

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0190921	(X3) Date Survey Completed 02/08/2021
Name of Provider or Supplier Allentown Women's Center Inc	Street Address, City, State 31 South Commerce Way Suite 100, Bethlehem, 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
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of Laboratory procedure manuals and interview with the Director of Nursing and testing personnel (TP) #1, the laboratory failed to establish a competency assessment policy to assess TP who performed Rhesus (Rh) D testing from 07/09 /2018 to the date of survey. Findings include: 1. On the day of survey, 02/08/2020, the Director of Nursing and TP#1 could not provide a written competency assessment policy that reviews how to assess the competency of TP who performed Rh D testing in 2018, 2019, 2020 and 2021. 2. The Director of Nursing and TP #1 confirmed the finding above on 02/08/2021 around 1:20 pm.</p>
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>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)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p>

This STANDARD is not met as evidenced by:

Based on review of laboratory procedure manuals and interview with the Director of Nursing and testing personnel (TP) #1, the laboratory Director failed to establish a proficiency testing (PT) procedure for TP who performed the American Association of Bioanalysts (AAB), Rhesus (Rh) D PT samples from 07/09/2018 to the date of survey. Findings include: 1. On the day of survey, 02/08/2020, the Director of nursing and TP #1 could not provide a written PT procedure that reviews how TP were to perform AAB Rh D PT samples in 2018, 2019, 2020 and 2021. 2. The Director of Nursing and TP #1 confirmed the finding above on 02/08/2021 around 1:30 pm.