

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2029711	(X3) Date Survey Completed 07/17/2025
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 07/17/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D2075	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(a)</p> <p>(a) Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to obtain an 80 percent or above for the analytes Rheumatoid Factor (RF) quantitative and RF qualitative for one testing event (TE) (TE #1 in 2024) of six TE's reviewed (TE's #2 and #3 2023, TE's #1 - #3 2024, TE #1 2025). Findings included: 1. American Proficiency Institute proficiency testing event scores and documents were reviewed for RF quantitative and qualitative. The scores for TE #1 in 2024 for RF quantitative and RCF qualitative were 40%. 2. Interview with the Facility Manager on 07/17/2025 at 11:00 a.m. confirmed the above.</p>
D2076	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(b)</p> <p>(b) Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on record review and interview, the laboratory failed to attain an overall test event score of at least an 80% for one test event (TE) (TE #1 in 2024) of six TE's reviewed (TE's #2 and #3 in 2023, TE's #1 - #3 in 2024, and TE #1 in 2025) for the subspecialty of General Immunology. Findings included: 1. American Proficiency Institute proficiency testing event records were reviewed. The score for TE #1 in 2024 for General Immunology was 70 percent. 2. Interview with the Facility Manager on 07/17/2025 at 11:00 a.m. confirmed the above.

D5211

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:
Based on record review and interview, the lab failed to evaluate eight of eight unacceptable performance proficiency testing results. Findings included: 1. American Proficiency Institute proficiency testing results were reviewed for Immunology. Test event #1 in 2024 documented unacceptable performance for the analytes Rheumatoid Factor (RF) qualitative and RF quantitative for samples #RF-01, #RF-03, and #RF-05, totaling six unacceptable results. 2. Review of the Performance Evaluation form signed 06/20/2024 by the Lab Director documented the samples were reran and results were within the expected range. There was no root cause analysis to determine the probable or potential cause for the unacceptable results. 3. Proficiency Testing with an outside entity for Immunology (ELISA) for Test Event #1 and #2 in 2024 were reviewed. Test event #1 documented unacceptable results for sample #TTL 15024 for the analytes anti-RF IgA antibody (anti-Rheumatoid Factor Immunoglobulin A) and anti-RF IgG antibody (anti-Rheumatoid Factor Immunoglobulin G) totaling two unacceptable results. 4. Performance review documentation dated and signed by the Lab Director 06/20/24 was reviewed. The unacceptable samples were reran and results were within the expected range. There was no root cause analysis to determine the probable or potential cause for the unacceptable results. 5. Interview with the Facility Manager and Lab Director on 07/17/2025 at 3:05 p.m. confirmed the above.

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:
Based on record review and interview, the laboratory failed to evaluate analytes that were not graded for the subspecialty of General Immunology. Finding included: 1. American Proficiency Institute proficiency testing results were reviewed. TE #1 2024, Immunology test sample ANA-01 were not graded for the analytes anti-dsDNA (anti-double stranded deoxyribonucleic acid antibodies) and anti-RNP/Sm (Anti-ribonucleoprotein/Anti-Smith antibodies). TE #2 2024, Immunology test sample ANA-07 were not graded for the analytes anti-dsDNA and Anti-Sm (anti-Smith

antibodies). TE #3 2024, Immunology test samples ANA-12 were not graded for the analyte anti-RNP/Sm and ANA-14 for the analyte anti-dsDNA . 2. Review of evaluation forms for all three test events revealed printouts of the Peer Group results however there was no evaluation of the results. 3. Interview with the Facility Manager and Lab Director on 07/17/2025 at 3:05 p.m. confirmed the above.