

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0938365	(X3) Date Survey Completed 11/19/2019
Name of Provider or Supplier Northern Westchester Internal Medicine	Street Address, City, State 1872 Commerce Street, Yorktown, 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
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on a review of proficiency test (PT) records and an interview with the laboratory testing person, the laboratory failed to perform PT testing in the same manner as patient specimen testing. Findings Include: It was confirmed by the laboratory testing person on November 19, 2019, at approximately, 11:00 am that PT specimens are always performed by one of two testing personnel, whereas, patient specimens are performed by both testing personnel.</p>
D5211	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(a)</p> <p>The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the American Proficiency Institute (API) proficiency test (PT) reports and an interview with the laboratory testing person, the laboratory did not</p>

evaluate, perform and document remedial action for the PT scores less than 100%. Findings Include: It was confirmed by the laboratory testing person on November 19, 2019, at approximately 11:00 am, that the laboratory failed to evaluate the following PT results: 2018 1st event Hematology Cell Identification = 93%

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 QA procedures, reviews and an interview with the laboratory testing person, the director failed to ensure that the laboratory's QA program for hematology was maintained for all phases of laboratory testing. Refer to: D2006, and D5209