

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  22D0664261	<b>(X3) Date Survey Completed</b>  09/12/2024
<b>Name of Provider or Supplier</b>  Northeast Urologic Surgery Pc	<b>Street Address, City, State</b>  231 Sutton Street, Suite 1 D, North Andover, MA	
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>	A CLIA recertification survey was conducted for the Northeast Urologic Surgery, PC laboratory on 09/12/2024 pursuant to the Clinical Laboratory Improvement Amendments (CLIA) of 1988 and CLIA regulations at 42 CFR 493.
<b>D5449</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(3)(ii)(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-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: . Based on record review and interview the laboratory did not run external quality control (QC) in the subspecialites of Bacteriology each day of patient testing. Findings include: 1. Record review of Quality Control (QC) for the Quant Studio 3 Microbiology PCR analyzer revealed QC was run once a week, not every day of patient testing. 2. Staff interview on 09/12/2024 at 11:00AM: Testing personnel stated "we run QC on the Quant Studio 3 each week."</p>