

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0994844	(X3) Date Survey Completed 10/09/2025
Name of Provider or Supplier Arthritis & Osteoporosis Associates Llp	Street Address, City, State 5220 80th Street, Lubbock, TX	
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
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based upon review of manufacturer's instructions, patient test records and interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for repeating borderline (BRD) results obtained when testing 20,338 patient specimens for analytes tested on the BIO RAD Evolis Immunology analyzer. The findings included: 1. Review of the BIO RAD Autoimmune EIA instructions for use found under the heading EXPECTED VALUE RANGE: "Retest borderline samples before reporting results. If repeated results are still borderline, the test sample has no significant antibodies." 2. Review of patient test results found the laboratory reported 12 patient reports as borderline (BRD) on 8 weekly testing dates in September 2024 and February- March 2025: September 5, 2024 - 24241039 was reported as BRD for Anti-SS-B September 5, 2024 - 24240057 was reported as BRD for Anti-SmRNP September 19, 2024 - 24261073 was reported as BRD for Anti-dsDNA September 26,2024 - 24268111 was reported as BRD for Anti-dsDNA February 27, 2025 - 25055096 was reported as BRD for Anti-Scl-70 February 27, 2025 - 25051020 and 25057003 were reported as BRD for Anti-dsDNA March 6, 2025 - 25063102 was reported as BRD for Anti-dsDNA March 13, 2025 - 2506932 was reported as BRD for Anti-dsDNA March 20, 2025 - 25077001 was reported as BRD for Anti-dsDNA March 27, 2025 - 25079016 was reported as BRD for Anti-Scl-70 March 27, 2025 - 25083050 was reported as BRD forAnti-SmRNP March 27, 2025 - 25079016 was</p>

	<p>reported as BRD for Anti-dsDNA. 3. During interview of technical consultant 1 conducted October 9, 2025 at 10:12 AM, she confirmed the laboratory reported results as BRD without repeating the tests before reporting.</p>
<p>D5807</p>	<p>TEST REPORT CFR(s): 493.1291(d)</p> <p>(d) Pertinent "reference intervals" or "normal" values, as determined by the laboratory performing the tests, must be available to the authorized person who ordered the tests and, if applicable, the individual responsible for using the test results.</p> <p>This STANDARD is not met as evidenced by: Based upon review of the laboratory's annual calculation verification and interview of facility personnel, the laboratory failed to ensure the Estimated Glomerular Filtration Rate (EGFR) calculations used excluded the race factor. The laboratory reported an estimated annual volume of 178,543 Chemistry tests. The findings included: 1. Review of the 2025 calculation verification documents found the laboratory used a formula that included the patient's race, sex age and creatinine when calculating the EGFR. 2. During interview of technical consultant 2 conducted October 8, 2025 at 9: 57 AM, she confirmed the laboratory includes the patient's race in the EGFR calculation of results.</p>
<p>D6061</p>	<p>CLINICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1419(c)</p> <p>(c) Ensure that reports of test results include pertinent information required for specific patient interpretation; and</p> <p>This STANDARD is not met as evidenced by: Based upon review of the laboratory's annual calculation verification and interview of facility personnel, the laboratory failed to ensure the Estimated Glomerular Filtration Rate (EGFR) calculations used excluded the race factor. (See D 5807)</p>