

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0129618	(X3) Date Survey Completed 04/27/2021
Name of Provider or Supplier Daniel M Libby Md Pllc	Street Address, City, State 407 E 70 St 3rd Floor, New York, 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
D1001	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of the manufacturer's package insert for Coaguchek XS PT /INR analyzer and interview with the technical consultant, the laboratory failed to follow the manufacturer's requirements for performing external controls with each new vial of test strips for PT/INR in the calendar years 2019 through survey date. FINDINGS: 1. The technical consultant confirmed on April 27, 2021 at approximately 2:00 PM confirmed the surveyor's findings that the laboratory did not follow the manufacturer's quality control requirements for performing external controls for each new lot of test strips. 2. The external Quality Control (QC) was not performed from January 1, 2019 through survey date. a. Surveyor could not determine the number of PT/INR test strips were used for patient testing. The laboratory did not record the lot numbers or expiration date for the previous lots of test strips. b. The current vial of test strips lot #47158918 expiration date 12/31/21 was not tested for quality control. 3. Approximately 50 patients' samples tested for PT/INR from January 1, 2019 through survey date.</p>