

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2102362	<b>(X3) Date Survey Completed</b>  06/14/2021
<b>Name of Provider or Supplier</b>  Nilogen Oncosystems Llc	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted at Nilogen Oncosystems LLC on 06/14/2021. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
<b>D2015</b>	<p><b>TESTING OF PROFICIENCY TESTING SAMPLES</b> CFR(s): 493.801(b)(5)(6)</p> <p>(5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.</p> <p>This STANDARD is not met as evidenced by: Based on College of American Pathologists (CAP) proficiency record review and interview with the Laboratory Director, the laboratory failed to have documentation of signed attestations for the Flow Cytometry (Cluster Differentiation (CD) - CD2, CD3, CD4, CD 8, CD 14, CD 16, CD20, CD19, CD45, and CD56 testing ) and Cytokines (Interleukin (IL) - 1 beta, IL -2, IL 6, IL - 8, IL - 10, Interferon gamma protein (IFN - gamma,) and Tumor Necrosis Factor Alpha (TNF - alpha) proficiency testing for two out of two years reviewed (2019-2021). Findings included: Review of CAP Flow records for 2020-2021 (FL - C 2020 and FLA - 2021) and CAP Cytokines records for 2019 -2021( CTKN - A 2019, CTKN - B 2019, CTKN - B 2020, and CTKN - A 2021) revealed the assigned attestation statement page was missing from the</p>

proficiency testing records. Interview on 06/14/21 at 3:25 P.M., the Laboratory Director confirmed the attestation statements were missing for 2019 - 2021. He stated that he had a change of staff, and the previous staff would provide him the proficiency attestation statements to sign.

**D5211**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(a)

The laboratory must review and evaluate the results obtained on proficiency testing performed as specified in subpart H of this part.

This STANDARD is not met as evidenced by:

Based on review of the College of American Pathologist (CAP) proficiency testing results and interview with the Laboratory Director, the laboratory director failed to review the CAP Flow Cytometry (for Cluster Differentiation (CD)2, CD3, CD 4, CD8, CD 14, CD16, CD 19 and CD 20, CD65) proficiency testing results for 2 out of 2 ( FL - C 2020 and FL - A 2021) proficiency testing events. Findings included: Review of CAP Flow proficiency testing results revealed that the Laboratory Director did not review the results for 2 out of 2 (FL - C 2020 and FL - A 2021) proficiency testing events. Interview on 6/14/21 at 3:35 p.m. with the Laboratory Director confirmed he had not signed the reports and stated that previous staff had not given him the proficiency testing results to sign.

**D5213**

**EVALUATION OF PROFICIENCY TESTING PERFORMANCE**

CFR(s): 493.1236(b)(1)

The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program.

This STANDARD is not met as evidenced by:

Based on record review of College of American Pathologists (CAP) proficiency testing records and interview with the Laboratory Director, the laboratory failed to verify the accuracy of Cytokines for the subspecialty of General Immunology (Interleukin (IL) - 1, IL - 2, IL - 6, IL - 10, Tumor Necrosis Factor (TNF) alpha, IL - 8, and Interferon (IFN) gamma) for two out of two years ( 2019 B event, 2020 A and B Events, and 2021 A Event). Findings included: Record review of CAP Cytokines proficiency testing records for 2019 A and B events, 2020 B Event, and 2021 A Event found that the proficiency testing results that had not been scored were not been graded by the laboratory. The following were the ungraded results and the corresponding codes: CTKN - A 2019 Cytokines Method IL - 2 Specimen #CTKN - 01, Code 26 (Educational Challenge), Specimen #CTKN - 02, Code 26, Specimen #CTKN - 03, Code 26 Method IL - 06 Specimen #CTKN - 01, Code 26, Specimen #CTKN - 02, Code 26, Specimen #CTKN - 03, Code 26 Method IL -10 Specimen #CTKN - 01, Code 26, Specimen #CTKN - 02, Code 26, Specimen #CTKN - 03, Code 26 Method TNF - alpha Specimen #CTKN - 01, Code 26, Specimen #CTKN - 02, Code 26, Specimen #CTKN - 03, Code 26 Method IL - 8 Specimen #CTKN - 04, Code 26, Specimen #CTKN - 05, Code 26, Specimen #CTKN - 06, Code 26 Method IFN gamma Specimen #CTKN - 07, Code 26, Specimen #CTKN -08, Specimen #CTKN - 09 CTKN - B 2019 Cytokines Method IL - 1 beta - Specimen #CTKN - 10, Code 26, Specimen #CTKN - 11, Code 26, Specimen #CTKN - 12, Code 26 Method

IL - 2 - Specimen # CTKN -10, Code 26, Specimen #CTKN - 11, Code 26, Specimen #CTKN - 12, Code 26 Method IL - 6 - Specimen #CTKN - 10, Code 26, Specimen #CTKN - 11, Code 26, Specimen #CTKN - 12, Code 26 Method IL - 10 - Specimen #CTKN - 10, Code 26, Specimen #CTKN - 11, Code 26, Specimen #CTKN - 12, 26 Method TNF - alpha - Specimen #CTKN - 10, Code 26, Specimen #CTKN - 11, Code 26, Specimen #CTKN - 12 - Code 26 Method IL - 8 - Specimen #CTKN - 13, Code 26, Specimen #CTKN - 14, Code 26, Specimen #CTKN - 15, Code 26 Method - IFN - gamma - Specimen #CTKN - 13, Code 28 (Response qualified with a greater than or less than sign; unable to quantitate), Specimen # CTKN - 14, Code 26, Specimen #CTKN - 15, Code 26 CTKN - B 2020 Cytokines Method IL - beta Specimen #CTKN - 10, Code 26, Specimen #CTKN - 11, Code 26, Specimen # 12, Code 26 Method IL - 2 Specimen #CTKN - 10, Code 26, Specimen #CTKN - 11 Code 26, Specimen #CTKN - 12, Code 26 Method IL - 6 Specimen #CTKN - 10, Code 26, Specimen #CTKN - 11, Code 26, Specimen #CTKN - 12, Code 26 Method IL - 10 Specimen #CTKN - 10, Code 26, Specimen #CTKN - 11, Code 26, Specimen #CTKN - 12, Code 26 Method TNF - alpha Specimen #CTKN - 10, Code 26, Specimen #CTKN - 11, Code 26, Specimen #CTKN - 12, Code 26 Method IL - 8 Specimen #CTKN - 13, Code 26, Specimen #CTKN - 14, Code 26, Specimen CTKN - 15, Code 26 Method IFN - gamma Specimen #CTKN - 16, Code 26, Specimen #CTKN - 17, Code 26, Specimen #CTKN - 18, Code 26 CTKN - A 2021 Cytokines Method IL - 1 beta Specimen #CTKN - 01, Code 26, Specimen #CTKN - 02, Code 26, Specimen #CTKN - 03, Code 26 Method IL - 2 Specimen #CTKN - 01, Code 26, Specimen #CTKN - 02, Code 26, Specimen #CTKN - 03, Code 26 Method IL - 6 Specimen #CTKN - 01, Code 26, Specimen #CTKN - 02, Code 26, Specimen #CTKN - 03, Code 26 Method IL - 10 Specimen #CTKN - 01, Code 26, Specimen #CTKN - 02, Code 26, Specimen #CTKN - 03, Code 26 Method IL - 8 Specimen #CTKN - 04, Code 26, Specimen #CTKN - 05, Code 26, Specimen #CTKN - 06, Code 26 Method IFN gamma Specimen #CTKN - 07, Code 26, Specimen #CTKN - 09, Code 26, Specimen #CTKN - 09, code 26 Method TNF alpha Specimen #CTKN - 10, Code 26, Specimen #CTKN - 11, Code 26, Specimen #CTKN - 12, Code 26 Interview on 06/14 /2021 at 03:30 PM with the Laboratory Director revealed he did not know he was to grade the ungraded proficiency testing results.

**D5417**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:  
Based on observation and interview with Laboratory Director, the laboratory failed to ensure cell culture wash and medium was removed from use after the expiration date. Findings Include: Observations on 06/14/21 at 1:25 PM revealed the following cell culture wash and mediums had expired: 2 open containers of Dulbecco's PBS expired 05/31/20 Gibco Dulbecco's Modified Eagle Medium expired 04/30/2019 IMDM High Glucose with L - Glutamine with HEPES Sterile - filtered expired 07/2020 EMEM With L - Glutamine Sterile - filtered expired 03/2021 Gibco RPMI medium with phenol expired 04/30/21 Interview on 06/14/21 at 4:00 PM with the Laboratory Director revealed that staff was supposed to perform inventory including observing expiration dates during the monthly evaluation of the laboratory.

**D5431**

**MAINTENANCE AND FUNCTION CHECKS**

CFR(s): 493.1254(a)(2)

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted.

This STANDARD is not met as evidenced by:

Based on observation and interview with the Laboratory Director, the centrifuge used to spin samples for flow cytometry was overdue for calibration. Findings include: Observation during the tour of lab on 06/14/21 at 1:20 PM revealed that the periodic maintenance sticker (which includes calibration) on the Eppendorf Centrifuge 5424 R was last completed on 10/03/2018 and was due 10/05/2019. Interview on 06/14/21 at 4:05 pm with the Laboratory Director revealed the centrifuge calibration had not been performed due to multiple factors such as change of staff and COVID.