

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2224637	(X3) Date Survey Completed 02/01/2022
Name of Provider or Supplier Onspot -Fl, Llc	Street Address, City, State 13770 Plantation Road, Ste 3, Fort Myers, 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 certification survey was conducted on 2/1/22 at Onspot-FL, LLC, a clinical laboratory in Fort Myers, Florida. Onspot-FL, LLC is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. The following is a description of the standard level deficiencies:
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (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 with the histotechnologist, the laboratory failed to label the toluidine blue with the identity, expiration, and lot number on two bottles. Findings Included: On 2/1/22 at 11:30 a.m., tour of the laboratory revealed two bottles that the label contained no identity of the reagent, lot number, or expiration date. On 2/1/22 at 1:20 p.m., the histotechnologist confirmed the bottles did not have the reagent name or expiration date and stated the bottles were toluidine blue. The doctor makes the toluidine blue from a powder and brings to the mobile lab. Histotechnologist does not have access to the reagent used to make the toluidine blue.</p>