

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1055020	(X3) Date Survey Completed 02/18/2025
Name of Provider or Supplier Melissa S Singer Md Pa	Street Address, City, State 12957 Palms West Dr Bldg 9 Ste 103, Loxahatchee, 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 validation survey was conducted at Melissa S Singer on February 18, 2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. A standard level deficiency was cited.
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to label three hematology controls with open and expiration dates before patient use. Findings included: On 2/18/2025 at 11:54 AM, a yellow container in the fridge had 3 Hematology controls. The following controls were normal control lot 50210711, low control- lot 50210712 and High control -lot 50210710 in use with no open dates and expiration written on vials for Sysmex serial B4521 Review of Sysmex Eight check 3WPX-TRA Hematology control for Sysmex analyzers with 3 part differentials read, "opened and recapped vials whose caps have been pierced will retain a stability for 14 days if stored at 2-8 degrees Celsius (C) after being recapped." On 2/18/2025 at 12:40 PM, the Laboratory Director confirmed there were no open and expiration dates written on hematology controls.</p>