

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2029711	(X3) Date Survey Completed 07/26/2023
Name of Provider or Supplier Vipul Joshi Md Pa D/B/A	Street Address, City, State 1355 Providence Rd, Brandon, 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 Vipul Joshi MD PA dba Bay Area Arthritis and Osteoporosis on 07/26/2023. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. 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 Office Manager, the laboratory failed to label a plastic bottle labeled "Vitamin D Wash" with preparation and expiration date. Findings included: On 07/26/23 at 10:40 AM, a plastic container was observed in the refrigerator labeled "Vitamin D Wash" that did not have the preparation date and expiration date. Record review of the laboratory's test instructions for "25-OH Vitamin D ELISA" revealed "The working strength wash buffer is stable for up to 28 days when stored at 2 degrees Celsius to 8 degrees Celsius and handled properly." During an interview on 07/26/23 at 11:30 AM, the Office Manager confirmed that the "Vitamin D Wash" container did not have preparation and expiration dates.</p>