

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D2056990	(X3) Date Survey Completed 01/31/2019
Name of Provider or Supplier Ofis Labs Inc	Street Address, City, State 44 Engle St, Englewood, NJ	
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
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 surveyor review of the Procedure Manual (PM), observation of two Auto Stainer (AS) and interview with the Office Manager (OM), the laboratory failed to label staining solutions used in the AS from 2/24/2017 to the date of the survey. The finding includes: 1. None of the 24 reagent wells were labled. 2 The OM comfirmed on 1/31/19 at 1:00 pm that all the reagnet wells were not labeled.</p>