

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 28D2220931	(X3) Date Survey Completed 01/25/2022
Name of Provider or Supplier Virtual Scientific Inc	Street Address, City, State 3710 Duke Firth St, Land O Lakes, 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	An announced CLIA initial certification survey was conducted at Virtual Scientific Inc on 01/20/22 through 01/25/22. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D3009	<p>FACILITIES CFR(s): 493.1101(c)</p> <p>The laboratory must be in compliance with applicable Federal, State, and local laboratory requirements.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with staff, the laboratory failed to be in compliance with the Florida Department of Health Clinical Laboratory Personnel regulatory requirements. Findings included: Record review of the CMS 116 CLIA Application signed by the laboratory director on 01/20/2022 revealed that this was an independent laboratory, which Florida regulation 483.813 requires Clinical laboratory personnel to have a Florida State Clinical Laboratory Personnel license. Record review of personnel records and the CMS 209 Laboratory Personnel Report dated 1/20 /2022 revealed that the Laboratory Director and General Supervisor did not have Florida Department of Health Clinical Laboratory Personnel licensure. Interview with the General Supervisor by electronic mail (email) on 01/25/22 at 7:17 p.m. revealed she was unaware of the personnel requirements for Florida.</p>