

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0871981	(X3) Date Survey Completed 12/05/2024
Name of Provider or Supplier Rational Therapeutics, Llc	Street Address, City, State 750 E 29th St, Long Beach, CA	
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 the surveyor's observation during the laboratory's tour and interviews with the chief operations officer (COO) and testing personnel (TP), it was determined that the laboratory failed to label various reagents and solutions used in the laboratory to indicate the reagent's name, opening, preparation, and expiration dates when such materials are used. The findings include: 1. Based on the surveyor's observation during the laboratory tour on December 5, 2024, at approximately 5:00 p.m., no opening, preparation, and/or expiration date labels were used or documented for various reagents and solutions (70% alcohol, 100% methanol, Hema 3 Fixative, Solution I, Solution II, etc.) used throughout the laboratory. 2. The laboratory's COO and TP affirmed in an interview conducted on December 5, 2024, at approximately 5:00 p.m. that the reagents and solutions mentioned in statement #1 were not labeled properly with the received date, opening, preparation, and/or expiration dates. 3. Based on the laboratory's annual testing declaration submitted at the time of the survey, the laboratory analyzed approximately 200 tests for Immunology in which various reagents and solutions were not labeled properly.</p>