

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D0655168	<b>(X3) Date Survey Completed</b>  05/09/2022
<b>Name of Provider or Supplier</b>  Unc Oral Microbiology Laboratory	<b>Street Address, City, State</b>  150 Dental Circle, Room 3030 First Dental Bldg, Chapel Hill, NC	
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>D5445</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(d)(1)(2)(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-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of 2019, 2020, 2021, and 2022 laboratory records and interview with the GS (general supervisor) 5/9/22, the laboratory failed to perform and document quality control each day of patient testing or establish an IQCP (Individualized Quality Control Plan) for antibiotic sensitivity testing. Review of 2019, 2020, 2021, and 2022 laboratory records revealed the laboratory had not performed quality control for Kirby-Bauer (disc diffusion) and E-test (minimum inhibitory concentration) each day of patient testing. The laboratory had performed quality control testing with ATCC (American Type Culture Collection) organisms weekly and with new lot numbers of discs or strips. There was no documentation available to indicate that the laboratory had established an IQCP to allow for weekly testing, including for new antibiotics added: a. Doripenem added to Kirby-Bauer 3/6/20 b. Linezolid added to Kirby-Bauer 9/10/20 c. Clindamycin added to E-test 1/8/21 d. Cefoxitin added to Kirby-Bauer 6/4/21 During interview at approximately 11:10 a.m., the GS confirmed that the laboratory did not have an IQCP in place.</p>
<b>D6086</b>	<b>LABORATORY DIRECTOR RESPONSIBILITIES</b>

CFR(s): 493.1445(e)(3)(ii)

The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.

This STANDARD is not met as evidenced by:

Based on review of 2019, 2020, 2021, and 2022 laboratory records and interview with the GS (general supervisor) 5/9/22, the laboratory director failed to ensure that verification procedures were adequate to determine all pertinent performance characteristics for media made in-house. Findings: Review of 2019, 2020, 2021, and 2022 laboratory records revealed the laboratory started making some media in-house during the pandemic. The laboratory had an "In-House Media Preparation" procedure which including specific instructions for each type of media. The procedure stated "... Regardless of the expiration date of the individual components in a batch of media, a new expiration date will be assigned as follows: a. Agar plates: 60 days b. Tubed media: 6 months ...". There was no documentation available to indicate when the laboratory started the in-house media preparation, and no documentation that the process (including media expiration dates) was validated and approved by the laboratory director. During interview at approximately 3:20 p.m., the GS stated they started making media in-house because of price increases and lack of availability. She verified they did not perform a validation. She stated they tried to find information about expiration dates, but there was nothing definite in the literature references or from the manufacturers of the ingredients used to make the media.

**D6127**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens.

This STANDARD is not met as evidenced by:

Based on review of personnel records, the absence of records, and interview with the GS (general supervisor) 5/9/22, the TS (technical supervisor) failed to evaluate the competency of the GS at least twice during the first year of testing. Review of personnel records revealed the GS was hired and was trained in August 2019. There was no documentation that the competency of the GS was evaluated semiannually during her first year of testing. During interview at approximately 2:45 p.m., the GS confirmed that there were no competency evaluations documented during her first year of testing patient specimens.

**D6128**

**TECHNICAL SUPERVISOR RESPONSIBILITIES**

CFR(s): 493.1451(b)(9)

The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least annually after the first year, unless test methodology or instrumentation changes, in which case, prior to reporting patient test results, the individual's performance must be reevaluated to include the use of the new test methodology or instrumentation.

This STANDARD is not met as evidenced by:

Based on review of personnel records, the absence of records, and interview with the GS (general supervisor) 5/9/22, the TS (technical supervisor) failed to evaluate the competency of the GS at least annually after the first year of testing. Review of personnel records revealed the GS was hired and was trained in August 2019. There was no documentation of an annual competency evaluation for the GS during 2021. During interview at approximately 2:45 p.m., the GS confirmed that she did not have a competency evaluation in 2021.