

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2021626	<b>(X3) Date Survey Completed</b>  01/26/2023
<b>Name of Provider or Supplier</b>  Golisano Children's Health Center	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Golisano Children's Health Center on 1/24/23 - 1/26/23, a clinical laboratory in Fort Myers, Florida. The Golisano Children's Health Center laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
<b>D6006</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(d)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (d) Each individual may direct no more than five laboratories.</p> <p>This STANDARD is not met as evidenced by: Based on record review of the CMS Laboratory Personnel Report (CMS 209) and the Clinical Laboratory Improvement Amendment (CLIA) Application (CMS 116) and interview with the Urgent Care Manager and CLIA Program Manager, the laboratory failed to ensure the laboratory director did not direct more than five laboratories at the time of survey, 1/24/23 - 1/26/23. The findings included: Record review of the CMS 209, signed and dated 1/26/23, included the name of a laboratory director that CMS listed as the current laboratory director. Record review of the CMS 116, signed and dated 1/19/23 revealed on page 5, "X. Director Affiliation with other Laboratories" listed five other laboratories that the laboratory director was directing. On 1/24/23 at 1:10 p.m., the Urgent Care Manager confirmed the laboratory director was directing more than five laboratories. She stated that one of the laboratories said they had submitted an application to remove the laboratory director from their CLIA certificate. In a phone interview on 1/25/2023 at 11:20 a.m., the CLIA program manager stated that her office had not received an application to remove this laboratory director from</p>

one of the five laboratories listed on the CMS 116 and confirmed the laboratory director was directing more than five laboratories.