

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0718249	(X3) Date Survey Completed 09/25/2018
Name of Provider or Supplier Ramapo Internal Medicine Pc	Street Address, City, State 156 Route 59, Suite B 2, Suffern, NY	
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
D5303	<p>TEST REQUEST CFR(s): 493.1241(b)</p> <p>The laboratory may accept oral requests for laboratory tests if it solicits a written or electronic authorization within 30 days of the oral request and maintains the authorization or documentation of its efforts to obtain the authorization.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the patient's records, and an interview with the laboratory director and testing person, verbal requests are made for patient testing performed on the Qualigen instrument. Findings Include: On September 25, 2018, at approximately 1:15 pm this surveyor reviewed five patient's charts; there was no documentation of test orders in the patient's chart. It was confirmed by the laboratory director and the testing person that verbal test orders are given and not followed up with written test orders for chemistry and endocrinology tests performed on the Qualigen instrument within 30 days</p>
D5421	<p>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on a review of instrument validation records and an interview with the laboratory testing person, the laboratory failed to have records for accuracy and precision. Findings Include: On September 25, 2018, at approximately 11:45 am and confirmed by the laboratory director and the testing person, the laboratory failed to have records documenting the accuracy and precision for the two Qualigen analyzers use to test PSA and TSH as part of the complete performance specifications.

D6021

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(5)

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. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:
Based on a review of validation and patient test records, and an interview with the laboratory testing person, the director failed to ensure: 1) complete signed and approved validation reports were available for review. 2) patient test orders are documented within the patient's chart within 30 days of a verbal request. Refer to D5421

D6029

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(11)

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. (e) The laboratory director must-- (e)(11) Ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results.

This STANDARD is not met as evidenced by:
Based on a review of personnel records and an interview with the laboratory testing person, the laboratory director failed to ensure that appropriate education was available for one of two testing personnel who began moderate complexity testing in May 2018.