

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 36D2132763	(X3) Date Survey Completed 11/21/2018
Name of Provider or Supplier Polaris Laboratories Llc	Street Address, City, State 2694 Sawbury Blvd, Columbus, OH	
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 record review and an interview with the Laboratory Director (LD), the laboratory failed to follow written policies and procedures for the rejection of specimens. Findings Include: 1. Review of the laboratory's policies and procedures, provided on the date of the inspection, found a "LC-MS/MS Initial Sample Processing and Storage" policy and procedure with reference to "Criteria for Sample Rejection" which contained the following statement: "All specimens that meet the criteria for rejection will be set aside and documented in sample rejection log." 2. The Surveyor requested the laboratory's sample rejection log from the LD. The LD confirmed the laboratory did not have a sample rejection log and was unable to provide the requested document on the date of the inspection. The interviews occurred on 11/21/2018 at 11:29 AM.</p>