

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  39D0707385	<b>(X3) Date Survey Completed</b>  03/16/2023
<b>Name of Provider or Supplier</b>  Oral Microbiology Testing Service	<b>Street Address, City, State</b>  3223 North Broad Street Room 365a, Philadelphia, PA	
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>D2000</b>	<p><b>ENROLLMENT AND TESTING OF SAMPLES</b> CFR(s): 493.801</p> <p>Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994.</p> <p>This CONDITION is not met as evidenced by: Based on review of the laboratory records and interview with the laboratory director, the laboratory failed to enroll in a proficiency testing (PT) program approved by HHS, for Bacteriology and Mycology tests in 2021 and 2022. Refer to Dtag: D6088</p>
<b>D6088</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(4)</p> <p>The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed.</p> <p>This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD), the LD failed to ensure that the laboratory was enrolled in a proficiency testing (PT) program that is approved by HHS for bacteriology and mycology testing performed from 01/28/2021 to the day of the survey. Findings include: 1. On the day</p>

of survey, 03/16/2023 at 09:45 am, review of laboratory records revealed that the laboratory was not enrolled in an approved PT program for bacterial and mycology identification, and antibiotic susceptibility testing from 01/28/2021 to 03/16/2023. 2. The laboratory provided documentation of internal PT records for bacteriology identification at the time of the inspection. The laboratory could not provide documentation of PT for mycology and antibiotic susceptibility testing. 3. The laboratory performed 586 microbiology examinations in 2022 (CMS-116 annual volume). 4. The LD confirmed the finding above on 03/16/2023 around 11:30 am.