Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2102362	05/29/2019
Name of Provider or Supplier	**Street Address, City, State**	
Nilogen Oncosystems Llc	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 05/29/19. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and staff interview, the facility failed to assure the accuracy of testing was verified twice annually for the analytes: Granulocyte macrophage colony stimulating factor (GM-CSF), Interleukin (IL) 3, 4, 7, 12, and 17, Macrophage inflammatory protein (MIPA), Granulocyte colony stimulating factor, (GCSF), and Monocyte chemoattractant protein 1 (MCP1) for two of two years (2017-2019) reviewed. Findings include: The record review of the College of American Pathologists (CAP) Proficiency Testing (PT) for 2017 Cytokines A and B Events, 2018 Cytokines A and B Events, and 2019 Cytokines A Event showed no enrollment for the following non regulated analytes: GM-CSF, IL3, IL4, IL7, IL12, and IL17, MIPA, GCSF, and MCP1 - General Immunology, Interview on 05/29/19 at 11:50 am with the Director of Research confirmed that the 9 analytes were not enrolled in proficiency testing, and the laboratory had never performed twice annual verification of accuracy by other means.