

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2017706	(X3) Date Survey Completed 04/04/2019
Name of Provider or Supplier Fenar Themistocle, Md Pc	Street Address, City, State 1973 University Avenue, Bronx, 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
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor review of patient reports/records and an interview with the laboratory technical consultant, the laboratory failed to have a written or electronic request order for patient testing. Finding Include: It was confirmed by the technical consultant on April 4, 2019, at approximately 1:30 PM the laboratory failed to have written documentation or an electronic request when six of six patient electronic charts were reviewed for toxicology tests.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of records and an interview with the technical consultant, the laboratory failed to have the maintenance records for the Pentra C400 available for review from February 2018 through March 29, 2018. The testing person stated on April 4, 2019, at approximately 1:15 pm, "I was never told by the previous testing person to document instrument maintenance".</p>

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 laboratory procedures and an interview with the technical consultant, the laboratory director failed to ensure that quality assessment programs are maintained to assure the quality of laboratory services provided. Refer to D5301 and D5411