Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	31D0120827	11/20/2018
Name of Provider or Supplier	**Street Address, City, State**	
Internal Medicine Associates, Pa	201 Laurel Heights Drive, Bridgeton, NJ	

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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency. This STANDARD is not met as evidenced by: Based on lack of the Competency Assessment (CA) records, review of the procedure manual and interview with the Testing Personnel (TP), the laboratory failed to perform a CA on one out of one testing personnel in the calandar year 2017. The TP confirmed on 11/20/18 at 10:25 am that CA procedure was not followed.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the Performance Specification records and interview with the Testing Personnel (TP), the laboratory failed to verify Reference Interval (RI) for Thyroxine, Thyroid-Stimulating Hormone, Total Thyroxine, Prostate-Specific Antigen performed on the Tosoh AIA-360 analyzer from August 2017 to the date of

	survey. The TP confirmed on 11/20/18 at 12:00 pm that the laboratory did not perform RI verification.