

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  11D0259351	<b>(X3) Date Survey Completed</b>  01/28/2021
<b>Name of Provider or Supplier</b>  Feminist Women's Health Center	<b>Street Address, City, State</b>  1924 Cliff Valley Way, Atlanta, GA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on January 28, 2021. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following deficiencies were cited:
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on proficiency test (PT) document review and staff interview, the laboratory failed to maintain a copy of all PT records as required. Findings include: 1. American Proficiency Institute (API) PT 2019-2020 document review revealed the lack of attestation statements for 2019 PT Immunohematology Event # 2 and 2020 PT Immunohematology Event # 3. 2. An interview with Office Manager on January 28,2021, in the consulting office at approximately 2:25 p.m. confirmed the lack of the aforementioned PT attestation statement at the time of survey.</p>
<b>D5211</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> CFR(s): 493.1236(a)</p>

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 proficiency test (PT) document review and staff interview, the laboratory director (LD) failed to ensure PT reports were reviewed as required. Findings include: 1. American Proficiency Institute (API) 2019 & 2020 PT document review revealed the 2020 Immunohematology Event # 2 report was not reviewed after results were received. 2. Interview with the Office Manager in the consulting office on January 28, 2021 at approximately 2:25 p.m. confirmed the lack of required PT report review for the aforementioned PT event.

**D6029**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(11)

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)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:

Based on testing personnel (TP) training document review and staff interview, the laboratory director (LD) failed to ensure TP receive appropriate training for moderate complexity testing as required. Findings include: 1. TP training document review revealed the lack of 2019/2020 initial training documents available at the time of survey for Staff #4 (CMS 209), Staff #5 (CMS 209), Staff #6 (CMS 209), and Staff #7 (CMS 209). 2. Interview with the Office Manager, in a consulting office, on January 28, 2021 at approximately 1:40 P.M. confirmed the lack of aforementioned 2019/2020 initial training for Staff #4 (CMS 209), Staff #5(CMS 209), Staff #6 (CMS 209), and Staff #7 (CMS 209).

**D6034**

**TECHNICAL CONSULTANT QUALIFICATIONS**

CFR(s): 493.1411

The laboratory must employ one or more individuals who are qualified by education and either training or experience to provide technical consultation for each of the specialties and subspecialties of service in which the laboratory performs moderate complexity tests or procedures. The director of a laboratory performing moderate complexity testing may function as the technical consultant provided he or she meets the qualifications specified in this section.

This STANDARD is not met as evidenced by:

Based on personnel document review and staff interview, the Laboratory Director failed to employ a Technical Consultant (TC) qualified by education and training experience. Findings include: 1. Personnel document review revealed, at the time of

the survey, the TC was not qualified by education and training/experience. Diplomas /equivalencies/Degrees/proof of experience were not available at the time of survey. 2. Interview with the Office Manager, in a consulting office, on January 28, 2021 at approximately 1:40 P.M. confirmed the TC was not qualified due to the lack of education/experience documentation at the time of the survey.

**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 testing personnel (TP) document review and staff interview, the Laboratory Director (LD) failed to evaluate and document the performance of TP for moderate complexity testing semiannually the first year of testing as required. Findings include: 1. TP competency document review revealed the LD failed to perform semiannual competencies in 2020 for Staff #6(CMS 209) and Staff #7 (CMS 209). 2. Interview with the Office Manager, in a consulting office, on January 28, 2021 at approximately 1:40 P.M. confirmed the lack of 2020 semiannual competency performed for the aforementioned TP.

**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 testing personnel (TP) competency document review and staff interview the Laboratory Director (LD) failed to evaluate and document the performance of moderate complexity TP annually as required. Findings include: 1. TP competency document review revealed the LD failed to perform 2020 annual competencies for Staff #6 (CMS 209) and Staff #7 (CMS 209). 2. Interview with the Office Manager, in the consulting office, on January 28, 2021 at approximately 1:40 P.M. confirmed the lack of 2020 annual competency performance for the aforementioned TP.

**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 testing personnel (TP) document review and staff interview the laboratory failed to employ qualified TP to perform moderate complexity testing as required.

Findings include: 1. TP document review revealed no education documentation for TP #2 (CMS 209), TP #3 (CMS 209), and TP#4 (CMS 209). Diplomas/equivalencies were not available at the time of survey. 2. An interview with the Office Manager on January 28, 2020 at approximately 1:45 PM, confirmed the aforementioned lack of education documentation at the time of survey.