

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D0132169	<b>(X3) Date Survey Completed</b>  01/18/2018
<b>Name of Provider or Supplier</b>  Physician Family Health Service Pc	<b>Street Address, City, State</b>  600 W 111th St, Suite 1e, New York, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5421</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> 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: Based on a review of raw data for method validation and an interview with the technical consultant, the laboratory failed to demonstrate that the raw data collected by the laboratory met the performance specifications comparable to that of the manufacturer method validation prior to patient testing. On January 16, 2018, at approximately 10:45am and confirmed in an interview with the technical consultant, the laboratory failed to have records showing accuracy, precision and reportable range for the laboratory's new hematology instrument, the Boule Medonic M Series, prior to patient testing which began November 3, 2016. Approximately 658 patient specimens were test and results resulted during that time.</p>
<b>D6021</b>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(5)</p> <p>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</p>

maintained to assure the quality of laboratory services provided.

This STANDARD is not met as evidenced by:

Based on a review of the raw data for the Boule Medonic M Series hematology analyzer and confirmed by the technical consultant during the survey interview on January 18, 2018, the director failed to ensure that a complete validation report was available, signed and approved by the director for the Medonic M Series hematology analyzer. Refer to: D5421

**D6063**

**LABORATORY TESTING PERSONNEL**

CFR(s): 493.1421

The laboratory must have a sufficient number of individuals who meet the qualification requirements of 493.1423, to perform the functions specified in 493.1425 for the volume and complexity of tests performed.

This CONDITION is not met as evidenced by:

Based on a review of personnel records and an interview with the technical consultant, the laboratory director failed to ensure that documentation of education was available at the time of the survey for 1 of 2 testing personnel. Refer to D6065

**D6065**

**TESTING PERSONNEL QUALIFICATIONS**

CFR(s): 493.1423(b)(1)(2)(3)(4)(i)

(b) Meet one of the following requirements: (b)(1) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located or have earned a doctoral, master's, or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; or (b)(2) Have earned an associate degree in a chemical, physical or biological science or medical laboratory technology from an accredited institution; or (b)(3) Be a high school graduate or equivalent and have successfully completed an official military medical laboratory procedures course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); or (b)(4)(i) Have earned a high school diploma or equivalent; and

This STANDARD is not met as evidenced by:

Based on a review of personnel records and an interview with the technical consultant, the laboratory failed to have educational documentation for one of two testing personnel. Finding Include: It was confirmed by the technical consultant on January 16, 2018, at approximately 11:00 am, the laboratory failed to have an evaluation of the foreign degree for one of two testing personnel to meet CLIA requirements to perform moderately complex testing.