

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0938505	(X3) Date Survey Completed 02/27/2024
Name of Provider or Supplier A Preferred Women's Health Center	Street Address, City, State 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
D6030	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(12)</p> <p>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)(12) 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;</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory procedures and records, absence of technical consultant (TC) competency assessment records and interview with clinic general manager 2/27/24, the laboratory director (LD) failed to establish a competency procedure for evaluating the responsibilities and duties of the TC and failed to annually assess the competency of the TC since 2021, a period of approximately 3 years. Findings: Review of laboratory procedures revealed no procedure to assess the competency of the TC. Review of TC competency assessment records revealed no documentation of an annual TC competency assessment for 2021, 2022, and 2023. Interview with clinic general manager at approximately 11:30 a.m. confirmed there was no procedure for assessing the competency of the TC and also confirmed there was no documentation of an annual TC competency assessment.</p>
D6032	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14)</p>

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 review of laboratory records, review of contract agreement with technical consultant (TC) and interview with clinic general manager 2/27/24, the laboratory director (LD) failed to specify in writing the specific duties and responsibilities delegated to the TC. Findings: Review of laboratory records revealed no documentation of the specific duties and responsibilities delegated by the LD to the TC. Review of TC contract agreement with laboratory revealed the contract fails to state the specific duties and responsibilities of the TC. Interview with clinic general manager at approximately 10:30 a.m. confirmed the laboratory records failed to reveal a delegation of specific duties and responsibilities of the TC signed by the LD.

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 review of 2021, 2022, 2023 and 2024 testing personnel (TP) competency records, absence of TP competency assessment records, review of 2021, 2022, 2023 and 2024 technical consultant (TC) site visit notes and interview with clinic general manager 2/27/24, the TC failed to evaluate the competency of 2 of 4 TP in 2021, 2 of 4 TP in 2022, 1 of 5 TP in 2023, and 1 TP in 2024. Findings: Review of 2021, 2022, 2023 and 2024 TP competency records, "APWHC Annual Laboratory Skills Evaluation" forms, revealed the following: a. 2021 - TP #1 competency assessment was signed by the office manager. No documentation of a competency assessment for TP #3. b. 2022 - No documentation of competency assessments for TP #2 and TP #3. c. 2023 - TP #2 competency assessment was signed by the clinic general manager. d. 2024 - TP #1 competency assessment was signed by the clinic general manager. Review of 2021, 2022, 2023 and 2024 TC site visit notes revealed no documentation the TC performed the competency assessment of TP #1 in 2021, TP #2 in 2023 and TP #1 in 2024. Interview with clinic general manager at approximately 10:15 a.m. confirmed the competency findings. She stated she thought someone other than the TC could perform TP competencies and the TC could sign off on the competencies that were accessed by other staff members.