

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 33D0686097	(X3) Date Survey Completed 05/22/2024
Name of Provider or Supplier Joseph Slomowits Md	Street Address, City, State 5117 15th Ave, 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 May 22, 2024, 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 Centers for Medicare & Medicaid Services (CMS) Proficiency Testing (PT) Certification and Survey Provider Enhanced Reporting system (CASPER 0155D) and American Proficiency Institute (API) PT summary reports, the laboratory failed to</p>

successfully participate in the CMS approved PT program for the ALT (SGPT) (Alanine Aminotransferase), Na (Sodium), BUN (Blood Urea Nitrogen), endocrinology specialty, triiodothyronine, TSH (Thyroid Stimulating Hormone), and Cell ID or WBC Diff (Cell Identification or White Blood Cell Differential) test analytes. FINDINGS: 1. A review of the CASPER 155 report revealed the following unsatisfactory scores: ALT (SGPT) Test Analyte: 2023 First Event = 20% 2023 Third Event = 0% Na Test Analyte: 2023 Second Event = 40% 2023 Third Event = 0% BUN Test Analyte: 2021 Third Event = 0% 2022 Second Event = 60% Endocrinology Specialty: 2021 Third Event = 35% 2022 First Event = 70% 2023 Second Event = 70% 2023 Third Event = 0% Triiodothyronine Test Analyte: 2021 Third Event = 0% 2022 First Event = 60% TSH Test Analyte: 2021 Third Event = 40% 2022 First Event = 20% 2022 Second Event = 40% 2023 Second Event = 0% 2023 Third Event = 0% Cell ID or WBC Diff Test Analyte: 2022 First Event = 53% 2022 Second Event = 60% 2022 Third Event = 67% 2. A review of the proficiency testing scores from API (2021, 2022, 2023, and 2024) confirmed the above findings. 3. Initial Offsite PT desk reviews were conducted August 2021, November 2021, March 2022, April 2022, July 2022, July 2023, December 2023, and April 2024. a. Subsequent plans of correction (POC) were respectively sent March 11, 2022, May 5, 2022, July 12, 2022, July 17, 2023, and December 18, 2023. b. Satisfactory POCs were accepted March 25, 2022, July 24, 2022, August 15, 2022, October 25, 2023, and January 31, 2024, respectively. This is considered non-initial unsuccessful PT.

D2087

ROUTINE CHEMISTRY
CFR(s): 493.841(a)

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.

This STANDARD is not met as evidenced by:
Based on CMS PT CASPER 0155D and API PT summary reports, the laboratory failed to attain a score of at least 80 percent of acceptable responses for the ALT (SGPT), Na, and BUN test analytes in each testing event. Refer to D2016.

D2099

ENDOCRINOLOGY
CFR(s): 493.843(b)

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 CMS PT CASPER 0155D and API PT summary reports, the laboratory failed to successfully participate in CMS approved proficiency testing program for the endocrinology specialty. Refer to D2016.

D2107

ENDOCRINOLOGY
CFR(s): 493.843(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>This STANDARD is not met as evidenced by: Based on CMS PT CASPER 0155D and API PT summary reports, the laboratory failed to achieve satisfactory performance for the triiodothyronine and TSH test analytes in two consecutive testing events. Refer to D2016.</p>
D2108	<p>ENDOCRINOLOGY CFR(s): 493.843(g)</p> <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 CMS PT CASPER 0155D and API PT summary reports, the laboratory failed to achieve an overall satisfactory testing performance event score for the endocrinology specialty in two consecutive testing events and two out of three consecutive testing events. Refer to D2016.</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 CMS PT CASPER 0155D and API PT summary reports, the laboratory failed to achieve satisfactory performance for the Cell ID or WBC Diff test analyte in two consecutive events and two out of three consecutive testing events. Refer to D2016.</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 CMS PT CASPER 0155D and API PT summary reports, the laboratory director (LD) failed to fulfill LD responsibilities and ensure that the laboratory achieved a satisfactory performance for the endocrinology specialty; the ALT (SGPT), Na, BUN, triiodothyronine, TSH, and Cell ID or WBC Diff test analytes; as well as successfully participate in the CMS approved PT program. Refer to D2016.</p>
D6016	<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</p>

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 CMS PT CASPER 0155D and API PT summary reports, the LD failed to test the endocrinology specialty; the ALT (SGPT), Na, BUN, triiodothyronine, TSH, and Cell ID or WBC Diff test analytes as required; as well as achieve a satisfactory performance in the CMS approved PT program. Refer to D2016.