Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D1044844	09/13/2018
Name of Provider or Supplier	**Street Address, City, State**	
Arthritis And Osteoporosis Associates	1255 Hillrise Circle, Las Cruces, NM	

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
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 the review of instrument printouts, manufacturer instructions, quality assurance records, patient records and interview with the laboratory staff, the laboratory failed to ensure that calibrations were not expired prior to patient testing using the TOSOH AIA 360. 25(P1-P22 and P28-P33) of 30 (P1-P30) patients were tested using expired calibration curves in 2017 and 2018. This deficient practice could result in the reporting of inaccurate patient test results. Findings are: A. Review of the manufacturer's instructions indicated that the calibration curves expired at the end of 90 days for TSH, TT3, T4, and PTH. The instructions also indicated that any testing performed using an expired calibration would be flagged on the printout with "CV". B. Review of 2017 - 2018 instrument printouts revealed the laboratory tested patients 4 days in 2017 and 1 day in 2018 (01/01/18-09/11/18) after the calibration curves had expired. There was no documentation available to show that the laboratory repeated the patient samples. 1. 05/16/17 PTH (Parathyroid Hormone) The last calibration curve was on 02/15/17. 5 patients; P1 - P5 2. 05/19/17 PTH The last calibration curve was on 02/15/17. 5 patients; P6 - P10 3. 10/04/2017 TSH (Thyroid Stimulating

	Hormone) The last calibration curve was on 06/30/17. 5 patients; P11 - P15 4. 11/17 /17 TT3 (Total T3 or Total Triiodothyronine) The last calibration curve was on 08/05 /17. 7 patients; P16 - P22 5. 02/09/18 T4 (Thyroxine) The last calibration curve was on 11/08/17. 5 patients; P23 - P27 C. Review of 2017 - 2018 instrument printouts revealed 3 additional days (03/06/18, 01/11/18, 11/27/17) that the laboratory performed testing using expired calibration curves. However patient testing was performed on only 1 day (07/13/18) and those patients were repeated on the next test day. D. Review of 2017 - 2018 monthly quality assurance reports revealed no documentation of corrective actions for these incidents. E. Review of patient reports confirmed the laboratory reported test results for the following patients: P1 - PTH on 05/16/17 P6 - PTH on 05/17/17 P14 - TSH on 10/04/17 P22 - TT3 on 11/17/17 P23 - T4 on 02/09/18 F. During interview on 09/12/18 at 3:27 pm, the technical supervisor (also the only testing person) confirmed that he had identified only one incident and repeated the patients. He also confirmed that no corrected reports were issued.