

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  34D0655168	<b>(X3) Date Survey Completed</b>  09/17/2024
<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>D6107</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(15)</p> <p>The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results.</p> <p>This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the GS (general supervisor) 9/17/24, the laboratory director failed to specify in writing the duties and responsibilities for the GS, the CC (clinical consultant), and 1 of 1 TP (testing personnel). Findings: Review of personnel records revealed there were no job descriptions / lists of duties and responsibilities available for duties delegated to the GS, the CC, and TP #1 by the laboratory director. During interview at approximately 9:25 a.m., the GS confirmed they did not have job descriptions for the GS, the CC, and TP #1 and they did not have duties delegated in writing by the laboratory director.</p>
<b>D6120</b>	<p><b>TECHNICAL SUPERVISOR RESPONSIBILITIES</b> CFR(s): 493.1451(b)(7)(8)</p> <p>(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly,</p>

accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on review of personnel records and interview with the GS 9/17/24, TS (technical supervisor) #1 failed to perform and document competency evaluations for TS #2 and the CC during 2022, 2023, and 2024. Findings: Review of personnel records for TS #2 and the CC revealed no documentation of competency evaluations for 2022, 2023, or 2024. During interview at approximately 9:30 a.m., the GS confirmed that TS #1 (laboratory director) had not documented competency evaluations for TS #2 and the CC during 2022, 2023, or 2024.

**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 and interview with the GS 9/17/24, TS #1 (laboratory director) failed to perform and document an annual competency evaluation for TP #1 during 2022, and for the GS during 2023. Findings: 1. Review of personnel records for TP #1 revealed competency evaluations documented in February 2023 and August 2024. There was no documentation of a competency evaluation performed in 2022. 2. Review of personnel records for the GS revealed competency evaluations documented in June 2022 and September 2024. There was no documentation of a competency evaluation performed in 2023. During interview at approximately 9:45 a. m., the GS stated her 2023 competency evaluation was missed.