

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1040166	(X3) Date Survey Completed 04/15/2024
Name of Provider or Supplier Simedhealth Llc	Street Address, City, State 4343 W Newberry Rd Suite 5, Gainesville, 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	At the time of the announced, onsite recertification survey, Simedhealth Llc was found to be not in compliance with the CLIA laboratory requirements of 42 CFR 493.
D5221	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to document corrective action for one unsatisfactory proficiency testing event in 2022 and 2 unsatisfactory proficiency testing events in 2023. The findings include: 1. The review of the College of American Pathologist (CAP) proficiency testing results for the event titled "ACL-B 2022" (ANTIPHOSPHOLIPID ANTIBODY) showed 2 of 3 samples for "Anticardiolipin antibody, IgG" passed resulting in a score of 67%. One of three samples for "Beta-2-glycoprotein I, IgG" passed resulting in a score of 33% and 2 of 3 samples for "Beta-2-glycoprotein I, IgM" passed resulting in a score of 67%. The correction action documented states "appears to be instrument bias, service called for pipette check." There was no other documentation indicating further corrective action was performed. 2. The review of the CAP proficiency testing results for the event titled "ACL-A-2023" showed two of three samples for "Beta-2-glycoprotein I, IgG" passed resulting in a score of 67% and 2 of 3 samples for "Beta-2-glycoprotein I, IgM" passed resulting in a score of 67%. There was no documentation indicating corrective action was performed. 3. The CAP proficiency testing results for the event titled "RDS-B 2023" (RHEUMATIC DISEASE SPECIAL SEROLOGIES) showed score 0% for the analyte Anti-Scl-70 (anti-DNA topoisomerase). There was no documentation indicating corrective action was performed. The interview on 4/15/25 at 10:30am with the General Supervisor confirmed the corrective action was missing.</p>