

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D0667463	<b>(X3) Date Survey Completed</b>  11/14/2019
<b>Name of Provider or Supplier</b>  Thomas Giannattasio	<b>Street Address, City, State</b>  1130 Park Blvd, Massapequa Park, NY	
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>D5471</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(1)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)(i) Check each batch (prepared in-house), lot number (commercially prepared) and shipment of reagents, disks, stains, antisera, (except those specifically referenced in 493.1261 (a)(3)) and identification systems (systems using two or more substrates or two or more reagents, or a combination) when prepared or opened for positive and negative reactivity, as well as graded reactivity, if applicable. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's Quality Control (QC) records and an interview with the laboratory director/testing person, the laboratory failed to check each new batch, lot number and/or shipment of 0.04 bacitracin disk for positive and negative reactivity from January 2019 through the survey date. FINDINGS: 1. The laboratory director/testing person confirmed on November 14, 2019 at approximately 9:30 AM, that the laboratory failed to check each new batch, lot number and/or shipment of 0.04 bacitracin disks for positive and negative reactivity from January 2019 through the survey date and, failed to document the lot number and the expiration dates of the bacitracin disks used from January 2019 through the survey date. 2. Approximately 50 patient specimens were tested and reported for throat culture during the above time period.</p>