

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0190807	(X3) Date Survey Completed 06/13/2018
Name of Provider or Supplier Planned Parenthood Keystone-Allentown	Street Address, City, State 29 N 9th Street, Allentown, 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's procedure manuals and interview with the Center Manager and Director of Health Center Operations, the laboratory failed to establish policies and procedures to assess the competency of Technical consultant (TC) delegated regulatory responsibilities from 2017 to the date of survey. Findings include: 1. On the date of survey, 06/13/2018, the laboratory could not provide a competency assessment procedure that included how to assess a TC delegated regulatory responsibilities. 2. The Center Manager and Director of Health Center Operations confirmed the findings on 06/13/2018 around 11:45 AM.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by: Based on laboratory testing personnel competency records review and interview with the Center Manager and Director of Health Center Operations, the technical consultant (Laboratory Director) failed to evaluate the competency assessment of all (6 of 6) Testing personnel (TP) in 2017 for KOH, Wet Prep and RH typing. Findings</p>

	<p>include: 1. On the day of survey (06/13/2018) the laboratory could not provide documentation of all (6 of 6) TP 2017 Competency assessments records for KOH, Wet Prep and RH typing. 2. 1483 patients specimen were performed in 2017. 3. The Center Manager and Director of Health Center Operations confirmed the findings above on 06/13/2018 around 01:00 PM.</p>
<p>D6063</p>	<p>LABORATORY TESTING PERSONNEL CFR(s): 493.1421</p> <p>The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.</p> <p>This CONDITION is not met as evidenced by: Based on review of the CLIA ' s Laboratory Personnel Report (Form CMS-209), review of personnel qualification records, and interview with the Center Manager and Director of Health Center Operations, the laboratory failed to ensure that each individual performing Moderate level Complexity testing is qualified. Refer to D6065</p>
<p>D6065</p>	<p>TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i)</p> <p>(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and</p> <p>This STANDARD is not met as evidenced by: Based on review of the CLIA ' s Laboratory Personnel Report (Form CMS-209), review of personnel qualification records, and interview with the Center Manager and Director of Health Center Operations, the laboratory failed to ensure that each individual performing Moderate level Complexity testing is qualified. Findings Include: 1. On the day of survey, 06/13/2018 the laboratory could not provide acceptable personnel credentials for testing personnel #2 and #4. 2. 1483 patient specimen were tests were performed in 2017. 3. The Center Manager and Director of Health Center Operations confirmed the findings above on 06/13/2018 around 11:30 am.</p>