

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0905023	(X3) Date Survey Completed 04/07/2023
Name of Provider or Supplier Childrens Skin Center Pa	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	A recertification survey conducted on 4/7/2023 found the CHILDRENS SKIN CENTER PA clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.</p> <p>This STANDARD is not met as evidenced by: Based on observation, records review, and interview, the laboratory failed to document the monitoring of the fridge temperature. The laboratory was required to store its test media and cultures at 2-8 C to maintain their viability, but there was no temperature monitoring documentation for the fridge temperatures over the past two years. The findings include: 1. On 4/07/23, the surveyor observed the refrigerator 2-8 C storage requirement for i) Remel Dermatube Dermatophyte Test Media, Ref # R241045, lot # 602249, ii) Thermo Scientific Culti-Loops Trichophyton interdigitale, Ref # R4608300, lot # 584250, and iii) Thermo Scientific Culti-Loops Escherichia coli, Ref # R4607050, lot # 613448. 2. A record review on 4/7/23 discovered that the testing person had not been keeping a log to document the monitoring of the refrigerator temperature during the last two years. 3. In an interview on 4/7/23 at 1pm, the testing person stated that they had not been documenting the daily monitoring of the fridge temperature over the past two years.</p>