| STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION | (X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER: | (X2) MULTIPLE CONSTRUCTION | (X3) DATE SURVEY COMPLETED |
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| | 11D0259351 | A. BUILDING _____ B. WING _____ | 10/25/2018 |

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| FEMINIST WOMEN'S HEALTH CENTER | 1924 CLIFF VALLEY WAY ATLANTA, GA 30329 |

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| D 000 | INITIAL COMMENTS<br><br>A Clinical Laboratory Improvement Amendments (CLIA) recertification survey was completed on October 25, 2018. 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: | D 000 | | |
| D5209 | PERSONNEL COMPETENCY ASSESSMENT POLICIES<br>CFR(s): 493.1235<br><br>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.<br>This STANDARD is not met as evidenced by:<br>A review of laboratory personnel records and an interview with the clinic's administrator, it was determined that the laboratory director failed to provide annual Competency Assessment for its testing personnel.<br><br>Findings include:<br><br>1. A review of testing personnel records revealed there was no competency evaluations for testing personnel (TP#s 2, 3,4,5,6 CMS 209) for 2017 and 2018.<br><br>2. The laboratory failed to have current written policy for semi-annual and annual competencies for testing personnel.<br><br>3. An interview with the laboratory's clinic administrator on October 25, 2018 at 02:36 PM in the review room confirmed that there was no current written policy in place and annual | D5209 | | 12/14/18 |

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE | TITLE | (X6) DATE 12/14/2018

Any deficiency statement ending with an asterisk (*) denotes a deficiency which the institution may be excused from correcting providing it is determined that other safeguards provide sufficient protection to the patients. (See instructions.) Except for nursing homes, the findings stated above are disclosable 90 days following the date of survey whether or not a plan of correction is provided. For nursing homes, the above findings and plans of correction are disclosable 14 days following the date these documents are made available to the facility. If deficiencies are cited, an approved plan of correction is requisite to continued program participation.

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| D5209 | Continued From page 1<br>competencies were not performed for testing personnel #s 2,3,4,5 and 6 on CMS 209. | D5209 | | |
| D5551 | IMMUNOHEMATOLOGY<br>CFR(s): 493.1271(a)(f)<br><br>(a) Patient testing. (a)(1) The laboratory must perform ABO grouping, D (Rho) typing, unexpected antibody detection, antibody identification, and compatibility testing by following the manufacturer's instructions, if provided, and as applicable, 21 CFR 606.151(a) through (e).<br>(a)(2) The laboratory must determine ABO group by concurrently testing unknown red cells with, at a minimum, anti-A and anti-B grouping reagents. For confirmation of ABO group, the unknown serum must be tested with known A1 and B red cells.<br>(a)(3) The laboratory must determine the D (Rho) type by testing unknown red cells with anti-D (anti-Rho) blood typing reagent.<br>(f) Documentation. The laboratory must document all control procedures performed, as specified in this section.<br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's maintenance records and an interview with the clinic's administrator, the laboratory failed to document daily Quality Control (QC) for Immunohematology ( Rh anti-D, Rh(-) controls) for 2017and 2018.<br><br>Findings include:<br><br>1. Review of Immunohematology maintenance and QC logs revealed no documentation of QC results on daily work sheets and logs for 2017, 2018. | D5551 | | 12/14/18 |

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| D5551 | Continued From page 2<br>2. An interview with the laboratory's clinic administrator on October 25, 2018 at approximately 01:40 pm in the review room confirmed QC was done but not documented on daily patient work sheets and logs. | D5551 | | |
| D6000 | MODERATE COMPLEXITY LABORATORY DIRECTOR<br>CFR(s): 493.1403<br><br>The laboratory must have a director who meets the qualification requirements of §493.1405 of this subpart and provides overall management and direction in accordance with §493.1407 of this subpart.<br><br>This CONDITION is not met as evidenced by:<br>Based on the review of laboratory documents and an interview with the Clinic's administrator, the laboratory's current laboratory director did not qualify for a moderate complexity laboratory director under CLIA standards.<br><br>Findings include:<br><br>1.) Review of laboratory documents and personnel records of the laboratory director, revealed that;<br><br>i.) The clinic did not apply to the Department of Community Health (DCH) for a change of Laboratory director in April of 2018 when the previous director was retiring.<br><br>ii.) The new director did not have the 20 CEUs lab director credits or meet other qualifications for laboratory director for moderate complexity | D6000 | | 12/14/18 |

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| D6000 | Continued From page 3<br>required by CLIA.<br><br>2.) An interview with the Clinic's administrator in the conference room on October 25, 2018 at approximately 02:30 PM confirmed that no change of laboratory director request (CMS form 116) was submitted in April 2018 and laboratory director did not meet requirements for a moderate complexity lab director by CLIA. | D6000 | | |
| D6003 | LABORATORY DIRECTOR QUALIFICATIONS<br>CFR(s): 493.1405 AND 493.1406<br><br>The laboratory director must be qualified to manage and direct the laboratory personnel and the performance of moderate complexity tests and must be eligible to be an operator of a laboratory within the requirements of subpart R of this part.<br>(a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if such licensing is required; and<br>(b) The laboratory director must--<br>(b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and<br>(b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification; or<br>(b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the Laboratory is located; and | D6003 | | 12/14/18 |

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| D6003 | Continued From page 4<br>(b)(2)(ii) Have had laboratory training or experience consisting of:<br>(b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or<br>(b)(2)(ii)(B) Beginning September 1, 1993, have at least 20 continuing medical education credit hours in laboratory practice commensurate with the director responsibilities defined in §493.1407; or<br>(b)(2)(ii)(C) Laboratory training equivalent to paragraph (b)(2)(ii)(B) of this section obtained during medical residency. (For example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine); or<br>(b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and<br>(b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or<br>(b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing;<br>(b)(4)(i) Have earned a master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution;<br>(b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and<br>(b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or<br>(b)(5)(i) Have earned a bachelor's degree in a | D6003 | | |

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| D6003 | Continued From page 5<br>chemical, physical, or biological science or medical technology from an accredited institution;<br>(b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and<br>(b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing;<br>(b)(6) Be serving as a laboratory director and must have previously qualified or could have qualified as a laboratory director under §493.1406; or<br>(b)(7) On or before February 28, 1992, qualified under State law to direct a laboratory in the State in which the laboratory is located.<br><br>Laboratory director qualifications on or before February 28, 1992<br>The laboratory director must be qualified to manage and direct the laboratory personnel and test performance.<br>(a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and<br>(b) The laboratory director must:<br>(b)(1) Be a physician certified in anatomical or clinical pathology (or both) by the American Board of Pathology or the American Osteopathic Board of Pathology or possess qualifications that are equivalent to those required for such certification;<br>(b)(2) Be a physician who:<br>(b)(2)(i) Is certified by the American Board of Pathology or the American Osteopathic Board of Pathology in at least one of the laboratory specialties; or<br>(b)(2)(ii) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of | D6003 | | |

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| D6003 | Continued From page 6 | D6003 | | |

Bioanalysis, or other national accrediting board in one of the laboratory specialties; or
(b)(2)(iii) Is certified by the American Society of Cytology to practice cytopathology or possesses qualifications that are equivalent to those required for such certification; or
(b)(2)(iv) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties;
(b)(3) For the subspecialty of oral pathology only, be certified by the American Board of Oral Pathology, American Board of Pathology or the American Osteopathic Board of Pathology or possesses qualifications that are equivalent to those required for certification;
(b)(4) Hold an earned doctoral degree from an accredited institution with a chemical, physical, or biological science as a major subject and
(b)(4)(i) Is certified by the American Board of Medical Microbiology, the American Board of Clinical Chemistry, the American Board of Bioanalysis, or other national accrediting board acceptable to HHS in one of the laboratory specialties; or
(b)(4)(ii) Subsequent to graduation, has had 4 or more years of full-time general laboratory training and experience of which at least 2 years were spent acquiring proficiency in one of the laboratory specialties;
(b)(5) With respect to individuals first qualifying before July 1, 1971, have been responsible for the direction of a laboratory for 12 months between July 1, 1961, and January 1, 1968, and, in addition, either:
(b)(5)(i) Was a physician and subsequent to graduation had at least 4 years of pertinent

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| D6003 | Continued From page 7<br>full-time laboratory experience;<br>(b)(5)(ii) Held a master's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 4 years of pertinent full-time laboratory experience;<br>(b)(5)(iii) Held a bachelor's degree from an accredited institution with a chemical, physical, or biological science as a major subject and subsequent to graduation had at least 6 years of pertinent full-time laboratory experience; or<br>(b)(5)(iv) Achieved a satisfactory grade through an examination conducted by or under the sponsorship of the U.S. Public Health Service on or before July 1, 1970; or<br>(b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located.<br><br>Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in paragraph (b)(5) of this section may be extended 1 year for each year of full-time laboratory experience obtained before January 1, 1958 required by State law for a laboratory director license. An exception to the July 1, 1971 qualifying date in paragraph (b)(5) of this section was made provided that the individual requested qualification approval by October 21, 1975 and had been employed in a laboratory for at least 3 years of the 5 years preceding the date of submission of his qualifications.<br><br>This STANDARD is not met as evidenced by:<br>Based on the review of laboratory documents and an interview with the Clinic's administrator, the laboratory's current laboratory director did not qualify for a moderate complexity laboratory director under CLIA standards. | D6003 | | |

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| D6003 | Continued From page 8<br><br>Findings include:<br><br>1.) Review of laboratory documents and personnel records of the laboratory director, revealed that;<br><br>i.) The clinic did not apply to the Department of Community Health (DCH) for a change of Laboratory director in April of 2018 when the previous director was retiring.<br><br>ii.) The new director did not have the 20 CEUs lab director credits or meet other qualifications for laboratory director for moderate complexity required by CLIA.<br><br>2.) An interview with the Clinic's administrator in the conference room on October 25, 2018 at approximately 02:30 PM confirmed that no change of laboratory director request (CMS form 116) was submitted in April 2018 and laboratory director did not meet requirements for a moderate complexity lab director by CLIA. | D6003 | | |
| D6033 | Ref for D-6000<br>TECHNICAL CONSULTANT-MODERATE COMPEXITY<br>CFR(s): 493.1409<br><br>The laboratory must have a technical consultant who meets the qualification requirements of §493.1411 of this subpart and provides technical oversight in accordance with §493.1413 of this subpart.<br><br>This CONDITION is not met as evidenced by: | D6033 | | 12/14/18 |

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| D6033 | Continued From page 9<br>Based on the review of laboratory documents and interviews with the clinic's administrator, the laboratory failed to employ an active and qualified person to fulfill the position of Technical Consultant (TC) to oversee laboratory operations.<br><br>Findings include;<br><br>1.) Personnel documents review revealed the laboratory's maintenance logs, testing personnel assessments, temperature logs and Quality Control (QC) logs for Immunohematology were not reviewed by the laboratory director who also acts as the TC in 2017 and 2018.<br><br>3.) An interview with the Clinic's administrator in the review room on October 25, 2018 at approximately 01:55 PM confirmed that the laboratory did not have a qualified and active Technical Consultant. | D6033 | | |
| D6035 | TECHNICAL CONSULTANT QUALIFICATIONS<br>CFR(s): 493.1411<br><br>(a) The technical consultant must be qualified and must possess a current license issued by the State in which the laboratory is located, if such licensing is required.<br>(b) The technical consultant must--<br><br>(b)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and<br><br>(b)(1)(ii) Be certified in anatomic or clinical pathology, or both, by the American Board of Pathology or the American Osteopathic Board of | D6035 | | 12/14/18 |

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| D6035 | Continued From page 10 | D6035 | | |

Pathology or possess qualifications that are equivalent to those required for such certification; or

(b)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and

(b)(2)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible (for example, physicians certified either in hematology or hematology and medical oncology by the American Board of Internal Medicine are qualified to serve as the technical consultant in hematology); or

(b)(3)(i) Hold an earned doctoral or master's degree in a chemical, physical, biological or clinical laboratory science or medical technology from an accredited institution; and

(b)(3)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible; or

(b)(4)(i) Have earned a bachelor's degree in a chemical, physical or biological science or medical technology from an accredited institution; and

(b)(4)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived

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| D6035 | Continued From page 11<br>testing, in the designated specialty or subspecialty areas of service for which the technical consultant is responsible.<br><br>Note: The technical consultant requirements for "laboratory training or experience, or both" in each specialty or subspecialty may be acquired concurrently in more than one of the specialties or subspecialties of service, excluding waived tests. For example, an individual who has a bachelor's degree in biology and additionally has documentation of 2 years of work experience performing tests of moderate complexity in all specialties and subspecialties of service, would be qualified as a technical consultant in a laboratory performing moderate complexity testing in all specialties and subspecialties of service.<br>This STANDARD is not met as evidenced by:<br>Based on the review of laboratory documents and interviews with the clinic's administrator, the laboratory failed to employ an active and qualified person to fulfill the position of Technical Consultant (TC) to oversee laboratory operations.<br><br>Findings include;<br><br>1.) Personnel documents review revealed the laboratory's maintenance logs, testing personnel assessments, temperature logs and Quality Control (QC) logs for Immunohematology were not reviewed by the laboratory director who also acts as the TC in 2017 and 2018.<br><br>3.) An interview with the Clinic's administrator in the review room on October 25, 2018 at approximately 01:55 PM confirmed that the laboratory did not have a qualified and active | D6035 | | |

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| D6035 | Continued From page 12<br>Technical Consultant.<br><br>Ref for D-6033 | D6035 | | |
| D6049 | TECHNICAL CONSULTANT RESPONSIBILITIES<br>CFR(s): 493.1413(b)(8)(iii)<br><br>The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records.<br>This STANDARD is not met as evidenced by:<br>Based on review of the laboratory's maintenance records and an interview with the laboratory's clinic administrator, the Technical Consultant (TC) who is also the laboratory director failed to review maintenance records in 2017, 2018.<br><br>Findings include:<br><br>1. Review of maintenance logs including refrigerators, room temperature, eye wash and problem logs revealed they were not reviewed and signed on a monthly basis by TC who is also the laboratory director.<br><br>2. An interview with the laboratory's clinic administrator on October 25, 2018 at approximately 02:00 pm in the review room confirmed maintenance logs were not reviewed and signed by the (TC) who is also laboratory director. | D6049 | | 12/14/18 |