Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0972490	11/08/2018
Name of Provider or Supplier	**Street Address, City, State**	
Tyler Internal Medicine Associates Pa	1910 Roseland Blvd, Tyler, 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
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: . Based on review of American Proficiency Institute (API) proficiency testing documentation for 2017 and 2018, confirmed by staff interview, the laboratory director failed to attest that proficiency testing was performed by routine integration of samples into the patient workload using the laboratory's routine methods or to delegate that attestation to an individual meeting the education requirements of a technical consultant for moderate complexity testing. 1. API proficiency testing documentation was reviewed. Examination of attestation forms revealed that the following were signed by testing person 1 (CMS form 209) as the laboratory director's designee: 2017 1st event--Chemistry, core 2017 1st, 2nd, 3rd events--Hematology 2017 2nd, 3rd events--Microbiology 2017 1st, 2nd, 3rd events--Immunology 2018 1st, 2nd events--Chemistry, miscellaneous 2018 1st, 2nd, 3rd events--Chemistry, core 2018 1st, 2nd events--Hematology 2018 1st, 2nd, 3rd events--Microbiology 2018 1st, 2nd events--Immunology 2. Review of laboratory employee education and training documentation revealed that testing person 1 held an associate's degree in medical laboratory technology and did not meet the educational requirements of a technical consultant for moderate complexity testing according to 42 CFR 493.1409. 3. In an interview at the site on 11-08-2018, testing person 1 stated she was not aware of the requirements regarding delegation of signatory authority for proficiency testing attestation forms. .
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 performance validation documentation for the Vitros 5600 chemistry analyzer, confirmed by staff interview, the laboratory failed to verify that reference ranges for chemistry testing were appropriate for the patient population served. Findings: 1. Validation studies for the Vitros 5600 chemistry analyzer, put in service in August 2017, were reviewed. No documentation of studies for the verification of reference ranges was found. 2. In an interview at the site on 11-08-2018, testing person 1 stated that the reference ranges in use had been established previously using a different platform and to her knowledge no validation data had been analyzed to verify the appropriateness of the ranges using the Vitros analyzer. .
D6004	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: . Based on review of laboratory testing personnel competency verification documentation for 2017 and 2018, confirmed by staff interview, the laboratory director failed to delegate the responsibility to verify the competency of testing personnel to a qualified technical consultant. Findings: 1. Competency verification documentation was reviewed. Examination of the Laboratory Competency Assessment Checklists for testing personnel revealed that the forms were signed by "evaluators" as follows: Testing person 1-2018 annual--signed by testing person 2 Testing person 2-2017 and 2018 annual--signed by testing person 1 Testing person 3-2017 6-month--signed by testing person 1 Testing person 4-2017 annual--signed by testing person 1 Testing person 5-2018 annual--signed by testing person 1 2. Review of laboratory employee education and training documentation revealed that testing person 1 held an associate's degree in medical laboratory technology and did not meet the educational requirements of a technical consultant for moderate complexity testing according to 42 CFR 493.1409. 3. In an interview at the site on 11-08-2018, testing person 1 stated she was unaware of the of the requirements regarding delegation of authority for testing personnel competency verification. .