

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2160182	(X3) Date Survey Completed 04/30/2019
Name of Provider or Supplier Nshoa	Street Address, City, State 1 Delaware Drive Suite A & Suite B, New Hyde Park, 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
D5291	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of Quality Assessment (QA) policy and confirmed in an interview with the practice manager, the laboratory supervisor and the technical consultant, the laboratory failed to establish a written QA policy and procedure for an ongoing mechanism to monitor, assess, and when indicated correct problems that may occur in the laboratory testing to include frequency of the QA reviews and to indicate the individual responsible for the QA reviews. On April 30, 2019 at approximately 11:00 AM the practice manager confirmed surveyor findings that the laboratory's written QA policy is kept at their Core laboratory which is a CLEP Certified laboratory.</p>
D6029	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(11)</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)(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.</p>

This STANDARD is not met as evidenced by:
Based on a surveyor review of personnel records and an interview with the practice manager, laboratory supervisor and the technical consultant, on April 30, 2019, at approximately 11:00 am, the laboratory director failed to ensure that appropriate training was documented for the two testing personnel performing moderate complexity test for hematology.

D6032

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(14)

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)(14) Specify, in writing, the responsibilities and duties of each consultant and each person, engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or results reporting, and whether consultant or director review is required prior to reporting patient test results.

This STANDARD is not met as evidenced by:
Based on the surveyor's review of personnel records and confirmed in an interview with the practice manager, laboratory supervisor and the technical consultant, the laboratory director failed to specify, in writing, the duties and responsibilities of the staff involved in all phases of the hematology laboratory.