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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 10D2102362 | (X3) Date Survey Completed 08/24/2023 |
| 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 onsite recertification survey was conducted at Nilogen Oncosystems on 08/14/23 - 08/24/23. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiency: |
| D5221 | <p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d)</p> <p>All proficiency testing evaluation and verification activities must be documented.</p> <p>This STANDARD is not met as evidenced by: Based upon record review of College of American Pathologists (CAP) proficiency testing and interview with the Director of Research, the Laboratory Director failed to evaluate for Cytokines (Interleukin (IL) - 1 Beta, IL -2, IL - 6, IL - 8, IL - 10, Interferon (INF) gamma, Tumor Necrosis Factor (TNF) - alpha) proficiency testing for 4 out of 4 proficiency testing events (CTKN - B 2021 Cytokines, CTKN-A and B 2022, and CTKN - A 2023) and failed to evaluate and to document corrective actions for unacceptable Flow Cytometry (Cluster Differentiation (CD)2+ Lymphocytes, CD3+ Lymphocytes, CD5+ Lymphocytes, T Lymph [sic] CD3+/CD4+, Cellular Therapy (CT) Supp [sic] Lymph CD3+/CD+8, B Lymph Differentiation (Diff) Antigen (Ag) CD20+, B Lymph Diff Ag CD 19+, Natural Killer (N K) Lymph CD16+ /CD3+, N K Lymph CD56+/CD+3, and N K Lymph CD16+/CD56+/CD3+) proficiency testing results for 6 out of 6 (FL - C 2021, FL - A 2022 , FL - B 2022, FL- C, FL - A 2023, and Fl - B 2023) for two out of two years(2021 - 2023). Findings included: Record review of the CAP Cytokines proficiency testing results revealed the proficiency testing results for four out of four(CTKN -B2021, CTKN-A and B 2022, and CTKN - A 2023) had not been reviewed by the laboratory director or their delegate. Record review of the CAP Flow Cytometry proficiency testing results revealed the following proficiency testing specimens had unacceptable results that had not been evaluated and corrective actions for the following specimens: 1. FL- C 2021</p> |

- CD3+ Lymphocytes - proficiency testing specimens FL - 13 - 15 2. FL - C 2021 - CD5+ Lymphocytes - proficiency testing specimens FL 13 - 15 3. FL - C 2021 - T Lymph CD3+/4+ - proficiency testing specimens FL 13 - 15 4. FL - C 2021 - CT Supp Lymph CD3+/CD8+ - proficiency testing specimens FL 13 - 14 5. FL - C 2021 - B Lymph Diff AG CD 19+ - proficiency testing specimen FL 14 6. FL - C 2021 - N K Lymph CD16+/CD3+ - proficiency testing specimens FL 13 - 15 7. FL - C 2021 - N K Lymph CD16+/CD56+/CD3+ - proficiency testing specimens FL 13 - 15 8. FL - A 2022 - CD2+ Lymphocytes - proficiency testing specimens FL 2 - 3 9. FL - A 2022 - CD3+ Lymphocytes - proficiency testing specimens FL 1-3 10. FL - A 2022 - CD5+ T Lymph - proficiency testing specimens FL 1-3 11. FL - A 2022 - T Lymph CD3+ /CD4+ - proficiency testing specimens - FL 1-3 12. FL - A 2022 - CT Supp Lymph CD3+/CD8+ - proficiency testing specimens - FL 1-3 13. FL - A 2022 - B Lymph Diff Ag CD 20+ - proficiency testing specimens - FL 2-3 14. FL - A 2022 - B Lymph Diff Ag CD19+ - proficiency testing specimens - FL 1,3 15. FL - A 2022 - N K Lymph CD16+/CD3+ - proficiency testing specimens - FL 2-3 16. FL - A 2022 - N K Lymph CD16+/56+/CD3+ - proficiency testing specimens FL - 1 - 2 17. FL - B 2022 - CT Supp Lymph CD3+/CD8+ - proficiency testing specimens FL - 7 - 8 18. FL - B 2022 - N K Lymph CD16+/56+/CD3+ - proficiency testing specimens FL - 8 - 9 19. FL - C 2022 - CT Supp Lymph CD3+/CD8+ - proficiency testing specimens FL - 14 - 15 20. FL - C 2022 - N K Lymph CD16+/CD3+ - proficiency testing specimens FL - 14 - 15 21. FL - C 2022 - N K Lymph CD16+/56+/CD3+ - proficiency testing specimens FL - 14 - 15 22. FL - A 2023 - T Lymph CD3+/CD4+ - proficiency testing specimens FL - 1-3 23. FL - A 2023 - CT Supp Lymph CD3+/CD8+ - proficiency testing specimens FL - 1 -2 24. FL - A 2023 - B Lymph Diff Ag CD20+ - proficiency testing specimens FL - 1 - 3 25. FL - A 2023 - B Lymph Diff AG CD19+ - proficiency testing specimens FL - 1 - 3 26. FL - A 2023 - N K Lymph CD16+/CD3+ - proficiency testing specimens FL - 1, 3 27. FL - A 2023 - N K Lymph CD16+/56+ /CD3+ - proficiency testing specimens FL - 1, 3 28. FL - B 2023 - N K Lymph CD16+ /56+/CD3+ - proficiency testing specimens FL - 1-3 On 08/14/23 at 11:30 am, the Director of Research confirmed the Laboratory Director had not signed the proficiency tests results attestation statements and confirmed corrective action was not documented for the unacceptable results.