

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  16D0387439	<b>(X3) Date Survey Completed</b>  03/20/2018
<b>Name of Provider or Supplier</b>  William J Schulte, Md	<b>Street Address, City, State</b>  1603 Morgan Street Suite 6, Keokuk, IA	
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><b>CONTROL PROCEDURES</b> 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 review of quality control (QC) records and confirmed by laboratory personnel identifier #2 (refer to the Laboratory Personnel Report) at approximately 10:45 am on 03/20/2018, the laboratory failed to check each new lot number of Taxo A bacitracin disks for positive and negative reactivity for six out of nine lot numbers of disks received from 01/08/2016- 01/23/2018. The findings include: 1. The laboratory received the following lot numbers of Taxo A bacitracin disks from 01/08/2018 to 01/23/2018: *5187786, expiration 01/31/2017; received 01/08/2016 *5275541, expiration 04/30/2017; received 03/11/2016 *6088601, expiration 09/30/2017; received 10/04/2016 *6157769, expiration 01/31/2018; received 11/29/2016 *6256782, expiration 03/31/2018; received 01/10/2017 *6292869, expiration 04/30/2018; received 03/14/2017 *6307550, expiration 05/31/2018; received 06/23/2017 *7132999, expiration 11/30/2018; received 11/16/2017 *7142417, expiration 04/24/2018; received 01/23/2018 2. Review of quality control records indicated that the laboratory did not perform QC on the following lot numbers: 6256782, 6292869, 6307550, 7132999, and 7142417. 3. At the time of the survey, personnel identifier # 2 confirmed that the laboratory did not have additional QC records.</p>