

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 05D0584503	<b>(X3) Date Survey Completed</b> 01/22/2025
<b>Name of Provider or Supplier</b> Planned Parenthood Of California	<b>Street Address, City, State</b> 518 Garden St, Santa Barbara, CA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D3031</b>	<p><b>RETENTION REQUIREMENTS</b> CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. In addition, retain the following:</p> <p>This STANDARD is not met as evidenced by: Based on surveyors' review of patients' test results, lack of quality control (QC) documentation for KOH, and interview with the laboratory's testing personnel (TP); it was determined that the laboratory failed to retrieve KOH QC and reagent log records for at least 2 years. The findings included: 1. At the time of the survey on January 22, 2025, at approximately 2:30 p.m. the TP fail to retrieve QC documentation records for KOH testing, including KOH reagent lot number and expiration date for 2 years of randomly chosen patients KOH results reviewed . 2. The TP affirmed that QC records for the years 2023 and 2024 were not retrievable at the time of the survey. 3. Based on the laboratory's testing declaration submitted at the time of the survey, the laboratory analyzed and reported approximately 6,078 KOH test samples.</p>
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> 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 the lack of policies and procedures for competency assessment,</p>

documentation of testing personnel competency assessments, and interview with the testing personnel (TP) on January 22, 2025, at approximately 2:00 p.m., as specified in the personnel requirements in subpart M, it was determined that the laboratory failed to establish and follow written policies and procedures to assess the testing personnel competency for the year 2024. Findings include: 1. Based on the lack of the laboratory's policies and procedures and competency evaluations' records, the laboratory failed to establish and follow written policies and procedures for competency assessment of the testing personnel (TP). 2. Based on review of competency assessment records for the year 2024, ten (10) TP out of 20 TP did not have competency assessment performed. 3. This deficient practice was affirmed by an interview with the TP at the time of the survey. 4. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory reported and performed approximately 13,444 test results for which competencies of the testing personnel were not performed.

**D6053**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

(b)(9) Evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:  
Based on the lack of policies and procedures for competency assessment of testing personnel, review of randomly chosen competency assessment records, lack of documentation for competency assessments for the year 2024, and interview with the testing personnel; it was determined that the laboratory's technical consultant failed to perform and document the performance of individuals responsible for moderate complexity testing at six months and annually the individual tests for patient specimens. (See D5209).