

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D0905023	<b>(X3) Date Survey Completed</b>  05/15/2025
<b>Name of Provider or Supplier</b>  Childrens Skin Center Pa	<b>Street Address, City, State</b>  3100 Sw 62 Ave, Miami, FL	
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>	An announced CLIA recertification survey was conducted at CHILDRENS SKIN CENTER PA from 05/14/2025 to 05/15/2025. The laboratory was not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: -D2000 CFR 493.801 Enrollment and Testing of Samples.
<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 lack of records and staff interview, the laboratory failed to enroll in a Proficiency Testing (PT) program approved by the Department of Health and Human Services (HHS) and Centers for Medicare and Medicaid Services (CMS) for Mycology since January 2025. Findings included: 1. Review of test menu listed on Form CMS-116 signed by Laboratory Director on 04/29/2025, revealed that the laboratory performed the Fungal Detection Test using the Hardy Dermatophyte Test Medium slant (DTM SLANT). 2. Review of Patient tests results revealed that the Laboratory tested 116 patients from 01/10/2025 to 05/13/2025. 3. No PT records found for 2025. 4. During an interview on 05/14/2025 at 12:30 PM, the office manager confirmed that the facility failed to enroll in PT since January 2025, she explained that the laboratory was not aware of the change of the DTM test to a Regulated test and that the laboratory must enroll in PT.</p>