Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	01D0908217	03/22/2023
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
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b) Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on a review of the Chemistry calibration verification records, the Quality Assurance (QA) plan, and an interview with Testing Personnel #1, the Laboratory failed to perform calibration verification on the Qualigen FastPack Chemistry analyzer every six months as per the QA policy and CLIA regulations. The laboratory failed to perform one of two calibration verifications due in 2022 on Station 2. The findings include: 1. A review of Qualigen Fastpack Chemistry analyzer records

	revealed only two calibrators are utilized for calibrations on the Testosterone and PSA (Prostatic Specific Antigen) test packs. Tests calibrated with less than three calibrators require calibration verification every six months. 2. A review of the Chemistry calibration verification (C-V) records revealed the Qualigen Fastpack station 2 analyzer had a C-V on 1/4/2022 and then 14 months later on 3/22/2023. There was no documentation of a C-V due the second half of 2022 for station 2. 3. A further review of the Fastpack QA log revealed "calibration verification every 6 months, perform calibration verification using the calibration verification log." 4. During an interview on March 22, 2023, at 11:23 AM, Testing Personnel #1 confirmed the above findings.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of the Chemistry Quality Control (QC) records, and an interview with Testing Personnel #1, the laboratory failed to ensure at least two levels of QC were run and acceptable, prior to analyzing patient specimens and reporting the results. This was noted five days out of ten months reviewed from April 2021 to February 2023. The findings include: 1) A review of the QC records for the Qualigen FastPack Chemistry analyzer revealed five days of patient testing when at least one level of QC was unacceptable, as follows: a) July 13th, 27th, and 29th, 2021: Low control was out of the acceptable range for PSA (Prostate-Specific Antigen); 18 patients were affected. b) August 11, 2022: High control was out of the acceptable range for Testosterone; one patient was affected. c) December 15, 2022: High control was out of the acceptable range for Testosterone; one patient was affected. 2. During an interview on March 22, 2023, at 11:04 AM, Testing Personnel #1 confirmed the above findings.