Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0994844	10/07/2020
Name of Provider or Supplier	**Street Address, City, State**	
Arthritis & Osteoporosis Associates Llp	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	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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. This STANDARD is not met as evidenced by: Based on observations, review of manufacturer's instructions for use and interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for the use of the Quantimetrix Dipper Urinalysis control level 1 and 2. The findings follow: 1. Observations made during the tour of the facility found the laboratory was currently using the Quantimetrix Dipper Urinalysis control level 1 and 2 lot 4487 expiration 2021-04-30. 2. Review of the manufacturer's instructions for use found under the heading Procedure for Dipstick Testing found "Caution - Once control fluid ids removed for hCG (Human Chorionic Gonadotropin) or confirmatory testing that control tube must not be used for dipstick immersion testing. Once a control tube is used for dipstick immersion testing it must not be used for hCG or confirmatory testing." 3. Interview of the Technical Consultant conducted on October 6, 2020 at 10: 28 AM confirmed that the laboratory opened a new vial of the Quantimetrix Dipper Urinalysis control level 1 and 2 once each month for use in quality control procedures for urinalysis. She confirmed that they would use the same vials if quality control procedures were required for the urine hCG test kit if needed.
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at

	least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: Based on review of the maintenance logs and interview, the laboratory failed to perform monthly maintenance on the Bio-Rad Evolis microplate system 5 out of 21 months reviewed. Findings follow. Review of the Monthly Maintenance Checklist for the Bio-Rad Evolis microplate system which is used to perform Anti-ds DNA, Anti-Sm, Anti-Sm/RNP, Anti-SSA, Anti -Scl-70, Anti-SS-B/La, and Anti-SS-A/Ro, showed monthly maintenance was not performed in November and December of 2019, and January, May and (was partially performed in) August of 2020. Monthly maintenance consists of: disinfect the System Liquid Container and Pipettor, perform the MNTC Washer Disinfect.asy procedure, Clean the Plate Transport area/ Room Temp Incubators, perform the PE Plate Transport Check Procedure, perform the PE Photometer Verification Procedure, and perform the Fluidics PE panel procedure. Interview with the technical consultant on the CMS form 209 on 10/07/2020 at 1050 hours in the breakroom confirmed maintenance had not been performed monthly on the Evolis.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2) Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, calibration records, temperature logs, and interview, calibrations performed on the Sysmex XT-1800i Hematology analyzer were not performed within the manufacturer's specified temperature range on 4 out of 5 events from 2/18/2019-8/13/2020. Findings follow. Review of the Sysmex XT-1800i Instructions for Use, rev. Aug 2004, under Calibrations in Chapter 10 stated, "Calibration should be performed under the controlled room temperature within 25 +/- 5 degrees C (Celsius)." Review of the Sysmex XT-1800i calibration records showed calibrations were performed on 2/18/2019, 8/26/2019, 2/10/2020, 2/11/2020, and 8/13/2020. Review of the Temperature Log showed the room temperature was 19 degrees C on 2/18/2019, 18 degrees C on 8/26/2019, 19 degrees C on 2/10/2020, within manufacturer's specified temperature on 2/11/2020, and 18 degrees C on 8/13/2020. Interview with the technical consultant on the CMS form 209 on 10/07/2020 at 1540 hours in the breakroom acknowledged there was a thermometer next to the chemistry analyzer, and they have a second thermometer at the second terminal in the laboratory that they could start documenting.
D5439	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(b)

	Unless otherwise specified in this subpart, for each applicable test system the laboratory must do the following: Perform and document calibration verification procedure - (b)(1) Following the manufacturer's calibration verification instructions; (b)(2) Using the criteria verified or established by the laboratory under 493.1253(b)(3) -- (b)(2)(i) Including the number, type, and concentration of the materials, as well as acceptable limits for calibration verification; and (b)(2)(ii) Including at least a minimal (or zero) value, a mid-point value, and a maximum value near the upper limit of the range to verify the laboratory's reportable range of test results for the test system; and (b)(3) At least once every 6 months and whenever any of the following occur: (b)(3)(i) A complete change of reagents for a procedure is introduced, unless the laboratory can demonstrate that changing reagent lot numbers does not affect the range used to report patient test results, and control values are not adversely affected by reagent lot number changes. (b)(3)(ii) There is major preventive maintenance or replacement of critical parts that may influence test performance. (b)(3)(iii) Control materials reflect an unusual trend or shift, or are outside of the laboratory's acceptable limits, and other means of assessing and correcting unacceptable control values fail to identify and correct the problem. (b)(3)(iv) The laboratory's established schedule for verifying the reportable range for patient test results requires more frequent calibration verification. This STANDARD is not met as evidenced by: Based on review of calibration verification records and interview, the laboratory failed to perform calibration verifications on Vitamin D (Vit-D) every 6 months on 2 out of 4 occurrences. Findings follow. Review of the calibration verification records for Vit-D performed on the Vitros 5600 Chemistry analyzer showed calibration verifications were performed on 4/12/2018, 10/30/2018, 8/18/2019 (elapsed time was 10 months), 2/27/2020, and 10/05/2020 (elapsed time was 8 months). Interview with the technical consultant on 10/06/2020 at 1530 hours in the breakroom verified calibration verifications had not been performed every 6 months for Vit-D.