Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D0058054	01/23/2024
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Of The Rocky Mountains	4630 Eubank Blvd Ne, Albuquerque, NM	

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
D0000	An onsite validation survey conducted at Planned Parenthood of the Rocky Mountains on January 23, 2024, found the laboratory to be out of compliance with the CLIA regulations found at 42 CFR, Part 493 Laboratory Requirements, with the following condition not met: 42 C.F.R. 493.1421 Condition: Moderate complexity testing personnel.
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on Review of American Proficiency Institute (API) records and confirmed in staff interview, the laboratory failed to verify the accuracy of ungraded proficiency testing results for vaginal wet preparation for 2 of 6 events in 2022 and 2023. Finding included: 1. Review of American Proficiency Institute (API) hematology / coagulation events revealed ungraded proficiency testing analytes were not reviewed for accurate results for: 1. Vaginal wet preparation event 2 of 2022 2. Vaginal wet preparation event 3 of 2023 2. Laboratory was asked to provide documentation verifying the accuracy of their ungraded results. None were provided. 3. Interview on 1/23/2024 at 10:30 am the technical consultant #1 confirmed the finding.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's D (Rho) Typing Quality Control records, review of patient test records, and staff interview, the laboratory failed to perform quality control each day of patient testing for 3 of 53 days (07/01/2023 through 09/30/2023). Findings included: 1. A review of the laboratory's D (Rho) Typing Quality Control log states: "External quality control procedures must be performed in the following situations (events): ... 2. At the beginning of each testing day." 2. A review of the laboratory's D (Rho) Typing Quality Control records from 07/01/2023 through 09/30 /2023 revealed the following dates quality control was not performed prior to patient testing: 08/01/2023 08/15/2023 08/30/2023 3. A review of patient test records from 07 /01/2023 through 09/30/2023 identified the following 8 patients were tested when quality control was not performed: 08/01/2024: ID 667372 Rh test at 10:28 am ID 644227 Rh test at 10:36 am ID 666787 Rh test at 11:56 am ID 672263 Rh test at 12: 07 pm 08/15/2024: ID 671225 Rh test at 10:55 am ID 666915 Rh test at 11:23 am 08 /30/2024 ID 673369 Rh test at 09:24 am ID 299241 Rh test at 09:30 am 4. In an interview on 01/23/2024 at 11:45 am, after review of the above records, technical consultant number 2 (as listed on CMS form 209) confirmed the findings.
D6063	LABORATORY TESTING PERSONNEL CFR(s): 493.1421 The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493. 1425 for the volume and complexity of tests performed. This CONDITION is not met as evidenced by: Based on review of the CMS form 209 and staff interview, the laboratory failed to have documentation of education to qualify 3 of 21 testing personnel (refer to D6065).
D6065	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1423(b)(1)(2)(3)(4)(i) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and This STANDARD is not met as evidenced by: Based on a review of the CMS form 209 and confirmed in staff interview, the laboratory failed to provide education records for 3 of 21 Testing Personnel (2022 and

	2023). Findings included: 1. A review of the CMS Form 209 (signed by the laboratory director on 01/14/2024) revealed the following patient testing personnel (TP) performing moderate complexity testing: a) TP number 6 b) TP number 16 c) TP number 20 2. The laboratory was asked to provide education records for the above personnel. No records were provided. 3. In an interview on 01/23/2024 at 10:30 am, after review of the above records, the technical consultant number 2 (as listed on CMS form 209) confirmed the findings.