Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D0938505	07/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
A Preferred Women's Health Center	1604 Jones Franklin Road, Raleigh, 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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of 2019, 2020 and 2021 quality control (QC) records and abscence of manufacturer assay sheets for QC reagent, ALBAcyte Antibody Screening cells, 7 /16/21, the laboratory failed to retain all Rh(D) QC records for at least two years. Findings: Review of 2019, 2020 and 2021 QC records revealed only 2 manufacturer assay sheets for the ALBAcyte Antibody Screening cells had been retained, Lot # V221377 with an expiration date of 7/6/20 and Lot # V222157 with an expiration date of 8/3/20. Review of 2019, 2020 and 2021 QC records revealed a new lot # of ALBAcyte Antibody Screening cells was opened and put into use approximately every 30 days due to expiration date. Approximately 20 manufacturer assay sheets for the QC reagent were not retained, for example: Lot #V219400, Lot #V220494 and Lot #V223104.
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 review of laboratory personnel records, review of testing personnel (TP)

	competency records and interview with Director of Patient Services 7/16/21, the technical consultant (laboratory director) failed to ensure the competency of TP#3 was accessed semiannually during their first year of testing. Findings: Review of laboratory personnel records revealed TP #3 was hired in 2/19. Review of laboratory competency records revealed TP #3 did not have their first competency assessment until 12/20, approximately 20 months in which competency was not accessed. During interview with Director of Patient Services at approximately 10:00, she stated all records should be in their file and if not in their file she was unsure where else it would be.
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 review of previous survey, 6/22/18, Laboratory Personnel Report (CMS-209), review of TP competency records and interview with Director of Patient Services 7/16/21, the technical consultant (laboratory director) failed to ensure the competency of TP#5 was accessed annually. Findings: Review of previous surveys CMS-209 revealed TP #5 began employment prior to 6/22/18. Review of laboratory personnel records revealed TP #5 had competency assessments in 12/20 and 5/21, there was no documentation of a competency assessment performed in 2019. During interview with Director of Patient Services at approximately 10:00, she stated all records should be in their file and if not in their file she was unsure where else it would be.
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as 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 result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of laboratory records, review of "AGREEMENT" document and interview with Director of Patient Services 7/16/21, the laboratory director (LD) failed to specify, in writing, the responsibilities and duties of the technical consultant (TC). Findings: Review of laboratory records revealed no delegation of responsibilities and duties for the TC hired in 1/21. Review of "AGREEMENT" submitted at time of survey revealed "Duties of ....1. To complete a quarterly lab audit...2. A report of all findings...3. Development of all needed procedures...5. Technical assistance...6. Training for the LD and staff for the items found during audits. The "AGREEMENT" fails to define the CLIA duties or responsibilities that a LD can delegate to a TC. For example; assessment of testing personnel competency, establishing a quality control

	program, and enrollment and participation in proficiency testing. Interview with Director of Patient Services at approximately 12:00 p.m. confirmed there was no documentation other than the "AGREEMENT" to specify the responsibilities and duties of the TC.