

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0714560	(X3) Date Survey Completed 01/15/2025
Name of Provider or Supplier Boro Park Medical Pc	Street Address, City, State 1379 54th Street, 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
D0000	Based on a proficiency testing (PT) desk review survey performed on January 15, 2025, the laboratory was found to be out of compliance based on the following CONDITION LEVEL DEFICIENCIES: D2016 - 42 C.F.R. 493.803 Condition: Successful participation. D6000 - 42 C.F.R. 493.1403 Condition: Laboratory Director, moderate complexity.
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 review of Centers for Medicare & Medicaid Services (CMS) Proficiency Testing (PT) Certification and Survey Provider Enhanced Reporting system (CASPER 0155D) and College of American Pathologists (CAP) PT summary reports,</p>

	<p>the laboratory failed to successfully participate in the CMS approved PT program for consecutive testing events in the General Immunology specialty for the Rubella test analyte in 2022, 2023, and 2024; Endocrinology subspecialty for the T3 Uptake test analyte in 2022, 2023, and 2024; and the Toxicology subspecialty for the Lithium test analyte in 2022, 2023, and 2024 resulting in unsuccessful performance. Refer to D2084, D2107, and D2118.</p>
<p>D2084</p>	<p>GENERAL IMMUNOLOGY CFR(s): 493.837(f)</p> <p>(f) Failure to achieve satisfactory performance for the same analyte or test in 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 CMS PT CASPER 0155D and CAP PT summary reports from 2022, 2023, and 2024, the laboratory failed to achieve satisfactory performance (80% or greater) for consecutive testing events in the General Immunology specialty for the Rubella test analyte. FINDINGS: 1. A review of the CASPER 155 report revealed the following unsatisfactory scores: Rubella Test Analyte: 2022 Second Event = 0% 2022 Third Event = 0% 2023 First Event = 0% 2023 Second Event = 0% 2023 Third Event = 0% 2024 First Event = 0% 2024 Second Event = 0% 2. A review of the proficiency testing scores from CAP (2022, 2023 and 2024) confirmed the above findings. 3. During the on-site survey conducted February 7, 2024, it was noted that the facility claimed to discontinue Rubella testing. 4. It was also noted that the laboratory updated all CAP portal reportable analytes on October 28, 2024.</p>
<p>D2107</p>	<p>ENDOCRINOLOGY CFR(s): 493.843(f)</p> <p>(f) Failure to achieve satisfactory performance for the same analyte or test in 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 CMS PT CASPER 0155D and CAP PT summary reports from 2022, 2023, and 2024, the laboratory failed to achieve satisfactory performance (80% or greater) for consecutive testing events in the Endocrinology subspecialty for the T3 Uptake test analyte. FINDINGS: 1. A review of the CASPER 155 report revealed the following unsatisfactory scores: T3 Uptake Test Analyte: 2022 Second Event = 0% 2022 Third Event = 0% 2023 First Event = 0% 2023 Second Event = 0% 2023 Third Event = 0% 2024 First Event = 0% 2024 Second Event = 0% 2. A review of the proficiency testing scores from CAP (2022, 2023, and 2024) confirmed the above findings. 3. During the on-site survey conducted February 7, 2024, it was noted that the facility claimed to discontinue T3 Uptake testing. 4. It was also noted that the laboratory updated all CAP portal reportable analytes on October 28, 2024.</p>
<p>D2118</p>	<p>TOXICOLOGY CFR(s): 493.845(f)</p> <p>(f) Failure to achieve satisfactory performance for the same analyte or test in two</p>

consecutive testing events or two out of three consecutive testing events is unsuccessful performance.

This STANDARD is not met as evidenced by:

Based on CMS PT CASPER 0155D and CAP PT summary reports from 2022, 2023, and 2024, the laboratory failed to achieve satisfactory performance (80% or greater) for consecutive testing events in the Toxicology subspecialty for the Lithium test analyte. FINDINGS: 1. A review of the CASPER 155 report revealed the following unsatisfactory scores: Toxicology Subspecialty: 2022 Second Event = 0% 2022 Third Event = 0% 2023 First Event = 0% 2023 Second Event = 0% 2023 Third Event = 0% 2024 First Event = 0% 2024 Second Event = 0% Lithium Test Analyte: 2022 Second Event = 0% 2022 Third Event = 0% 2023 First Event = 0% 2023 Second Event = 0% 2023 Third Event = 0% 2024 First Event = 0% 2024 Second Event = 0% 2. A review of the proficiency testing scores from CAP (2022, 2023, and 2024) confirmed the above findings. 3. During the on-site survey conducted February 7, 2024, it was noted that the facility claimed to discontinue Lithium testing. 4. It was also noted that the laboratory updated all CAP portal reportable analytes on October 28, 2024.

D6000

MODERATE COMPLEXITY LABORATORY DIRECTOR

CFR(s): 493.1403

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.

This CONDITION is not met as evidenced by:

Based on review of CMS PT CASPER 0155D and CAP PT summary reports from 2022, 2023, and 2024, the laboratory director (LD) failed to provide overall management and direction of the laboratory services. Refer to D6016.

D6016

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1407(e)(4)(i)

(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;

This STANDARD is not met as evidenced by:

Based on review of CMS PT CASPER 0155D and CAP PT 2022-2, 2022-3, 2023-1, 2023-2, 2023-3, 2024-1, and 2024-2 summary reports, the LD failed to ensure successful participation in an HHS approved proficiency testing program. Refer to D2084, D2107, and 2118.