Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	12D0669361	07/03/2018
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Great Nw, Hi, Ak, In, Ky	839 S Beretania Street, Honolulu, HI	

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
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event. This STANDARD is not met as evidenced by: Based on the lack of proficiency test records and an interview with the Hawaii Health Center Manager on 07/03/2018 at 08:15 a.m., it was determined that the laboratory failed to maintain copies of all its proficiency testing records to include the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens. The findings include: a. The laboratory's American Proficiency Institute (API) Rh proficiency testing records for 3 of 3 events in 2016 and 3 of 3 events in 2017 were not available for review. b. The laboratory's protocol titled "Proficiency Testing: Rh & Provider Performed Microscopy (PPM) Test" states: i. In the section titled "Testing Process-Health Centers, 2. API logs, documents: If present with kit, discard. DO NOT USE API FORMS OR SEND RESULTS TO API." Rh proficiency testing results are recorded and sent to the Assistant to the COO for electronic submission to API. ii. In the section titled "Reporting and Documentation of Proficiency Test Results" - "Final

	results will be kept by the Assistant to the COO," and that "the following documents will be scanned and retained by the Assistant to the COO for each testing event: PPGNHI Rh Proficiency Test Log, API Submission Form, API Results Form." iii. The Health Center Manager stated that the manager who preceded him did not retain copies of the laboratory's API PT records. He was unable to locate a laboratory contact who could assist in retrieving these documents for review. c. The laboratory's protocol titled "Proficiency Testing: Rh & Provider Performed Microscopy (PPM) Test" states: i. In the section titled "Rh Proficiency Testing: Control results and proficiency test results must be logged on the Rh Patient test log just as patient tests are logged." ii. The Health Center Manager stated that API Rh proficiency testing results were not logged on to this test log. Results were recorded on the Planned Parenthood Rh PT Log and Attestation Statement form.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual and an interview with the Health Center Manager on 07/03/2018 at 08:15 a.m., it was determined that the laboratory failed to ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. The findings include: a. 8 of 8 procedures reviewed were not approved and signed by the Hawaii Laboratory Director. These procedures included: i. Laboratory Policies and Patient Test Management, 09/16 ii. Lab Specimen Collection and Processing, 09/16 iii. Laboratory Quality Assurance Plan, 09/16 iv. Proficiency Testing: Rh & Provider Performed Microscopy (PPM) Tests, 09/16 v. Laboratory Quality Control Procedures, 04/17 vi. Required Laboratory Quality Control and Documentation Logs, 11/17 vii. Rh Testing-Annual Laboratory Competency, 09/16 viii. Rh Testing with Eldon Log, 09/16 b. The Health Center Manager stated that approved laboratory procedures were available on line. The Manager and testing personnel were unable to locate these procedures during the survey. c. NOTE: THIS DEFICIENT PRACTICE WAS PREVIOUSLY CITED AT THE LABORATORY'S 03/31/2016 CLIA SURVEY. The laboratory's 04 /21/2016 corrective action for this deficiency stated: "Hawaii locations will no longer use the on line laboratory procedures and policies. All will be revised to be made specific to locations in Hawaii, personally signed as approved by the Laboratory Director, and maintained in printed form in the health centers lab areas."
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each

	consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of the laboratory procedure manual and an interview with the Health Center Manager on 07/03/2018 at 08:15 a.m., it was determined that the laboratory failed to specify in writing, the responsibilities and duties of each person engaged in the performance of Eldon card Rh testing. The findings include: a. The Health Center Manager stated that the Technical Consultant present during the 03/31 /2016 CLIA survey left the laboratory prior to April 2017 and that this position remains vacant. The PPGNHI Laboratory Organization and Structure, December 2015 procedure currently in use, states in Section Laboratory Testing Personnel the name and responsibilities of the departed Technical Consultant. The procedure also states the name and responsibilities of a Clinical Consultant who is no longer with the laboratory. b. In the section titled "Laboratory Testing Personnel of the PPGNHI Laboratory Organization and Structure, December 2015," it listed "Orienting/training staff" as the responsibility of the Technical Consultant. The Health Center Manager stated that 6 of 6 testing personnel present during the 03/31/2016 CLIA survey were no longer employed by the laboratory. Following the departure of the Technical Consultant, initial trainings, 6 month trainings and annual trainings for 4 of 4 new employees were conducted by the Laboratory Director of Alaska/Washington state and the Hawaii Medical Director who signed as Technical Consultants on training documents. Neither individual is listed on the laboratory's CMS-209 Laboratory Personnel Report form. c. In the section titled "Laboratory Testing Personnel of the PPGNHI Laboratory Organization and Structure, December 2015," it stated that the responsibilities of "Moderate Complexity Personnel; Trained Staff, Rh Factor" as "Moderate complexity require three external test events per year." The procedure failed to specify whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. d. NOTE: THIS DEFICIENT PRACTICE WAS PREVIOUSLY CITED AT THE LABORATORY'S 03/31/2016 CLIA SURVEY.