STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	11D2025053	A. BUILDING _____ B. WING _____	07/22/2019

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
COLUMBUS WOMENS HEALTH ORG	3850 ROSEMONT DRIVE COLUMBUS, GA 31904

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D 000	INITIAL COMMENTS A Clinical Laboratory Improvement Amendments (CLIA) Recertification survey was completed on July 22, 2019. The laboratory was not in compliance with applicable CLIA requirements found at 42 CFR 493.1 through 42 CFR 493.1780. The following condition/deficiencies were cited:	D 000		
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under §493.1253. This STANDARD is not met as evidenced by: Based on review of a procedural change for determining Rh factor with Albaclone reagents, review of the reagent package insert, review of the patient logs(with temperature documents at the bottom), and staff interview, the laboratory was not following the manufacturer's specifications for the room temperature during test performance. Findings: 1. Review of the procedural change for determining the Rh factor of the sample, stated "if no agglutination occurs, incubate the test for five minutes at 18-24 degrees Celsius (64.4 to 75.2 degrees Fahrenheit)." 2. Review of the package insert for the Albaclone	D5411		7/23/19

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

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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D5411	Continued From page 1 Rh factor reagent, states "incubate the slide for 5 minutes at 20 - 24 degrees Celsius (68 to 75.2 degrees Fahrenheit)." 3. Review of the Patient logs, the room temperature range was listed as 18 to 24 degrees Celsius, but according to manufacturer's specifications the temperature range should have been 20 to 24 degrees Celsius. 4. Interview with staff #1 (CMS 209 form) on July 22, 2019, at approximately 3pm, in the Consultation Room, confirmed the aforementioned statements.	D5411		
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the maintenance documents and staff interview, the laboratory did not have any documentation of maintenance on the Adams MicroHematocrit II centrifuge. Findings: 1. Upon observation during the lab tour, the Adams MicroHematocrit II (MHCTII) had a sticker that indicated the voltage and amps had been checked. 2. Review of maintenance documents confirmed that there was no documentation of timer or speed (RPM) checks performed on the MHCTII.	D5429		8/23/19

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D5429	Continued From page 2 3. Interview with staff #1 (CMS 209 form), on July 22, 2019, at approximately 12:20 pm, in the Consultation Office, confirmed that the timer checks and RPM had not been checked on the MHCTII centrifuge.	D5429		
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 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. This CONDITION is not met as evidenced by: Based on review of personnel records and staff interview, the laboratory director (LD) failed to meet the qualification requirements during the time period of August 1, 2018 to July 22, 2019. Findings include: Refer to D6003 for details	D6000		9/30/19
D6003	LABORATORY DIRECTOR QUALIFICATIONS CFR(s): 493.1405 AND 493.1406 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. (a) The laboratory director must possess a current license as a laboratory director issued by the State in which the laboratory is located, if	D6003		9/30/19

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D6003	Continued From page 3 such licensing is required; and (b) The laboratory director must-- (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 (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 (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 had laboratory training or experience consisting of: (b)(2)(ii)(A) At least one year directing or supervising non-waived laboratory testing; or (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 (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 (b)(3) Hold an earned doctoral degree in a chemical, physical, biological, or clinical laboratory science from an accredited institution; and (b)(3)(i) Be certified by the American Board of Medical Microbiology, the American Board of	D6003		

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D6003	Continued From page 4 Clinical Chemistry, the American Board of Bioanalysis, or the American Board of Medical Laboratory Immunology; or (b)(3)(ii) Have had at least one year experience directing or supervising non-waived laboratory testing; (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; (b)(4)(ii) Have at least one year of laboratory training or experience, or both in non-waived testing; and (b)(4)(iii) In addition, have at least one year of supervisory laboratory experience in non-waived testing; or (b)(5)(i) Have earned a bachelor's degree in a chemical, physical, or biological science or medical technology from an accredited institution; (b)(5)(ii) Have at least 2 years of laboratory training or experience, or both in non-waived testing; and (b)(5)(iii) In addition, have at least 2 years of supervisory laboratory experience in non-waived testing; (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 (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. Laboratory director qualifications on or before February 28, 1992 The laboratory director must be qualified to manage and direct the laboratory personnel and test performance.	D6003		

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D6003	Continued From page 5 (a) The laboratory director must possess a current license as a laboratory director issued by the State, if such licensing exists; and (b) The laboratory director must: (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; (b)(2) Be a physician who: (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 (b)(2)(ii) 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 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	D6003		

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D6003	Continued From page 6 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 full-time laboratory experience; (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; (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 (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 (b)(6) Qualify under State law to direct the laboratory in the State in which the laboratory is located. Note: The January 1, 1968 date for meeting the 12 months' laboratory direction requirement in	D6003		

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D6003	Continued From page 7 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. This STANDARD is not met as evidenced by: Based on review of personnel records and staff interview, the laboratory director (LD) failed to meet the qualification requirements during the time period of August 1, 2018 to July 22, 2019. Findings include: 1. Review of personnel records (08/01/2018 to 07/22/2019) revealed the LD did not have the proper lab training or experience required to direct a moderate complexity lab. 2. Interview with staff #1(CMS 209 form) on 9/19/18 at approximately 10:30 AM in the breakroom, confirmed the lab director did not meet the training or experience requirements	D6003		
D6033	TECHNICAL CONSULTANT-MODERATE COMPEXITY CFR(s): 493.1409 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.	D6033		9/30/19

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D6033	Continued From page 8 This CONDITION is not met as evidenced by: Based on review of personnel records and staff interview, the Technical Consultant (TC) failed to meet the qualification requirements during the time period of August 1, 2018 to July 22, 2019. Findings include: Refer to D6034 for details	D6033		
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 review of personnel records and staff interview, the Technical Consultant (TC) failed to meet the qualification requirements during the time period of August 1, 2018 to July 22, 2019. Findings include: 1. Review of personnel records (08/01/2018 to 07/22/2019) revealed the TC did not have the proper lab training or experience required to direct a moderate complexity lab. 2. Interview with staff #1(CMS 209 form) on	D6034		9/30/19

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D6034	Continued From page 9 9/19/18 at approximately 10:30 AM in the breakroom, confirmed the TC did not meet the training or experience requirements	D6034		
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 review of the Employee documents and staff interview, there was a staff member listed as a Testing Personnel (TP) that did not provide a copy of a high school diploma, or equivalency. Findings: 1 Based on review of the employee documents, staff member #1 (CMS-209), did not have a copy	D6065		8/23/19

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D6065	Continued From page 10 of a high school diploma or equivalency, required for moderate complexity testing personnel. 2 Interview with staff #1 (CMS-209) on July 22, 2019, at approximately 3pm, in the Consultation Room, confirmed that the aforementioned staff member did not have a copy of a high school diploma or equivalency.	D6065		