Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0908217	03/31/2021
Name of Provider or Supplier	**Street Address, City, State**	
North Alabama Urology	825 Adams Street, Huntsville, AL	

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
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the installation records for four Qualigen IP FastPack analyzers (used to perform PSA [Prostatic Specific Antigen] and Testosterone), and an interview with Testing Personnel #1, the laboratory failed to ensure the manufacturer's reference ranges (normal values) were validated and documented as appropriate for the laboratory's patient population. This affected two of two tests performed on the instruments since 7/15/2020. The findings include: 1. A review of the installation records for four Qualigen IP FastPack analyzers (two instruments each at "Station 1" and "Station 2") revealed the laboratory validated accuracy, precision and reportable ranges for PSA and Testosterone on 7/8 - 7/9/2020. However, there was no documentation the reference ranges were validated as appropriate for the laboratory's patient population. 2. During an interview on 4/1/2021 at 4:50 PM, the surveyor asked if the normal reference ranges had been validated on the FastPack instruments, and if there had been any change in the ranges from the previous analyzer. Testing Personnel #1 explained the PSA reference ranges had remained the same, however normal ranges for Testosterone had changed from 280-800 nanograms per milliliter (ng/ml) to 240-1200 ng/ml; Testing Personnel #1 was unable to remember how the manufacturer's reference ranges were validated. SURVEYOR #32885 Licensure and Certification Surveyor