

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2102362	(X3) Date Survey Completed 07/24/2025
Name of Provider or Supplier Nilogen Oncosystems Llc	Street Address, City, State 3802 Spectrum Blvd Suite 207, Tampa, FL	
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	An announced CLIA recertification survey was conducted at Nilogen Oncosystems LLC on 7/24/25. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D6092	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4)(iv)</p> <p>(e)(4)(iv) An approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory;</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to approve and follow a corrective action plan when four of four College of American Pathologists (CAP) proficiency events (FL-B 2024 Flow Cytometry, FL-C 2024 Flow Cytometry, FL-A 2025 Flow Cytometry, and CTKN-1 2024 Cytokines) had unacceptable results for General Immunology. Findings included: 1. Review of CAP records showed the following unacceptable/outside expected range results with Laboratory Director review but without any corrective plan identified or documented. FL-B 2024 Flow Cytometry for analyte NK Lymp CD16+/56+/CD3- sample FL-09 reported 17 with expected results of 18-25 and graded as unacceptable. FL-C 2024 Flow Cytometry for analyte NK Lymp CD16+/56+/CD3- sample FL-15 reported 17 with expected results of 18-25 and graded as unacceptable. FL-A 2025 Flow Cytometry for analyte CT Supp Lymp CD3+/CD8+ sample FL-01 reported as 49 with expected results of 33-44, FL-02 reported as 46 with expected results of 19-27 with both results graded as unacceptable. CTKN-1 2024 with self graded results Cytokines for analyte IL-1 beta sample CTKN-02 reported as 26 with acceptable range of 28-43, CTKN-03 reported as 2 with acceptable range of 3-5, for analyte IL-2 sample CTKN-04 reported as 93 with acceptable range of 169-246, CTKN-05 reported as 815 with acceptable range of 1170-1837, CTKN-06 reported as 406 with acceptable range of 711-1084, for analyte</p>

IL-10 sample CTKN-06 reported as 35 with acceptable range of 43-106, for analyte IL-8 sample CTKN-08 reported as 164 with acceptable range of 178-227, and for analyte TNF-alpha sample CTKN-13 reported as 52 with acceptable range of 56-158 all of these results were graded as fail. 2. The Procedure Manual approved by the Laboratory Director 1/6/2025 with a procedure for CAP samples, approved by the Laboratory Director 11/21/2024, failed to include a process for approving and following corrective action plan when proficiency results were not acceptable or outside expected range. 3. The Director of Research and Compliance on 7/24/25 at 11:05 a.m. confirmed the above proficiency results, which were unacceptable outside expected range, failed to have any corrective actions documented and that the procedure for CAP samples failed to include a process for approving and following corrective action plan when proficiency results were not acceptable or outside expected range.

D6093

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1445(e)(5)

(e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur;

This STANDARD is not met as evidenced by:
Based on record review and interview, the Laboratory Director failed to establish a comprehensive quality assessment program to encompass all laboratory services from 9/2023 to 7/2025. Findings included: 1. The Procedure Manual approved by the Laboratory Director 1/6/2025 failed to include a quality assessment procedure to encompass General, Pre-Analytic, Analytic, and Post-Analytic systems. There was no documentation provided for review at the time of the survey of the Laboratory Director performing quality assessment checks of the laboratory systems. 2. The Director of Research and Compliance on 7/24/25 at 11:05 a.m. confirmed there was no policy or documents to review of comprehensive quality assessments by the Laboratory Director.