

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0969008	(X3) Date Survey Completed 08/23/2019
Name of Provider or Supplier Planned Parenthood Of Pasadena	Street Address, City, State 1045 N Lake Ave, Pasadena, 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
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of patient testing records, quality control data, and interview with the laboratory testing personnel, the laboratory failed to perform quality control procedure each day patient specimens were assayed for 15 days out of 44 days, reviewed from January - August 2019. The findings include: a. The laboratory's quality control log for blood Rh type test showed that it did not perform quality control on the following days of the year 2019 even though the patients' results were released on those days: 1/3, 1/4, 1/16, 1/30, 2/6, 3/21, 3/23, 4,23, 5/7, 5/15, 6/18, 6/26, 6/28, 8/6 and 8/16. b. On 8/23/2019 at 12:35 pm, laboratory testing personnel affirmed that it did not perform quality control procedure on the above days. c. The laboratory's testing declaration form, signed by the laboratory Director on 8/12/2019, stated that the laboratory performs 536 tests, annually.</p>
D6020	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5)</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)(5) Ensure that the quality control program is established and</p>

maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on Surveyor review of patient testing records, quality control data, laboratory policy and procedure, and interview with the laboratory testing personnel, it was determined that the laboratory director failed to ensure that the quality control programs are maintained to assure the quality of laboratory services provided. The findings include: See D5449.