

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0986074	(X3) Date Survey Completed 01/15/2019
Name of Provider or Supplier Biological Specialty Company, Llc	Street Address, City, State 2165 North Line Street, Colmar, PA	
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
D6053	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of competency assessment records and interview with the Technical Consultant (TC), the TC failed to evaluate and document the performance of one out of six testing personnel (TP) responsible for the total protein test for their semi-annually competency during the first year. Findings include: 1. At the time of survey, the laboratory was unable to produce the competency assessment records for TP #6 . 2. During the interview on 01/15/2019 around 10: 15 am, the TC (Laboratory Director) confirmed TP #6 was hired on August 2017. The initial competency assessment was completed in December 2017, but no competency assessment was performed at the semi-annual requirement the first year.</p>