Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D0678750	(X3) Date Survey Completed 01/24/2022
Name of Provider or Supplier Physicians For Women Of Greensboro	**Street Address, City, State** 802 Green Valley Road, Suite 300, Greensboro, NC	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of 2019, 2020, and 2021 sperm wash records and interview with testing personnel (TP #1) 1/24/22, the laboratory failed to verify the accuracy of the sperm wash testing at least twice a year in 2021. Review of sperm was records revealed the laboratory verified the accuracy of the sperm wash testing twice in 2019 (5/10/19, 6/6/19) and twice in 2020 (2/29/20, 7/10/20), but only once in 2021 (6/7/21). During interview at approximately 12:10 p.m., TP #1 stated that one of the testing personnel left in August 2021, and only one person was left to perform sperm wash testing after that. She verified the accuracy verification was performed only once in 2021.
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 review of personnel records, review of the laboratory's policies and procedures, and interview with the TC (technical consultant) 1/24/22, the laboratory director failed to ensure that prior to testing patient specimens 1 of 14 testing personnel (TP #11) had received appropriate training and had demonstrated the ability to perform testing operations reliably to provide and report accurate patient wet prep test results. Review of personnel records revealed TP #11 was trained in October 2019 for the BD Affirm VP III and the Cepheid Gene Xpert. There was no documentation of wet prep training available for TP #11. Review of the "AFFIRM/WET PREP TESTING PERSONNEL" policy revealed "1. Only employees who have had prior experience or in office training will be certified to perform these tests. 2. After completing a training period where they will observe by following current qualified staff and then demonstrating with 100% competency, employee will be qualified to perform testing. ..." During interview at approximately 10:00 a.m., the TC confirmed that TP #11 does perform wet preps. She stated TP #11 had performed wet preps at a previous job, and she verified that they had not documented any training for TP #11.
D6032	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(14) 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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the TC (technical consultant) 1/24/22, the laboratory director failed to specify, in writing, the duties and responsibilities for the laboratory director, the TC, and CC (clinical consultant) #2. Review of personnel records revealed there were no job descriptions or lists of authorized duties for the laboratory director, the TC, and CC #2 available for review. During interview at approximately 2:30 p.m., the TC confirmed that there were no job descriptions or lists of authorized duties available for the laboratory director, the TC, and CC #2.