Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1014173	08/23/2023
Name of Provider or Supplier	**Street Address, City, State**	
A Preferred Women's Health Center	3220 Latrobe Dr, Charlotte, NC	

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
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based upon review of the laboratory's 2021, 2022 and 2023 API proficiency testing records, interview with TP (Testing Personnel) #6 on 8/23/2023 and review of 2022 and 2023 patient test logs, the laboratory failed to handle proficiency testing samples in the same manner as patient samples. Findings: Review of the proficiency testing records from seven events from 2021, 2022 and 2023 revealed that the same testing personnel performed the last 3 proficiency testing events received by the laboratory. TP#6 performed all proficiency testing challenges contained within the First and Second Proficiency Testing Events of 2023 as well as the Third Proficiency Testing Event of 2022. The laboratory has a total of 11 Testing Personnel. Review of these proficiency testing records also revealed the absence of patient logs documenting the integration of proficiency testing samples within the routine patient workload. An interview with TP #6 at approximately 10:55 a.m. confirmed that proficiency testing results are not documented on the routine patient test logs.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by:

	Based upon review of the laboratory's procedure manual, review of patient test logs, interviews with TP (Testing Personnel) #6 and the Office Manager on 8/23/23 and an email received from the Office Manager on 9/1/23, the Laboratory Director did not review, approve, sign and date a revised Anti-D (Rh Type) Reagent Test procedure when the quality control protocol for this test changed in May 2021. Findings: Review of the laboratory's "Anti-D (Rh Type) Reagent Test" procedure revealed in "Section D: Test Procedure-Slide Method" the steps to perform one negative external control and one positive external control. "Section F. Quality Control" states " #1. Quality Control testing is required to confirm reactivity of the product. Positive and negative external controls must be run daily, before patient testing." A review of the patient test log revealed the documentation of two positive external controls and one negative external control each day of patient testing as well as an additional BGS external quality control that is performed along with each patient sample. An interview with TP #6 at approximately 10:30 a.m. confirmed that the quality control protocol detailed in the laboratory's "Anti-D (Rh Type) Reagent Test" procedure is not the current protocol in use in the laboratory. An interview with the Office Manager at approximately 12:05 p.m. revealed the laboratory changed its quality control protocol due to supply chain issues. Via email on 9/1/23, it was confirmed by the Office Manager that the change occurred in May 2021.
D6038	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(a) The technical consultant must be accessible to the laboratory to provide on-site, telephone, or electronic consultation. This STANDARD is not met as evidenced by: Based upon review of the laboratory's procedure manual, interview with TP (Testing Personnel) #6 on 8/23/23 and review of the TC (Technical Consultant)'s Agreement, the TC failed to maintain a procedure that detailed how to perform Anti-D testing on patient samples in the laboratory. Findings: A review of the laboratory's "Anti-D (Rh Type) Reagent Test" procedure revealed that "Section D. Test Procedure-Slide Method" did not contain step by step directions for the performance of Anti-D testing on a patient sample. A review of this section also revealed that the quality control protocol detailed in the procedure is not the current quality control protocol in use in the laboratory. An interview with TP (Testing Personnel) #6 at approximately 10:30 a.m. confirmed that the quality control protocol detailed in the laboratory's "Anti-D (Rh Type) Reagent Test" procedure is not the current protocol in use in the laboratory. A review of the TC's Agreement revealed the following responsibility in the "Duties" section: " #3. Development of all needed procedures/forms for the laboratory department for continuous on-going CLIA compliance."
D6070	TESTING PERSONNEL RESPONSIBILITIES CFR(s): 493.1425(b)(1) Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results. This STANDARD is not met as evidenced by: Based upon review of the laboratory's procedure manual and interview with TP

	(Testing Personnel) #6 on 8/23/23, TP #6 failed to follow the laboratory's policy. Findings: The laboratory's "Anti-D (Rh Type) Reagent Test" procedure states in "Section D. Test Procedure-Slide Method...#3. Add 1 drop of Anti-D to each of the labeled wells, or to each of the labeled glass slides." An interview with TP #6 at 10:30 a.m. revealed that this employee uses 2 drops of Anti-D when performing this test. TP #6 stated she was trained to perform the test using 2 drops of Anti-D.