

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0597943	(X3) Date Survey Completed 03/22/2022
Name of Provider or Supplier Planned Parenthood Shasta Diablo	Street Address, City, State 2185 Pacheco St, Concord, CA	
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
D5215	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(2)</p> <p>The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's proficiency testing (PT) records and interview with the laboratory director on March 22, 2022, at 12:10 pm, the laboratory failed to provide any evidence showing that the laboratory director had reviewed not graded PT results. The findings include: 1. The laboratory participated in the American Proficiency Institute's (API) PT program in 2021. API did not grade the laboratory's reported results for the sample VKP-03 and RH-15 at the 3rd event. The laboratory must have a mechanism for routine review of its proficiency testing results that are evaluated by its PT providers. This includes a review of its actual PT results against the PT provider's participant summary results for the particular PT event and when the PT provider notifies the laboratory that its results were not evaluated. Therefore, the test accuracy can not be assured. 2. The laboratory director on March 22, 2022, at 12:10 pm, affirmed that the laboratory did not evaluate its not graded PT results. 3. The laboratory's testing declaration form, signed by the laboratory director on 3/21/2022, stated that the laboratory performs approximately 2,096 Rh tests, annually.</p>
D6018	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iii)</p> <p>The laboratory director is responsible for the overall operation and administration of</p>

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)(4)(iii) Ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action;

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's proficiency testing (PT) records and interview with the laboratory director on March 22, 2022, at 12:10 pm, the laboratory director failed to ensure that all proficiency testing reports received are reviewed by the appropriate staff to evaluate the laboratory's performance and to identify any problems that require corrective action. The findings include: See D5215.