

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D2144340	(X3) Date Survey Completed 04/13/2022
Name of Provider or Supplier Dr Sharon Rais & Dr Melinda Mann Llp	Street Address, City, State 855 East 7th Street - Apt 1p, 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
D2005	<p>ENROLLMENT CFR(s): 493.801(a)(4)</p> <p>Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.</p> <p>This STANDARD is not met as evidenced by: Based on a proficiency testing (PT) desk review of the Center for Medicare and Medicaid Services (CMS) PT records and the verified with the College of American Pathologists (CAP) PT program, the laboratory failed to have the PT test results released to New York State Department of Health (NYSDOH), Physician Office Laboratory Evaluation Program (POLEP) in the calendar years 2021 and 2022.</p>
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</p>

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.

This CONDITION is not met as evidenced by:
Based on a PT desk review of the CMS PT and CAP PT program records, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the test specialities General Immunology, Hematology, sub-speciality Bacteriology and the test analyte's Anti- Human Immunodeficiency Virus (HIV), Hepatitis B Surface Antigen (Hbs-Ag), Anti- Hepatitis Core Antibody (HBC) and Cell Identification (Cell I.D.), Red Blood Cell Count (RBC), Hemoglobin (Hgb), Hematocrit (Hct), White Blood Cell Count (WBC) and Platelets. The following scores were assigned: General Immunology and Anti-HIV, HBS AG, Anti-HBC 2021 third event = 0% 2022 first event = 0% Sub-speciality Bacteriology. 2021 second event = 9% 2021 third event = 100% 2022 first event = 0% This is considered unsuccessful PT performance Speciality Hematology, Cell I.D., RBC, Hgb, Hct, WBC and Platelets 2021 second event = 0% 2021 third event = 60% 2022 first event = 0% This is considered repeatedly unsuccessful PT performance. Refer to D2028, D2085 and D2130.

D2028

BACTERIOLOGY
CFR(s): 493.823(e)

Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:
Based on PT desk review of the CMS PT data reports and PT records from the CAP PT program, the laboratory failed to participate successfully in proficiency testing for the sub-speciality Bacteriology. The following scores were assigned: 2021 second event = 9% 2021 third event = 100% 2022 first event = 0% This is considered unsuccessful PT performance.

D2066

SYPHILIS SEROLOGY
CFR(s): 493.835(a)

Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.

This STANDARD is not met as evidenced by:
Based on PT desk review of the CMS PT data reports and PT records from the CAP PT program, the laboratory failed to participate successfully in proficiency testing for the speciality Syphilis Serology. The following scores were assigned: 2021 third event = 0% This is considered unsatisfactory PT performance

D2085

GENERAL IMMUNOLOGY
CFR(s): 493.837(g)

	<p>Failure to achieve an overall testing event score of satisfactory performance for two consecutive testing events or two out of three consecutive testing events is unsuccessful performance.</p> <p>This STANDARD is not met as evidenced by: Based on a PT desk review of CMS PT reports and lack of PT records from the CAP PT program, the laboratory failed to participate and perform successfully in a PT program approved by CMS, for the specialty General Immunology and test analyte's Anti-HIV, HBS AG, Anti-HBC. The following scores were assigned: General Immunology and Anti-HIV, HBS AG, Anti-HBC 2021 third event = 0% 2022 first event = 0% This is considered unsuccessful PT performance.</p>
D2087	<p>ROUTINE CHEMISTRY CFR(s): 493.841(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 CAP PT program, the laboratory failed to participate successfully in proficiency testing for the test analyte Glucose. The following scores were assigned: 2021 third event = 60% This is considered unsatisfactory PT performance.</p>
D2130	<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 a PT desk review of the CMS PT reports and PT records from the CAP PT program, the laboratory failed to participate and perform successfully in a PT program, approved by CMS, for the speciality Hematology and the test analyte's Cell I. D., RBC, Hgb, Hct and Platelets. The following scores were assigned: Speciality Hematology, Cell I.D., RBC, Hgb, Hct, WBC and Platelets 2021 second event = 0% 2021 third event = 60% 2022 first event = 0% This is considered repeatedly unsuccessful PT performance.</p>
D6000	<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 CAP PT program records, the laboratory director failed to fulfill the laboratory director's responsibilities and ensure</p>

that the laboratory achieved a satisfactory performance and successfully participate in a PT program, approved by CMS, for the specialities Syphilis Serology, General Immunology, Hematology, sub-speciality Bacteriology and the test analyte's Anti-HIV, Hbs-Ag, Anti-HBC, Cell I.D., RBC, Hgb, Hct, WBC, Platelets and Glucose. Refer to D6016.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(4)(i)

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;

This STANDARD is not met as evidenced by:
Based on PT desk review of the CMS PT and CAP 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 specialities specialities General Immunology, Hematology, sub-speciality Bacteriology and the test analyte's Anti-HIV, Hbs-Ag, Anti-HBC, Cell I.D., RBC, Hgb, Hct, WBC, Platelets and Glucose. The following scores were assigned: General Immunology and Anti-HIV, HBS AG, Anti-HBC 2021 third event = 0% 2022 first event = 0% Sub-speciality Bacteriology. 2021 second event = 9% 2021 third event = 100% 2022 first event = 0% This is considered unsuccessful PT performance Speciality Hematology, Cell I.D., RBC, Hgb, Hct, WBC and Platelets 2021 second event = 0% 2021 third event = 60% 2022 first event = 0% This is considered repeatedly unsuccessful PT performance. Speciality Syphilis Serology. 2021 third event = 0% Glucose. 2021 third event = 60% This is considered unsatisfactory PT performance.