

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 44D0307008	<b>(X3) Date Survey Completed</b> 05/29/2019
<b>Name of Provider or Supplier</b> Vanderbilt University Medical Center	<b>Street Address, City, State</b> 807 Meadowlark Lane, Goodlettsville, TN	
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>D5477</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(4)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Quality Control (QC) records for Microbiology and interview with the laboratory supervisor the laboratory failed to 1) check each batch of media for sterility for Strep Select and Trypticase Soy Agar (TSA)/ Levine EMB/ Mastits agar triplate and 2) failed to check each batch of TSA/EMB media for select or inhibit specific organisms for growth between November 7, 2017 and May 29, 2019. Findings include: 1. Review of the Microbiology QC records did not show sterility checks for Strep Select agar and TSA/EMB between November 7, 2017 and May 29, 2019. 2. Review of the Microbiology QC records did not show each batch of TSA /EMB agar media for select or inhibit specific organisms for growth between November 7, 2017 and May 29, 2019. 3. Interview with the laboratory supervisor on May 29, 2019 at 11:45 am confirmed the laboratory failed to perform sterility checks and select or inhibit specific organisms for growth on microbiology media between November 7, 2017 and May 29, 2019.</p>
<b>D6046</b>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of</p>

all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, personnel records and interview with the laboratory supervisor, 2 of 2 Technical Consultant's (TC) failed to ensure competency assessments were performed on 5 out of 5 testing person's (TP) for urine and throat cultures in 2017 and 2018. The findings include: 1. Review of the CMS 209 revealed there were 5 testing persons reading urine and throat cultues in 2017 and 2018. 2. Review of personnel records revealed 5 of 5 testing persons lacking competency assessments for urine and throat cultures in 2017 and 2018. 3. Interview with the laboratory supervisor on May 29, 2019 at 11:45 am confirmed 2 of 2 TCs failed to perform personnel competencies on testing persons 1-5 for urine and throat cultures in 2017 and 2018.