Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	25D0316529	11/17/2022
Name of Provider or Supplier	**Street Address, City, State**	
Internal Medicine Associates Of Oxford	551 Azalea Dr, Oxford, MS	

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
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 chemistry laboratory records from 03/26/2021 through 11/17/2022 and confirmation with the laboratory director/technical consultant LD/TC and testing personnel (TP) #1 at 2:00 p.m. on 11/17/2022, the laboratory failed to perform calibration verification on the Siemens Dimension EXL chemistry analyzer every 6 months for sodium, potassium and chloride. Findings include: 1. Review of Siemens Dimension EXL calibration verification records revealed that Sodium (Na), Potassium

	(K), and Chloride (Cl) each are calibrated with a 2 point calibrator. 2. Calibration verification is required on any assay which is calibrated with less than 3 calibration materials. 3. No documentation of calibration verification was available for review since 03/01/2022. 4. The LD/TC and TP #1 confirmed in an interview at 2:00 p.m. on 11/17/2022 that Na, K and Cl calibration verifications were not performed every 6 months in 2022. The last calibration was performed on 03/01/2022.
D6049	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(iii) The procedures for evaluation of the competency of the staff must include, but are not limited to review of intermediate test results or worksheets, quality control records, proficiency testing results, and preventive maintenance records. This STANDARD is not met as evidenced by: Based on review of laboratory testing records from 3/26/2021 through 11/17/2022 and interview with the laboratory director/technical consultant (LD/TC) and TP #1 at 2:00 p.m. on 11/17/2022, all laboratory records had not been documented as reviewed by the technical consultant (TC). Findings Include: 1. The surveyor reviewed laboratory records from 03/26/2021 through 11/17/2022. The review revealed the following records had not been documented as reviewed by a qualified technical consultant: a. Temperature logs (room, freezer, humidity and refrigerators) from 06/1/2022 through 11/17/2022 b. Dimension EXL chemistry analyzer maintenance (Daily System Chek and Weekly, Monthly maintenance) from 6/1/2022 through 11/17/2022. 2. The LD /TC and TP #1 confirmed in an interview at 2:00 p.m. on 11/17/2022 that there was no documented review of these records by the TC.