

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0905023	(X3) Date Survey Completed 06/15/2021
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 completed on 06/15/2021 found that the CHILDRENS SKIN CENTER PA clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and Laboratory Director (LD) interview, the laboratory failed to do competency evaluation for 3 out of 7 testing personnel (TP) in 2020. Findings include: -Review of CMS 209 Laboratory Personnel Report dated and signed by the LD on 06/7/2021 revealed that there were 7 TP (A, B, C, D, E, F and G). -Review of personnel records revealed that the laboratory failed to have documentation of competency assessment for TP (A, B and C) in 2020. During an interview on 06/15 /2021 at 12:30 pm, with LD, she confirmed that the laboratory failed to have competency assessment for the TP of reference in 2020.</p>
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to perform twice a</p>

year accuracy verification of fungal cultures in 1 out of 2 years reviewed (2019-2020)
Findings include: -Quality Assurance records review revealed that the laboratory performs the accuracy verification using peer review. Peer review records revealed that the laboratory performed one verification in June 2019, no records found of a second peer review in 2019 During an interview on 06/15/21 at 12:30 p.m., the laboratory director stated that they performed the 2 evaluations in 2019 but confirmed that the laboratory had no documentation on site during the survey to proof that they performed the twice a year accuracy verification for the fungal culture in 2019.