

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2074024	(X3) Date Survey Completed 03/25/2019
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
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory director, the laboratory director did not provide documentation to verify the discipline of graduate study completed, for one of six technical supervisors, credentialed by the surveyor on the day of survey. Findings: 1. The laboratory provided the diploma and curriculum vitae of staff to show that they meet educational and experience requirements to perform their duties as technical supervisor; 2. The diploma for one of six technical supervisors evaluated did not name the discipline of study on the diploma. The curriculum vitae was used to identify the discipline; and 3. The laboratory director reported, during interview on the day of survey, that their was no other record to verify the field of study for the technical supervisor.</p>