Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	34D1071891	09/11/2024
Name of Provider or Supplier	**Street Address, City, State**	
Ah Wake Forest Baptist Urology - Charlois	140 Charlois Boulevard, Winston-Salem, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures and review of 2023 and 2024 CAP (College of American Pathologists) proficiency testing records 9/11/24, the testing personnel failed to attest that proficiency samples were tested in the same manner as patient specimens are routinely tested for 3 of 6 proficiency testing events. Findings: Review of the "Quality Ambulatory Assurance Plan Point of Care Testing" revealed "... C. Proficiency Testing: ... Attestation statements are signed by testing personnel and Lab Director/designee. ..." Review of 2023 and 2024 CAP proficiency testing records revealed testing personnel failed to sign attestation statements for the following events: 1. 2023 CM-A; 2. 2023 CM-B; 3. 2023 SEM-A.
D6015	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4) 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)(4) Ensure that the laboratory is enrolled in an HHS approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by:

	Based on review of job descriptions and review of 2023 and 2024 CAP proficiency testing records 9/11/24, the laboratory director failed to ensure the laboratory was enrolled in an approved proficiency testing program for the testing performed. Findings: Review of the "Technical Consultant for Moderate Complexity Lab" job description revealed "... The Urology Technical Consultant position is served by the Lab Director. ..." The job description included a list of duties for the technical consultant (laboratory director), including "Enrolls the laboratory in an approved PT program." Review of 2023 and 2024 CAP proficiency testing records revealed the laboratory was not enrolled in proficiency testing for the first clinical microscopy, urinalysis, and semen analysis test events of 2024. Review of the laboratory's 2024 proficiency testing order revealed the laboratory enrolled 7/11/24 after the lapse was discovered.
D6019	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(iv) 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)(4)(iv) Ensure that an approved corrective action plan is followed when any proficiency testing results are found to be unacceptable or unsatisfactory. This STANDARD is not met as evidenced by: Based on review of 2023 and 2024 CAP proficiency testing records and interview with the "point of care coach" 9/11/24, the laboratory director failed to ensure all ungraded results were evaluated to identify the need for corrective action. Findings: Review of 2023 and 2024 CAP proficiency testing records revealed no evaluation documented for the following ungraded proficiency testing results from the 2023 CM-A event: 1. sample CMP-05 2. sample USP-02 During interview at approximately 10: 15 a.m., the "point of care coach" confirmed that there was no documentation to show ungraded samples CMP-05 and USP-02 were evaluated.
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of personnel records, and review of 2023 and 2024 CAP proficiency testing records 9/11/24, the laboratory director failed to ensure that the laboratory's quality assessment program was maintained to assure the quality of laboratory services provided. Findings: 1. Review of the "Quality Ambulatory Assurance Plan Point of Care Testing" revealed "... A. Personnel Records: ... Employees performing laboratory testing must have training and competency on file. ... Non-Waived employees must have training

	records, 6 month (first year of testing) and annual competency. ..." Review of the "Post-Vas Semen Procedure" revealed "... 6 Months and Annual Competency: Six (6) months after the initial training and annually thereafter, it is a CLIA '88 requirement to perform competency assessment to show that personnel are competent to continue to perform testing. ..." Review of personnel records revealed the technical consultant (laboratory director) failed to perform and document semiannual competency evaluations for 4 of 5 testing personnel during their first year of testing. See the deficiency cited at D6053. 2. Review of the "Post-Vas Semen Procedure" revealed "... D. Proficiency Testing (PT): Each site needs to verify the accuracy of their testing yearly. Participation in a CLIA-approved PT program will satisfy this requirement. ... 1. Proficiency Testing Guidelines: a. The Laboratory Director as indicated on the CLIA certificate (and/or their designee) will supervise the PT program and ensure compliance with the PT standards..." Review of the "Quality Ambulatory Assurance Plan Point of Care Testing" revealed "... C. Proficiency Testing: ... Failed PT or ungraded PT are evaluated and action taken for failures. ..." Review of 2023 and 2024 CAP proficiency testing records revealed: a. The laboratory director failed to ensure the laboratory was enrolled in proficiency testing for 2024 until 7/11/24. See the deficiency cited at D6015. b. The laboratory director failed to ensure evaluation of all unacceptable and ungraded proficiency testing results. See the deficiency cited at D6019.
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 the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of job descriptions, and review of personnel records 9/11/24, the technical consultant (laboratory director) failed to perform and document semiannual competency evaluations for 4 of 5 testing personnel (TP #2, TP #3, TP #4, TP #5) during their first year of testing. Findings: Review of the laboratory's "Quality Ambulatory Assurance Plan Point of Care Testing" procedure revealed "... PLAN DETAILS: ... A. Personnel Records: ... Non-Waived employees must have training records, 6 month (first year of testing) and annual competency. ..." Review of the "Technical Consultant for Moderate Complexity Lab" job description revealed "... The Urology Technical Consultant position is served by the Lab Director. ..." The job description included a list of duties for the technical consultant (laboratory director), including "Evaluates the competency of all testing personnel on an ongoing basis". Review of personnel records revealed no semiannual competency evaluations for TP #2, TP #3, TP #4, or TP #5 who were all trained in September 2023.