

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0221560	<b>(X3) Date Survey Completed</b> 09/19/2018
<b>Name of Provider or Supplier</b> Northern Virginia Endocrinologists	<b>Street Address, City, State</b> 3201 Jermantown Rd - Suite 250, Fairfax, VA	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Northern Virginia Endocrinologists on September 19, 2018 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
<b>D5469</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(10)(g)</p> <p>Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, quality control (QC) records, and interview, the laboratory failed to perform evaluations to establish QC ranges for four (4) of four (4) lot numbers of Endocrinology QC materials used for monitoring accuracy of patient testing for Thyroid Stimulating Hormone (TSH), Free T four (FT4) and Free T three (FT3) from October 2016 to September 2018. Findings include: 1. Review of the laboratory's procedure manual revealed no TOSOH A1A chemistry instrument procedure for the establishment of QC ranges for new lot numbers of Bio-Rad Lyphochek Immunoassay Plus Control Levels 1, 2, and 3. 2.</p>

Review of the laboratory's TOSOH A1A QC records from October 2016 to the date of the survey on September 19, 2018 revealed the following four (4) Bio-Rad Lyphochek Immunoassay Plus Control lot numbers were utilized to monitor patient TSH, FT3 and FT4 test results analyzed on the laboratory's TOSOH A1A instrument: 40270, 40300, 40320, and 40350. The inspector requested to review the laboratory's documentation that the ranges for each of the four (4) new lot numbers of QC were established prior to with use. No documentation was available. 3. In an interview with Testing Personnel A (TP A) at approximately 10:30 AM, it was confirmed that the laboratory failed to establish the QC ranges for four (4) of four (4) new lot numbers of Bio-Rad Lyphochek Immunoassay Plus Controls as outlined above.