STATEMENT OF DEFICIENCIES AND PLAN OF CORRECTION	(X1) PROVIDER/SUPPLIER/CLIA IDENTIFICATION NUMBER:	(X2) MULTIPLE CONSTRUCTION	(X3) DATE SURVEY COMPLETED
	AB0028	A. BUILDING: _____ B. WING _____	03/08/2016

NAME OF PROVIDER OR SUPPLIER	STREET ADDRESS, CITY, STATE, ZIP CODE
A WOMAN'S CHOICE OF RALEIGH, INC	3305 DRAKE CIRCLE RALEIGH, NC 27607

(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) COMPLETE DATE
E 165	.0314 Cleaning of Materials and Equipment 10A-14E .0314 (a) All supplies and equipment used in patient care shall be properly cleaned or sterilized between use for different patients. (b) Methods of cleaning, handling, and storing all supplies and equipment shall be such as to prevent the transmission of infection through their use. This Rule is not met as evidenced by: Based on review of the facility's policy and procedures, observation during tour, review of the manufacturer's guidelines for autoclave biological testing, facility's autoclave testing log and staff interviews, the facility failed to prevent the transmission of infection by failing to perform biological testing according to manufacturers' recommendation for steam sterilization of the surgical instruments. The findings include: Policy and procedure review on 03/08/2016 did not reveal a policy/ procedure on the autoclave for frequency of biological/ spore testing (testing to ensure items are sterile after processing). Direct observation during tour on 03/08/2016 at 1130 revealed an autoclave (heat/ steam sterilizer) for sterilizing instruments. Review of the manufacturer's guidelines on the back of the testing material used by the facility for testing of the autoclave revealed the "Accepted Practice Guidelines for Sterilization Monitoring" was at least weekly as recommended by the CDC	E 165	A Womans Choice of Raleigh has revised the policy and procedure for biological testing on March 9, 2016. The test will be conducted on a weekly basis. The Director of Patient Services has trained the current staff at A Womans Choice of Raleigh on March 9 2016 on how to do biological testing. She taught staff how to do a spore test, how to log the results and actions to take if the test failed. The Director of Patient Services will train all current and future staff on how to do biological testing. A Womans Choice of Raleigh did the Prosure Test on March 09, 2016. The results were faxed on March 15 with a "passed" result.	5/10/16

Division of Health Service Regulation
LABORATORY DIRECTOR'S OR PROVIDER/SUPPLIER REPRESENTATIVE'S SIGNATURE: Rita Spear — TITLE: Regional Manager — (X6) DATE: 5/10/16

Division of Health Service Regulation

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E 165	Continued From page 1 (Centers for Disease Control), AAMI (Association for the Advancement of Medical Instrumentation), AORN (Association of PeriOperative Registered Nurses) and ASHCSP (American Society for Healthcare Central Service Professionals). Review of the facility's autoclave testing log on 03/08/2016 revealed biological testing results on the following dates: 06/30/2015, 07/27/2015, 08/27/2015, 09/23/2015, 10/20/2015, 11/22/2015, 12/28/2015, 01/26/2016 and 02/25/2016 (monthly). Interview on 03/08/2016 at 1235 with administrative staff revealed the autoclave biological testing should be performed weekly. Interview revealed the facility's autoclave biological testing had been performed monthly and the facility would need to start doing weekly testing.	E 165	The results will be kept in a log yearly, after a year the results will be stored on the premises. If the results show "failed" the auto clave will be sent to a local vendor (Henry Schein pro repair) for repair, they will provide a loaner while the damage auto clave is being repaired. The loaner will also be tested weekly by the Director of Patient Services and staff	Monitor r following
E 171	.0308 Quality Assurance 10A NCAC 14E .0308 (a) The governing authority shall establish a quality assurance program for the purpose of providing standards of care for the clinic. The program shall include the establishment of a committee that shall evaluate compliance with clinic procedures and policies. (b) The committee shall determine corrective action, if necessary. (c) The committee shall consist of at least one physician who is not an owner, the chief executive officer or designee, and other health professionals. The committee shall meet at least once per quarter. (d) The functions of the committee shall include development of policies for selection of patients,	E 171		

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E 171	Continued From page 2 approval for adoption of policies, review of credentials for staff privileges, peer review, tissue inspection, establishment of infection control procedures, and approval of additional procedures to be performed in the clinic. (e) Records shall be kept of the activities of the committee for a period not less than 10 years. These records shall include: (1) reports made to the governing authority; (2) minutes of committee meetings including date, time, persons attending, description and results of cases reviewed, and recommendations made by the committee; and (3) information on any corrective action taken. (f) Orientation, training, or education programs shall be conducted to correct deficiencies that are uncovered as a result of the quality assurance program. This Rule is not met as evidenced by: Based on policy and procedure review, facility documents, and staff interview, the facility failed to ensure the establishment of a Quality Assurance program, with a designated committee that included at least one non-owner physician that met at least once a quarter. The findings include: Policy and procedure review, on 03/08/2016, did not reveal documentation of a Quality Assurance plan or the establishment of a Quality Assurance Committee with identified functions, reporting responsibility to the Governing Authority, and membership including at least one non-physician member. Further review did not reveal documentation of any minutes demonstrating activities of such a committee. Interview with Administrative Staff (AS) # 1, on 03/08/2016 at 1515 revealed there was no	E 171	The owner of A Womans Choice of Raleigh established a Quality Control Community in March 2016. The community consist of, Director of operations, Medical Director, Reg. Nurse and the Regional Manager. The Director of operations will make sure the community meets once quarterly to ensure the clinic is in compliance. They will discuss Quality Assurance, make recommendations if needed and determine corrective actions if neccessary. The Regional Manager will make sure the corrective action is implemented. The Regional Manager will be responsible for staff training and education for policy	5/10/16

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E 171	Continued From page 3 available documentation of a Quality Assurance Plan, the members of a Quality Assurance Committee, or any minutes from a Quality Assurance meeting. Interview revealed the facility had not held a Quality Assurance Committee meeting that included a non-owner physician.	E 171	changes, corrective actions, orientation and training programs to correct deficiencies The first meeting will be on April 24, 2016 at 1pm. The minutes of committe ~~mmtt~~ meeting and person attending and description and results will be kept by the Regional Manager. The log of the meeting will be kept at the clinic - , and a copy by the Regional Manager.	