Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	24D0668676	01/18/2024
Name of Provider or Supplier	**Street Address, City, State**	
Planned Parenthood Vandalia Health Center	671 Vandalia Street, Saint Paul, MN	

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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the Laboratory Director (LD) failed to attest to the routine integration of proficiency testing (PT) samples into the patient workload using the laboratory's routine methods on one of six occasions reviewed from 2022 and 2023. Findings are as follows: 1. The laboratory performed RhD antigen Immunohematology testing as confirmed by the Health Center Manager (HCM) during a tour of the laboratory at 9:35 a.m. on January 18, 2024. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. The LD failed to sign the attestation statement for one of six Immunology /Immunohematology API PT events reviewed for 2022 and 2023. The 2022 Immunology/Immunohematology 2nd event, Attestation Statement, was missing the LD's signature. 4. The laboratory established the following policy, found in the Laboratory Policy and Procedure Manual, Proficiency Testing Instructions, Appendix G. "6. Each tester is to sign the Attestation Page. The Laboratory Director will sign the Attestation page following its completion." 5. In an interview at 10:02 a.m. on January 18, 2024, the HCM confirmed the above findings. .
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 document review and interview with laboratory personnel, the laboratory failed to ensure immunohematology proficiency testing (PT) samples from one of six PT events from 2022 and 2023 were tested consistent with the number of times the laboratory routinely tests patient specimens. Findings are as follows: 1. The laboratory performed RhD antigen Immunohematology testing as confirmed by the Health Center Manager (HCM) during a tour of the laboratory at 9:35 a.m. on January 18, 2024. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. D (Rho) Type PT samples, RH-01 through RH-05, from the API 2023 Immunology/Immunohematology 1st Event, were tested twice, each time by a different testing personnel, as indicated on the signed attestation statement. 4. In an interview at 9:53 a.m. on January 18, 2024, the HCM confirmed the above findings. .
D3037	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(4) Proficiency testing records. Retain all proficiency testing records for at least 2 years. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to retain proficiency testing (PT) records for one of six events from 2022 and 2023. Findings are as follows: 1. The laboratory performed RhD antigen Immunohematology testing as confirmed by the Health Center Manager (HCM) during a tour of the laboratory at 9:35 a.m. on January 18, 2024. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. The 2022 Immunology/Immunohematology 2nd Event final results were not present in laboratory records on date of survey. The laboratory was unable to provide a copy of this document that had been reviewed by the appropriate staff at the time the results were received by the laboratory. 4. The laboratory established the following policy, found in the Laboratory Policy and Procedure Manual, Proficiency Testing Instructions, Appendix G. "12. Proficiency test score results are kept for a minimum of three years by the health center manager." 5. In an interview on at 10:02 a.m. on January 18, 2024, the HCM confirmed the above findings. .
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 document review and interview with laboratory personnel, the laboratory failed to review proficiency testing (PT) results for one of six PT events completed in 2022 and 2023. Findings are as follows: 1. The laboratory performed RhD antigen Immunohematology testing as confirmed by the Health Center Manager (HCM) during a tour of the laboratory at 9:35 a.m. on January 18, 2024. 2. The laboratory performed PT using the American Proficiency Institute (API) provider. 3. The results from the 2022 Immunology/Immunohematology 2nd Event were not found in the laboratory records on the day of survey. The laboratory was unable to provide evidence of PT result review for this event upon request. 4. The laboratory established

	the following policy, found in the Laboratory Policy and Procedure Manual, Proficiency Testing Instructions, Appendix G. "7. Laboratory Director, Technical Consultant, Senior Director of Quality and Clinical Development and clinic staff will review API's test scores and results of proficiency testing upon receipt." 4. In an interview on at 10:02 a.m. on January 18, 2024, the HCM confirmed the above findings. .
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 observation, document review, and interview with laboratory personnel, the Technical Consultant failed to assess competency at least semi-annually (initial and /or 6 month competencies) during the first year of patient specimen testing for eight of eleven testing personnel (TP) hired between January 2022 and January 2024. Findings are as follows: 1. The laboratory performs moderately complex RhD antigen testing under the specialty of Immunohematology as confirmed by the Health Center Manager (HCM) during a tour of the laboratory at 9:35 a.m. on January 18, 2024. 2. The Eldon Cards used to perform RhD antigen testing were observed as present and available for use during the tour of the laboratory. 3. The laboratory established the following policy regarding competency of newly hired staff, found in the Laboratory Policy and Procedure Manual, Section 9: Approval of Laboratory Personnel, 3. Competency/skills testing. "Approval to perform lab services will be completed within 45 days of employment." 4. Review of the Rh Factor Test Competencies, found that six of the eleven testing personnel hired in the past two years did not have their initial competency performed within 45 days of their date of hire (DOH) as established in policy. TP# DOH Initial competency date, lapse TP1 09/11/23 01/08 /24, 120 days TP4 11/13/23 Not done as of 01/18/24 (date of survey), 57 days TP10 02 /14/22 No initial competency performed, 6 month done after 640 days TP11 06/20/22 10/05/22, 108 days TP12 08/04/22 10/05/22, 63 days TP16 01/03/22 03/07/22, 64 days 5. Six-month competencies were either not performed or not performed at the correct time intervals for five of the eleven testing personnel hired in the past two years. TP# DOH Initial 6-month, lapse TP7 10/24/22 12/01/22 11/16/23, 11+ months TP10 02/14/22 none 11/16/23, 21+ months from DOH TP11 06/20/22 10/05/22 12/16 /23, 14+ months TP12 08/04/22 10/05/22* none, annual done 11/16/23, 13+ months TP15 09/22** 11/07/22 none, annual done 12/16/2023 13+ months 6. The laboratory was unable to provide the missing documents upon request. 7. In an interview at 10:35 a.m. on January 18, 2024, the HCM confirmed the above finding. * labeled as 6 month competency ** exact date of hire could not be provided .
D6054	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 annually, after the first year.

	This STANDARD is not met as evidenced by: . Based on observation, document review, and interview with laboratory personnel, the Technical Consultant failed to assess competency at least annually for four of five tenured testing personnel in the past two years, January 2022 to January 2024. Findings are as follows: 1. The laboratory performs moderately complex RhD antigen testing under the specialty of Immunohematology as confirmed by the Health Center Manager (HCM) during a tour of the laboratory at 9:35 a.m. on January 18, 2024. 2. The Eldon Cards used to perform RhD antigen testing were observed as present and available for use during the tour of the laboratory. 3. The laboratory established the following policy regarding annual competency assessments of staff, found in the Laboratory Policy and Procedure Manual, Section 9: Approval of Laboratory Personnel, 4. Annual reviews. "Will be completed on all employees performing moderately complex and PPM services." 4. Review of the Rh Factor Test Competencies, found that four of the five testing personnel that had been employed by the laboratory for more than two years did not have their competencies assessed at 1 year (12 month) intervals. TP# 2022 competency 2023 competency TP6 10/10/2022 12/12/2023 TP8 10/10/2022 12/16/2023 TP13 09/21/2022 01/08/2024 TP14 10/05 /2022 12/16/2023 5. In an interview at 10:35 a.m. on January 18, 2024, the HCM confirmed the above finding. .
D6056	CLINICAL CONSULTANT CFR(s): 493.1415 The laboratory must have a clinical consultant who meets the qualification requirements of 493.1417 of this part and provides clinical consultation in accordance with 493.1419 of this part. This CONDITION is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to employ a qualified Clinical Consultant in accordance with 493.1417 of this subpart . Findings are as follows: The Form CMS-209, Laboratory Personnel Report (CLIA), collected on the day of survey, January 18, 2024, did not list a Clinical Consultant. The form had been completed by the laboratory and signed by the Laboratory Director on January 12, 2024. See D6057. .
D6057	CLINICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1417 The clinical consultant must be qualified to consult with and render opinions to the laboratory's clients concerning the diagnosis, treatment and management of patient care. The clinical consultant must-- (a) Be qualified as a laboratory director under 493. 1405(b)(1), (2), or (3)(i); or (b) Be a doctor of medicine, doctor of osteopathy or doctor of podiatric medicine and possess a license to practice medicine, osteopathy or podiatry in the State in which the laboratory is located. This STANDARD is not met as evidenced by: . Based on document review and interview with laboratory personnel, the laboratory failed to ensure a qualified clinical consultant was employed. The laboratory performs approximately 2,742 non-waived tests annually. Findings are as follows: 1. The Form CMS-209, Laboratory Personnel Report (CLIA), collected on the day of survey, January 18, 2024, did not list a Clinical Consultant. The form had been completed by

	the laboratory and signed by the Laboratory Director on January 12, 2024. 2. In an interview at 12:15 p.m. on January 18, 2024, the Health Center Manager (HCM) stated she did not know who would perform the role. The HCM called the Clinical Quality Assurance Officer during the survey to discuss. After the call the HCM stated this would have the be discussed further prior to assigning someone to that role. 3. On the day of survey, January 18, 2024, the CLIA surveyor gave the laboratory 5 business days to name an individual to the Clinical Consultant role and get the credentials for the named person to the CLIA surveyor. 4. As of the close of business day, January 30, 2024 (8 business days later), the CLIA surveyor had not received notification from the laboratory on who they wanted named as the Clinical Consultant or credentials for someone to fill that role. .
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 personnel records and interview with laboratory personnel, the laboratory failed to ensure staff performing moderately complex testing meet the qualification requirements of 493.1423 to perform the functions specified in 493.1425 for the complexity of testing performed. Findings are as follows: Documentation was not provided for eight (8) of sixteen (16) testing personnel showing educational requirements under 493.1423 were met. See 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 document review and interview with laboratory personnel, the laboratory failed to ensure eight (8) of sixteen (16) testing personnel had the required educational credentials to perform moderate complexity testing. Findings are as follows: 1. The laboratory performed moderately complex RhD antigen Immunohematology testing as confirmed the Health Center Manager (HCM) during a tour of the laboratory at 9:35 a. m. on January 18, 2024. The laboratory performed approximately 1,315 moderately complex Immunohematology tests annually. 2. Documents verifying moderate complexity testing personnel requirements were met were not found for eight of

	sixteen testing personnel. Testing personnel for which educational documents were not found: Testing Personnel #3 (TP3) Testing Personnel #4 (TP4) Testing Personnel #5 (TP5) Testing Personnel #7 (TP7) Testing Personnel #10 (TP10) Testing Personnel #11 (TP11) Testing Personnel #12 (TP12) Testing Personnel #13 (TP13) 3. Survey document, Form CMS-209, Laboratory Personnel Report (CLIA), signed by the Laboratory Director on January 12, 2024, listed TP3, TP4, TP5, TP7, TP10, TP11, TP12 and TP13 as qualified to perform moderate complexity testing. 4. The laboratory established the following policy regarding documents required for newly hired staff, found in the Laboratory Policy and Procedure Manual, Section 9: Approval of Laboratory Personnel, 1. Education Requirements. "Employees performing waived & moderately complex tests will be required to provide documentation of graduation from High School or the equivalent." 5. In an interview at 12:15 p.m. on January 18, 2024, the HCM confirmed minimum qualification documents were not present for the above eight testing personnel, who had all been hired within the past two years. 6. On the day of survey, January 18, 2024, the CLIA surveyor gave the laboratory 5 business days to obtain and give the minimum educational credentials for the above eight testing personnel to the CLIA surveyor. 7. As of, the close of business day, January 30, 2024, (8 business days later) the CLIA surveyor had not received minimum educational credentials for any of the eight above listed testing personnel. .