

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0683891	(X3) Date Survey Completed 09/21/2021
Name of Provider or Supplier Fred Grunseid, Md Pc	Street Address, City, State 1687 Ralph Avenue, Brooklyn, 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 the surveyor's review of the laboratory's Quality Assessment (QA) polices /procedures and confirmed in an interview with the testing person, the laboratory failed to follow it's QA policy and perform the monthly QA review for hematology testing for the calendar year 2019 and 2020.</p>
D6022	<p>LABORATORY DIRECTOR RESPONSIBILITIES 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 the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor's review of lack of QA records, laboratory procedure manuals and an interview with the laboratory testing person, the laboratory director failed to identify failures in the QA programs. Refer to: D5291.</p>