

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  33D1043251	<b>(X3) Date Survey Completed</b>  01/16/2025
<b>Name of Provider or Supplier</b>  Asloyan Medical Pc	<b>Street Address, City, State</b>  2626 East 14 Street, Suite 104, Brooklyn, NY	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	Based on a proficiency testing (PT) desk review survey performed on January 16, 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.
<b>D2016</b>	<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 &amp; 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 Alpha-fetoprotein (AFP) (Tumor Marker) test analyte in 2022, 2023, and 2024 and Immunoglobulin E (IgE) test analyte in 2024; Endocrinology subspecialty for the Cortisol, Human Chorionic Gonadotropin (hCG), and T3 Uptake test analytes in 2024; and the Toxicology subspecialty for the Lithium test analyte in 2023 and 2024 resulting in unsuccessful performance. Refer to D2084, D2107, and D2118.</p>
<p><b>D2084</b></p>	<p><b>GENERAL IMMUNOLOGY</b> 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 AFP (Tumor Marker) and IgE test analytes. FINDINGS: 1. A review of the CASPER 155 report revealed the following unsatisfactory scores: General Immunology Specialty: 2022 Third Event = 60% 2023 First Event = 50% 2023 Third Event = 50% 2024 First Event = 0% 2024 Second Event = 0% AFP (Tumor Marker) Test Analyte: 2022 Third Event = 0% 2023 First Event = 0% 2023 Third Event = 0% 2024 First Event = 0% 2024 Second Event = 0% IgE Test Analyte: 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. It was noted that the laboratory claimed to discontinue AFP (Tumor Marker) and IgE analyte testing in response to the PT desk review performed October 21, 2024.</p>
<p><b>D2107</b></p>	<p><b>ENDOCRINOLOGY</b> 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 2024, the laboratory failed to achieve satisfactory performance (80% or greater) for consecutive testing events in the Endocrinology subspecialty for the Cortisol, hCG, and T3 Uptake test analytes. FINDINGS: 1. A review of the CASPER 155 report revealed the following unsatisfactory scores: Cortisol Test Analyte: 2024 First Event = 0% 2024 Second Event = 0% hCG Test Analyte: 2024 First Event = 0% 2024 Second Event = 0% T3 Uptake Test Analyte: 2024 First Event = 0% 2024 Second Event = 0% 2024 Third Event = 0% 2. A review of the proficiency testing scores from CAP (2024) confirmed the above findings. 3. It was noted that the laboratory claimed to discontinue Cortisol and hCG analyte testing in response to the PT desk review performed October 21, 2024.</p>
<p><b>D2118</b></p>	<p><b>TOXICOLOGY</b></p>

	<p>CFR(s): 493.845(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 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: 2023 Third Event = 0% 2024 First Event = 0% 2024 Second Event = 0% Lithium Test Analyte: 2023 Third Event = 0% 2024 First Event = 0% 2024 Second Event = 0% 2. A review of the proficiency testing scores from CAP (2023 and 2024) confirmed the above findings. 3. It was noted that the laboratory claimed to discontinue Lithium analyte testing in response to the PT desk review performed October 21, 2024.</p>
<p><b>D6000</b></p>	<p><b>MODERATE COMPLEXITY LABORATORY DIRECTOR</b> 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 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.</p>
<p><b>D6016</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(4)(i)</p> <p>(e)(4)(i) The proficiency testing samples are tested as required under Subpart H of this part;</p> <p>This STANDARD is not met as evidenced by: Based on review of CMS PT CASPER 0155D and CAP PT 2022-3, 2023-1, 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.</p>