

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 36D0674771	<b>(X3) Date Survey Completed</b> 04/29/2025
<b>Name of Provider or Supplier</b> Lucas County Regional Health District	<b>Street Address, City, State</b> 635 North Erie St, Toledo, OH	
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>D0000</b>	A revisit was conducted on 05/07/2025 at Lucas County Regional Health District 36D0674771 for all previous deficiencies cited on 04/29/2025. All deficiencies have been corrected and no new noncompliance was identified. The laboratory is in compliance with the Conditions of Participation at 42 CFR Part 493, Laboratory Requirements.
<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 record review and an interview with the Director of Health Services, the laboratory failed to enroll in a proficiency testing (PT) program for the wet prep test system in the subspecialties of Mycology and Parasitology. This deficient practice had the potential to affect 34 out of 34 patients tested under the subspecialties of Mycology and Parasitology from 01/01/2025 through 04/29/2025. Findings Include: 1. The laboratory failed to enroll in a PT program for wet prep test system in the subspecialties of Mycology and Parasitology. (Refer to D2001)</p>
<b>D2001</b>	<p><b>ENROLLMENT</b> CFR(s): 493.801(a)(1)(2)(i)</p>

The laboratory must-- (1) Notify HHS of the approved program or programs in which it chooses to participate to meet proficiency testing requirements of this subpart. (2)(i) Designate the program(s) to be used for each specialty, subspecialty, and analyte or test to determine compliance with this subpart if the laboratory participates in more than one proficiency testing program approved by CMS; and

This STANDARD is not met as evidenced by:

Based on record review and an interview with the Director of Health Services, the laboratory failed to enroll in a proficiency testing (PT) program for the wet prep test system in the subspecialties of Mycology and Parasitology. This deficient practice had the potential to affect 34 out of 34 patients tested under the subspecialties of Mycology and Parasitology from 01/01/2025 through 04/29/2025. Findings Include:

1. Review of the "Wet Prep Manual" signed and dated by the Laboratory Director on 04/15/2024, failed to find policies and procedures for enrollment in a PT program for the wet prep test system in the subspecialties of Mycology and Parasitology.
2. The inspector requested the 2025 PT records for the wet prep test system in the subspecialties of Mycology and Parasitology from the Director of Health Services.
3. The Director of Health Services confirmed the laboratory was not enrolled with an HHS approved PT provider for the wet prep test system in the subspecialties of Mycology and Parasitology and was unable to provide the requested documentation on the date of the inspection. The interview occurred on 04/29/2025 at 1:59 PM.