

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR MEDICARE & MEDICAID SERVICES

PRINTED: 03/16/2021  
FORM APPROVED  
OMB NO. 0938-0391

STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION		(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:  <b>11D0259351</b>	(X2) MULTIPLE CONSTRUCTION A. BUILDING _____  B. WING _____		(X3) DATE SURVEY COMPLETED  <b>R</b> <b>03/16/2021</b>
NAME OF PROVIDER OR SUPPLIER  <b>FEMINIST WOMEN'S HEALTH CENTER</b>			STREET ADDRESS, CITY, STATE, ZIP CODE <b>1924 CLIFF VALLEY WAY</b> <b>ATLANTA, GA 30329</b>		
(X4) ID PREFIX TAG	SUMMARY STATEMENT OF DEFICIENCIES (EACH DEFICIENCY MUST BE PRECEDED BY FULL REGULATORY OR LSC IDENTIFYING INFORMATION)	ID PREFIX TAG	PROVIDER'S PLAN OF CORRECTION (EACH CORRECTIVE ACTION SHOULD BE CROSS-REFERENCED TO THE APPROPRIATE DEFICIENCY)	(X5) COMPLETION DATE	
{D 000}	INITIAL COMMENTS  On 03/09/21, an off site review of the laboratory's Plan of Correction (POC) was completed. The review revealed corrections for all standards were not acceptable. The facility is not in compliance with all regulations surveyed. The following standards still need to be corrected.	{D 000}			
{D5211}	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)  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:	{D5211}	1.Per FWHC protocol all Lab results are reviewed by the Flow Nurse, CRNA and Physician prior to surgery. This provides eligibility confirmation before any patient undergoes the procedure. The Rh test (which is the only moderate complex test performed) is currently one element of FWHC's pregnancy termination protocol for Rhogam. Per our medical staff, due to unique nature of abortion whether a patient receives Rhogam does not affect the the health of the patient as it pertains to the abortion. Therefore, medically the RH clinical result cannot adversely affect the patient when terminating the pregnancy.  2.The deficient practice has been corrected and FWHC has obtained all 2019 & 2020 results. Results have been reviewed by the LD, signed and placed in the API Manual. The Immunohematology Event#2 report has been reviewed and signed. SEE ATTACHMENT*  3.Systems in place prevented any adverse affects on any patient due to the failure of LD failure to review and sign off on the 2020 Immunohematology Event#2. The API results for this event was 100%, review and sign off has been completed for this Event.  4. Measures which have been put in place: Every week (Thursday) the LD is scheduled to review all Rh Log test, and all Lab Logs, Proficiency Test (as required) and will review and sign. Lead Lab Personnell will double check the stated procedure..	3/1/21	
{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	{D6029}	1.Per FWHC protocol all lab results are revied by the Flow Nurse, CRNA & Physician prior to surgery. This provides eligibility confirmation, The Rh test (which is the only moderate complex test performed) is currently one element of FWHC's pregnancy		

LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE

TITLE

(X6) DATE

*Tyrone C. Malloy, MD*

Laboratory Director

March 24, 2021

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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{D6029}	Continued From page 1 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).	{D6029}	protocol for Rhogam. Per our medical staff, due to the unique nature of abortion whether a patient receives Rhogam does not affect the health of the patient as it pertains to the abortion. Therefore, medically the Rh clinical result cannot adversely affect the patient when terminating the pregnancy.  2. Training documents are now housed along with the current CMS (209) forms to allow for strict continuity.  3All TP personnel have received appropriate training and documentation of same is in place.  4. Remedial Action: Initial, 6 months when required, and annual technical competency/training will now require the signature of the Clinical Administrator prior to testing personnel performing laboratory testing  5. Monitoring of Corrective Actions will be performed by the LD in accordance with the schedule for completion of TP assessments.	3/1/21	
{D6034}	TECHNICAL CONSULTANT QUALIFICATIONS CFR(s): 493.1411  The laboratory must employ one or more	{D6034}	1. Per FWHC protocol all Lab results are reviewed by the Flow Nurse, CRNA & Physician prior to surgery. This provides eligibility confirmation before any patient undergoes the procedure. The Rh test	3/31/21	

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{D6034}	Continued From page 2 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.	{D6034}	(which is the only moderate complex test performed) is currently one element of FWHC's pregnancy termination protocol for Rhogam. Per our medical staff, due to the unique nature of abortion, whether a patient receives Rhogam does not affect the health of the patient as it pertains to the abortion. Therefore, medically the Rh clinical cannot adversely affect the patient when terminating the pregnancy.  2. There were no negative effects to any patients due to the lack of Credentialing information.  3.FWHC LD is the CC and TC.  4. LD will monitor all aspects of proper documentation required.		
{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	{D6053}	1. Per FWHC protocol all Lab results are reviewed by the Flow Nurse, CRNA & Physician prior to surgery. This provides eligibility confirmation before any patient undergoes the procedure. The Rh test (which is the only moderate complex test performed) is currently one element of FWHC's pregnancy termination protocol for Rhogam. Per our medical staff due to	3/1/21	

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{D6053}	Continued From page 3 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.	{D6053}	the unique nature of abortion hether a patient receives Rhogam does not affect the health of the patient as it pertains to the abortion. Therefore, medically the Rh clinical result cannot adversely affect the patient when terminating the pregnancy.  2. Corrective Action has been completed. CMS (209) has been revised to reflect the current Laboratory personnel. CMS (209) will be revised when the following conditions present: New Hire Trained Employees, Terminated Employees 6 month review 12 month review  3. Systemic Change: CMS (209) will be reviewed, documentation changed (when necessary) on a monthly basis by the TC as presented by the Clinic Administrator.		
{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	{D6054}	4.LD will review CMS (209) on a Quarterly basis.Should changes occur before the Quarter ends the LD shall have changes submitted as soon as they occur by the Clinic Administrator.  D6054  1.Per FWHC protocol all Lab results are reviewed by the Flow Nurse, CRNA & Physician prior to eligibility confirmation before any patient undergoes the procedure. The Rh test (which is the only moderate test performed) is currently one element of the FWHC's pregnancy termination protocol for Rhogam. Per our medical staff, due to the unique nature of abortion whether a patient recieves	3/31/21	

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{D6054}	Continued From page 4 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.	{D6054}	Rhogam does not affect the health of the patient as it pertains to the abortion. Therefore, medically the Rh clinical result cannot adversely affect the patient terminating the pregnancy.  2. Corrective action has been completed. CMS (209) revisions have eeb completed to reflect current Laboratory personnel. Changes in TP personnel will be revised when New TP personnel are hired, terminated, 6 month review & 12 month review.	
{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.	{D6065}	3. Systemic change: CMS (209) will be reviewed, documentation changed (when necessary) on a mothly basis by the TC as presented by the Clinic Administrator.  4. LD will review CMS (209) on a Quarterly basis. Changes before the Quarter ends / or during will be submitted to the TC by the Clinic Administrator.  <b>D6065</b>  1. Per FWHC protocol all Lab results are reviewed by the Flow Nurse, CRNA & Physician prior to surgery. This provides eligibility confirmation before any patient undergoes the procedure. The Rh test (which is the only moderate test performed) is currently one element of the FWHC's pregnancy termination protocol for Rhogam. Per our medical staff, due to the unique nature of abortion, whether a patient receives Rhogam does not affect the health of the patient as it pertains to the abortion. Therefore, medically the Rh clinica result cannot adversely affect the patient when terminating the pregnancy.  2. Corrective Action: The LD/TC is responsible for review of all CLIA requirements for TP qualifications upon hire: High School or Equivalent & Certification (s). This has been completed for all current Laboratory personnel. Inclusive of same has been the completion for 6 month competency and annual competencies.	2/26/21

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{D6065}	Continued From page 5 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.	{D6065}	3. Duties and responsibilities of the CC, TC and LD are assigned and documented properly. TC is responsible for the technical and scientific oversight of the laboratory. Clinical Consultant provides consultation regarding the appropriateness of testing ordered and the interpretation of test results. LD qualifications are documented.  4. Due to systemic change in assuring competency in the FWHC lab there were no adverse effects to any patients as per FWHC protocols as each patients lab results were reviewed with the Flow Nurse, CRNA and Physician prior to the surgical procedure.  5. All monitoring will be accomplished with the joint Team of LD, CC, TC, along with the Lead Testing personnel and Clinic Administrator. The monitoring of Lab staff is in place to assure competency and requirements for our laboratory.	