboratory failed to perform negative Anti-D quality control (QC) testing 2 of 3 immunohematology patient testing days (04/02 and 04/03) in April 2022. The laboratory performed Anti-D testing for two patients on the days in April 2022 with no negative Anti-D QC performance. Findings include: 1. Reviewed at 1:25 p.m. on 07/28/22, the April 2022 immunohematology patient testing and QC records indicated the laboratory did not perform negative Anti-D QC for Anti-D patient testing on the following days: 04/02/22 Patient #11380 04/03/22 Patient #8514 2. During interview at 2:30 p.m. on 07/28/22, a technical supervisor (#1) confirmed the laboratory should perform positive and negative Anti-D QC each day of patient testing, and the laboratory did not document performance of negative Anti-D QC on two patient testing days in April 2022. 3. Reviewed on 07/28/22, the procedure "Blood Bank: RH TYPING," effective 02/12/13, stated, ". . . Quality Control: . . . Reagents are quality controlled with known positive and negative controls each day that blood bank work is done. . . ." 4. Reviewed on 07/28/22, the manufacturer's instructions "Blood Grouping Reagent Anti-D (Monoclonal Blend) Gamma-clone," dated 03/2019, stated, ". . . Quality Control: The reactivity of blood grouping reagents should be confirmed on each day of testing with red blood cells known to be negative and positive for the relevant antigen. . . ."</p>