

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 49D0224557	(X3) Date Survey Completed 01/26/2023
Name of Provider or Supplier Inova Laboratories At Mark Center	Street Address, City, State 1800 N Beauregard Street Suite 350, Alexandria, VA	
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 the INOVA Laboratories at Mark Center on 01/26/23 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D2005	<p>ENROLLMENT CFR(s): 493.801(a)(4)</p> <p>Authorize the proficiency testing program to release to HHS all data required to-- (i) Determine the laboratory's compliance with this subpart; and (ii) Make PT results available to the public as required in section 353(f)(3)(F) of the Public Health Service Act.</p> <p>This STANDARD is not met as evidenced by: Based on the review of the Centers for Medicare and Medicaid Services CLIA Laboratory Application for Certification form (CMS 116), CASPER Survey Summary (Report 0096D), proficiency testing (PT) records, lack of documentation, and interview, the lab failed to release PT results to the regulatory agencies of Centers of Medicare and Medicaid Services (CMS) and the Virginia Department of Health (VDH) for 14 of 14 events reviewed in 2021 and 2022. Findings include: 1. A pre-survey preparation review of the CMS 116 on 01/24/23 revealed the lab performs testing in the subspecialties of hematology and chemistry. In addition, the review of the Report 0096D revealed a lack of documentation of PT scores in the subspecialties of hematology and chemistry for calendar years 2021 and 2022. 2. Review of the College of American Pathologists (CAP) PT documents (CAP # 8960492-01) revealed the lab was enrolled and participated in the following specialties and events (14): Hematology Auto Differentials, FH 9- B and C 2021, Hematology Auto Differentials, FH 9- A, B and C 2022, Reticulocyte Sysmex RT 4- A and B 2021, Reticulocyte Sysmex RT 4- A and B 2022, Chemistry, C- B and C 2021 and Chemistry, C- A, B and C 2022. 3. In an interview with the technical supervisor on 01</p>

/26/23 at approximately 09:20 AM, the inspector inquired about the missing PT scores for the site. They stated, "We will have to contact CAP. We thought they were released to CMS and VDH." 4. An exit interview with the technical supervisor on 01 /26/23 at approximately 11:35 AM confirmed the findings.