Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0969008	08/23/2021
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Of Pasadena	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
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of the American Proficiency Institute (API) proficiency testing (PT) records for the years of 2019, 2020, and 2021 and interview with the laboratory's technical consultant TC on August 3, 2021 the laboratory failed to test PT samples the same number of times that it routinely tests patient samples. The findings include: 1. The laboratory tested API samples for Rh (D) for the years 2019, 2020, and 2021 by multiple testing personnel (TP) multiple times before reporting results. 2. The laboratory TC affirmed on August 23, 2021 at approximately 3:00 p.m. that the PT samples are tested multiple times by multiple TP before reporting to API. 3. The laboratory's testing declaration form stated that the laboratory performs 814 Rh grouping annually.
D3027	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(1) Test requisitions and authorizations. Retain records of test requisitions and test authorizations, including the patient's chart or medical record if used as the test requisition or authorization, for at least 2 years. This STANDARD is not met as evidenced by: Based on the lack of documentation, review of randomly chosen patient test results, and interviews with the technical consultant (TC) and testing personnel (TP); it was determined that the laboratory failed to provide test requisition and sample testing log

	records for the years 2019 and 2020. Findings included: 1. The laboratory had no available documentation to show requisition for tests ordered and sample results logs for the years 2019 and 2020. 2. For three (3) out of five (5) randomly chosen patient test results reviewed covering period from 11/26/2019 to 09/15/2020 no documentation was retained or accessible for all tests performed in the laboratory for the years 2019 and 2020. 3. The TC and TP affirmed on August 23, 2021 at approximately 3:30 p.m. that the laboratory had no documentation to show for the tests requisition or patient log results for the years 2019 and 2020. 4. 5. The laboratory reportedly performs approximately 2,968 tests annually.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on the lack of documentation, random patient records review, and interview with the technical consultant (TC) and testing personnel (TP) on August 23, 2021 as specified in the personnel requirements in subpart M, the laboratory failed to establish and follow written policies and procedures to assess testing personnel competency. Findings include: 1. Based on review of the laboratory's policies and procedures, the laboratory failed to establish and follow written policies and procedures for competency assessment of the TP. 2. The laboratory listed in the CMS 209 Form twenty TP. 3. For five (5) out of five (5) randomly chosen TP from the laboratory personnel report Form CMS-209 and final test reports, the laboratory fail to provide documentation of training or competency assessment for the TP performing testing at the laboratory for the years 2019, and 2020. 4. This deficient practice was affirmed by interview with the TC and TP on 8/23/2021 at approximately 4:00 p.m. 5. The laboratory reportedly performs approximately 2,968 tests annually.
D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) 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)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on the lack of laboratory personnel competency evaluations, the lack of laboratory written policies and procedures for competency assessment, testing proficiency samples not in the same manner as patients' samples are tested, failure to provide testing requisitions and testing logs, and interviews with the technical consultant and testing personnel; the laboratory director failed to: 1. Ensure that policies and procedures including competency assessment, document retention, and

	proficiency testing policies are established and followed for all the test performed in the laboratory. . 2. Monitor that competency assessments of testing personnel are performed in a timely manner on all individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures, and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills. See D2010, D3027, D5209 and D6053.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for 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 review of randomly chosen competency assessmnet records and the lack of documentation for competency assessments for the years 2019 and 2020, and interview with the technical consultant and 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 annually the individual tests patient specimens. (See D5209).