

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2021626	(X3) Date Survey Completed 01/14/2025
Name of Provider or Supplier Golisano Children's Health Center	Street Address, City, State 3361 Pine Ridge Rd, Naples, 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 was conducted from January 08, 2025 to January 14, 2025. GOLISANO CHILDREN'S HEALTH CENTER clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D2007	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1)</p> <p>(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the laboratory failed to have one out of two testing personnel (TP) rotate through the testing of Proficiency Testing (PT) for Hematology and Chemistry specialties in 2 out of 2 years reviewed. Findings included: Review of FORM CMS-209 signed and dated by the Laboratory Director (LD) on 12/31/2024 revealed the laboratory had two TP listed (TP#1 and TP# 2). - Review of personnel records revealed that TP#1 and TP#2 had competencies during 2023 and 2024. -Review of American Proficiency Institute (API) PT records for 2023 (first, second and third event), 2024 (first, second and third event) in the specialties of Chemistry and Hematology, revealed that TP#1 had no PT participation during 2023 for Hematology and for 2024 TP#1 failed to participate in PT during 2024. During an interview on 01/08/2025 at 12:30 PM, the Technical Consultant confirmed that the laboratory failed to rotate the PT between all TP for the period of reference.</p>
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,</p>

consultant competency.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the laboratory failed to have the annual competency assessment for 1 out of 2 Technical Consultant (TC) signed by the laboratory director for 2024. Findings include: 1) Review of CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director (LD) on 12/31/2024 revealed that: The Laboratory Director and Clinical Consultant was the same person, there was two technical Consultant (TC) (TC#1 and TC#2), and had two Testing Person (TP) (TP#1) and TP#2. 2) Review of TC#1 annual competency assessment on 02/15/2024 revealed that a person not listed in the 209 signed the competency of reference. During an interview on 01/08/2025 at 11:00 AM, with TC#1, she confirmed that a person not listed in the 209 signed her annual competency for 2024.