Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	39D0986074	06/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
Biological Specialty Company, Llc	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
D3009	FACILITIES CFR(s): 493.1101(c) The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements. This STANDARD is not met as evidenced by: Based on surveyor record review (Application for Exception to Section 5.22(f)) and interviews with the Technical Consultant (TC) and Sr. Operations Manager, the laboratory failed to ensure that the State of Pennsylvania (PA) regulations were met regarding having a supervisor on site during all normal scheduled working hours in which tests are being performed. Findings include: 1. The PA regulations (5.23 (b)(1)) states: "A general supervisor who meets all the requirements of subsection (a)(1), (2) or (3) and is on the laboratory premises during all normal scheduled working hours in which tests are being performed." 2. Review of the application for Exception to Section 5.22 (f) form signed by the laboratory director (LD) on 09/12/2022 states: " the laboratory director will appoint a qualified general supervisor for each laboratory who will be on-site to oversee laboratory operations during all hours in which testing is being performed and who will review quality control records on a weekly basis". 3. On the day of survey 06/15/2023 at 11:35 am, during an interview, TC stated that the laboratory did not have a qualified supervisor onsite for every hour of patient testing as required by the State of PA.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory

	director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the Quality Assurance/Quality Control standard operating procedure, lack of documentation and interview with the Technical Consultant (TC) and Sr. Operations Manager, the Laboratory Director (LD) failed to ensure Quality Assessment (QA) programs were maintained and documented to assure the quality of laboratory services provided from June 2021 to the date of the survey. Findings include: 1. The Quality Assurance/Quality Control standard operating procedure states (page 7) that "A quarterly comprehensive facility audit will be performed by a trained quality auditor to monitor compliance with regulatory requirements. The results of this audit will be reported to the CQI/TQM (Continuous Quality Improvement/Total Quality Management) committee". 2. On the day of survey, 06/15/2023 at 10:47 am, the laboratory could not provide QA documentation of periodic evaluation used by the laboratory to assess its preanalytical, analytical, and postanalytical processes from 06 /22/2021 to 06/15/2023. 3. The TC and Sr. Operations Manager confirmed the findings above on 06/15/2023 around 11:50 am.