

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 39D0203526	(X3) Date Survey Completed 01/03/2024
Name of Provider or Supplier Planned Parenthood Sepa	Street Address, City, State 8 South Wayne Street, West Chester, 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 a lack of the laboratory's competency assessment records and interview with the Center Manager (CM) and Office Director (OD), the laboratory failed to establish a competency assessment procedure to assess and follow the competency of 3 of 3 Technical Consultant (TC) for their supervisory responsibilities performed in 2022 and 2023. Findings include: 1. On the day of survey, 01/03/2024, at 11:45 am, the laboratory failed to provide a competency assessment procedure to assess 3 of 3 TC for their supervisory responsibilities. 2. The laboratory could not provide competency assessment records for the 3 of 3 TC (CMS 209 personnel #2, #3, #4) for their supervisory responsibilities performed in 2022 and 2023. 3. The CM and OD confirmed the findings above on 01/03/2024 at 01:00 pm.</p>
D6054	<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 annually, after the first year.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory's competency assessment records and interview with the Center Manager (CM) and Office Director (OD), the Technical Consultant (TC)</p>

#3 (CMS 209) failed to evaluate the competency assessment for 1 of 2 Testing Personnel (TP) who performed moderate complexity testing in mycology and parasitology in 2022. Findings include: 1. On the day of the survey, 01/03/2024 at 11:30 am, a review of laboratory's competency records revealed that the laboratory failed to perform a competency assessment for 1 of 2 TP (CMS 209 TP #1) who performed Potassium hydroxide and wet mount testing in 2022. 2. The laboratory performed 186 Mycology and Parasitology tests in 2022 (per CMS 116 total estimated annual test volume). 3. The CM and OD confirmed the findings above on 01/03/2024 at 01:00 pm.