

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2074024	(X3) Date Survey Completed 05/25/2023
Name of Provider or Supplier Smithers Pharmaceutical Development Services Llc	Street Address, City, State 11 Firstfield Road Ste C, Gaithersburg, MD	
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on review of written procedures, the laboratory director did not document their review and approval of written procedures. Findings: 1. Approval of procedures and changes to procedures is the responsibility of the laboratory director. This responsibility cannot be delegated. 2. The review and approval of the written procedure to measure neutralizing antibodies in human serum was delegated to the product manager. The documentation showing approval of the written procedure did not show the laboratory director's review and approval.</p>