

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2236549	(X3) Date Survey Completed 04/28/2026
Name of Provider or Supplier Cny Fertility Pllc	Street Address, City, State 5922 Cattleman Lane, Sarasota, 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 recertification survey was conducted at CNY Fertility PLLC on 4/28/2026. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
D5449	<p>CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g)</p> <p>(d)(3)(ii) Each qualitative procedure, include a negative and positive control material;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview it was determined for moderate qualitative patient testing for pregnancy (hCG) procedure for three of three months reviewed (3/2026, 5/2025, and 11/2024) failed to document a negative and positive control material results each day of testing. Findings include: 1. The hCG qualitative test worksheet documented testing was performed using serum as the sample type in 3/2026 for 17 days, in 5/1/25 for for 17 days, and in 11/2024 for 11 days. The hCG qualitative test worksheet documented external negative and positive control material results one day per month for 3/2026, 5/2025, and 11/2024. 2. The hCG procedure for serum approved by the Laboratory Director 3/24/2025 directed external controls were to be performed upon receipt of new lot/shipment and each 30 days. There was no evidence of policy requiring negative and positive control material results each day of testing. 3. Technical Consultant B (TC-B) on 4/28/2026 at 10:20 AM confirmed the laboratory did not perform and document negative and positive control material results each day of testing for moderate qualitative patient testing for pregnancy (hCG) for the three months reviewed 3/2026, 5/2025, and 11/2024.</p>