

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 34D2135196	(X3) Date Survey Completed 07/22/2019
Name of Provider or Supplier Atrium Wfbh Immunodiagnostics Laboratory	Street Address, City, State 145 Kimel Park Drive Suite 250, 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
D6102	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12)</p> <p>The laboratory director must 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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures, review of personnel records, and interview with TP (testing personnel) 7/22/19, the laboratory director failed to ensure that 1 of 5 testing personnel (TP #3) had documented training for the APOL1 test. The laboratory's General Policy 14 "New Employee Training" (effective 5/20/05) states "... training will be required for new test methodologies and/or instruments prior to a technologist reporting patient test results. ..." Review of personnel records revealed there was no documentation of APOL1 training for TP #3. During interview at approximately 12:35 p.m., TP #1 stated that she trained TP #2, but all other training was done by the Ph.D. from the hospital that developed the test. She stated TP #3 was trained and had been performing the test, but she was unsure whether the training was documented or whether the records might have been misplaced.</p>
D6103	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(13)</p> <p>The laboratory director must ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to</p>

process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, review of personnel records, and interview with staff 7/22/19, the laboratory director failed to ensure that specific policies and procedures were established for evaluating the competency of testing personnel (TP) who perform the APOL1 test. Findings: 1. The laboratory's General Policy 14 "New Employee Training" (effective 5/20/05) states "... Reassessment of the new technologist will be required 6 months after completion of orientation/training and then yearly thereafter. ..." The policy did not include the criteria for acceptable performance, did not describe the steps to take in the event that performance criteria are not met, and did not indicate who was responsible for evaluating and documenting testing personnel competency. During interview at approximately 10:40 a.m., the general supervisor stated that the laboratory director has a "designee" perform the competency evaluation for each TP. He stated the laboratory did not have a written delegation of duties from the laboratory director to specific personnel qualified to perform competency evaluations. 2. Review of personnel records revealed the records did not include a competency evaluation specific for the APOL1 test which included the six elements of competency. During interview at approximately 12:30 p.m., TP #1 verified that they did not have a specific competency evaluation for APOL1 which included the required elements.