Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	50D0697375	08/15/2023
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Of Greater Wa And N Idaho	1117 Tieton Dr, Yakima, WA	

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 proficiency testing (PT) record review and an interview with the compliance personnel (CP), the laboratory failed to retain attestations signed by the laboratory director (LD) from the American Proficiency Institute (API) Hematology/Coagulation for "Sperm (presence/absence) (PPM)" and "Vaginal Wet Preparation" testing for year 2021 to day of survey. Findings include: 1. Review of API PT record request, the laboratory failed to retain signed API PT attestations for Hematology/Coagulation for "Sperm (presence/absence) (PPM)" and "Vaginal Wet Preparation" testing for year 2021 to day of survey. 2. Interview on 8/17/2023 at 06:38 pm confirmed that the CP did not provide signed API PT attestations. 3. The laboratory reports a combined 1571 wet mount and semen analysis 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 record review of PPGWNI Laboratory Manual, Vaginal Wet Mount and Post Vasectomy Semen analysis competency, and interview with compliance personnel (CP), the laboratory failed to follow written policies and procedures to assess employees. Findings include: 1. Review of 5 of 5 testing personnel (TP) competencies for Rhesus blood typing test, failed to have annual competencies assessed by the Laboratory Director. 2. Review of 13 of 13 Provider Performed Microscopy (PPM) of Vaginal Wet Mount and Post Vasectomy Semen analysis proficiency testing (PT) failed to have an assessment by the Laboratory Director. 3. Review of PPM records revealed no annual competencies for 5 of 5 TP reviewed for the year(s) 2021 to the day of survey. 4. Interview with the CP confirmed on 08/16 /2023 at 11:51 am that their "prior form did not split out wet mounts/ semen analysis." 5. Interview with the laboratory manager on 7/28/2023 at 12:30 am confirmed that the LD did not review the competency assessments.
D5211	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a) The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part. This STANDARD is not met as evidenced by: Based on proficiency testing (PT) record review and an interview with the compliance personnel (CP), the laboratory director failed to review the American Proficiency Institute (API) Hematology/Coagulation for "Sperm (presence/absence) (PPM)" and "Vaginal Wet Preparation" testing. Findings include: 1. Review of American Proficiency Institute (API) PT the laboratory director (LD) failed to review the PT performance for events: a) 2023 1st event b) 2022 3rd event 2. Interview on 8/17/2023 at 06:38 pm confirmed that the CP did not provide an API evaluation of PT testing. 3. The laboratory reports a combined 1571 wet mount and semen analysis annually.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on review of EldonCard Rhesus blood typing test manufacturer instructions, laboratory tour, and interview with the laboratory manager, the laboratory failed to label the open expiration date on the bag of EldonCard Rhesus typing test cards. Findings include: 1. EldonCard Rhesus blood typing test manufacturer state that the expiration date is six months after the bag is open. 2. Tour of the laboratory showed that the laboratory failed to label the revised expiration date on the EldonCard Rhesus

	bag lot#22071, expiration 02/28/2024, opened on 3/28/2023. 3. Interview with the laboratory manager on 7/28/2023 at 1:00 pm confirmed that the revised expiration for the EldonCard Rhesus card was not listed. 4. The laboratory performs 176 Rhesus blood typing test annually.
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 record review and interview with the laboratory manager, the laboratory director (LD) failed to specify in writing the responsibility and duties to a qualified technical consultant (TC) for the review of competency assessments and quality assurance (QA) review. 1. Review of Quality Assurance (QA) of the Rhesus blood typing patient log "RH Factor results" and Competency Assessment of Rhesus blood type testing personnel (TP), revealed that the LD failed to review. 2. Review of QA of Rhesus blood typing patient log and 5 of 5 TP Competency Assessment of Rhesus blood type testing revealed that a nonqualified TC documented the review. 3. Review of the laboratory documents revealed the laboratory failed to specify in writing the responsibilities and duties of the technical consultant listed on the CMS-209 Personnel Report form. 4. Interview with the laboratory manager on 7/28/2023 at 12: 30 am confirmed that the LD did not review the QA reports.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory manager (LM), the laboratory failed to evaluate 10 of 10 competencies for testing personnel (TP) performing EldonCard Rhesus blood type testing by a qualified individual from the year 2021 to the day of survey. Findings include: 1. Review of Rhesus blood type testing 3 of 3 initial competencies, 2 of 2 semiannual competencies, and 5 of 5 annual competencies revealed that the laboratory failed to have a qualified individual to review for the year 2021 to the day of survey. 2. Interview with the LM on 7/28/2023 at 1:00 pm confirmed that the TP was not qualified to review competencies. 3. The laboratory performs 176 Rhesus blood type tests annually.

D6103	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13) The laboratory director must ensure that policies and procedures are established for monitoring 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. This STANDARD is not met as evidenced by: Based on record review and interview with the laboratory manager and compliance personnel (CP), the Laboratory Director (LD) failed to establish policies and procedures for monitoring testing personnel (TP). Findings include. 1. Review of 5 of 5 Rhesus blood typing TP semiannual and annual competencies assessments revealed that the laboratory director failed to establish policies to include a review by the LD or qualified technical consultant (TC). 2. Review of PPMP testing for Wet mount and Seman analysis revealed the laboratory did not establish a competency assessment policy to include the six competency assessment criteria for testing personnel competency. 3. Interview with the laboratory manager on 7/28/2023 at 12:30 am confirmed that the LD did not review the competency assessments. 4. Interview with the CP confirmed on 08/16/2023 at 11:51 am that their competencies "prior form did not split out wet mounts/ semen analysis." 5. The laboratory performs 176 Rhesus blood typing test and 1571 wet mount and semen analyses annually.