

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0129569	(X3) Date Survey Completed 11/26/2022
Name of Provider or Supplier Michael S Frank Md Pc	Street Address, City, State 9 East 63rd Street, 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
D2016	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on Proficiency Test (PT) desk review of the Center for Medicaid & Medicare Services (CMS) PT data reports and PT summary reports from American Proficiency Institute (API) PT program, the laboratory failed to participate successfully in CMS approved proficiency testing program, for the test analyte Erythrocyte Count/Red Blood Cell Count (RBC) The following scores were assigned: 2021 third event = 60% 2022 first event = 60% 2022 second event = 60% This is considered repeatedly unsuccessful PT performance. Refer to D2130</p>
D2121	HEMATOLOGY

	<p>CFR(s): 493.851(a)</p> <p>Failure to attain a score of at least 80 percent of acceptable responses for each analyte in each testing event is unsatisfactory analyte performance for the testing event.</p> <p>This STANDARD is not met as evidenced by: Based on PT desk review of the CMS PT data reports and PT records from the API PT program, the laboratory failed to participate successfully in proficiency testing for the test analytes Hematocrit (HCT), Hemoglobin (Hgb), White Blood Cell Count (WBC) and Platelet Count. The following scores were assigned: 2022 second event = 60% This is considered unsatisfactory PT performance.</p>
<p>D2130</p>	<p>HEMATOLOGY CFR(s): 493.851(f)</p> <p>Failure to achieve satisfactory performance for the same analyte in two consecutive events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on PT desk review of the CMS PT data reports and PT summary reports from API PT program, the laboratory failed to participate successfully in CMS approved proficiency testing program, for the test analyte Erythrocyte Count/RBC. The following scores were assigned: 2021 third event = 60% 2022 first event = 60% 2022 second event = 60% This is considered repeatedly unsuccessful PT performance.</p>
<p>D6000</p>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on PT desk review of the CMS PT and API PT program records, the laboratory director failed to fulfill the laboratory director's responsibilities and ensure that the laboratory achieved a satisfactory performance and successfully participate in a PT program, approved by CMS, for the test analyte's RBC, Hct, Hgb, WBC and Platelet. Refer to D6016.</p>
<p>D6016</p>	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</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)(4)(i) Ensure that the proficiency testing samples are tested as required under Subpart H of this part;</p>

This STANDARD is not met as evidenced by:

Based on PT desk review of the CMS PT data reports and API PT program records, the laboratory director failed to fulfill the laboratory director's responsibilities and ensure that the laboratory achieved a satisfactory performance and successfully participate in a PT program, approved by CMS, for the test analyte's Erythrocyte Count/RBC The following scores were assigned: RBC 2021 third event = 60% 2022 first event = 60% 2022 second event = 60% This is considered repeatedly unsuccessful PT performance. Hct,Hgb,WBC,and Platelet 2022 second event = 60% This is considered unsatisfactory PT performance.