

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  49D2133895	<b>(X3) Date Survey Completed</b>  08/12/2020
<b>Name of Provider or Supplier</b>  Inova Lab At Isci	<b>Street Address, City, State</b>  8081 Innovation Park Drive, Fairfax, VA	
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 unannounced off-site proficiency testing desk review of INOVA Laboratories at INOVA Schar Cancer Institute was conducted on August 12, 2020 by a Medical Facilities Inspector of the Virginia Department of Health's Office of Licensure and Certification. The laboratory was inspected under 42 CFR Part 493 CLIA regulations. Specific deficiencies cited are as follows:
<b>D2016</b>	<p>SUCCESSFUL PARTICIPATION CFR(s): 493.803(a)(b)(c)</p> <p>(a) Each laboratory performing nonwaived testing must successfully participate in a proficiency testing program approved by CMS, if applicable, as described in subpart I of this part for each specialty, subspecialty, and analyte or test in which the laboratory is certified under CLIA. (b) Except as specified in paragraph (c) of this section, if a laboratory fails to participate successfully in proficiency testing for a given specialty, subspecialty, analyte or test, as defined in this section, or fails to take remedial action when an individual fails gynecologic cytology, CMS imposes sanctions, as specified in subpart R of this part. (c) If a laboratory fails to perform successfully in a CMS-approved proficiency testing program, for the initial unsuccessful performance, CMS may direct the laboratory to undertake training of its personnel or to obtain technical assistance, or both, rather than imposing alternative or principle sanctions except when one or more of the following conditions exists: (1) There is immediate jeopardy to patient health and safety. (2) The laboratory fails to provide CMS or a CMS agent with satisfactory evidence that it has taken steps to correct the problem identified by the unsuccessful proficiency testing performance. (3) The laboratory has a poor compliance history.</p> <p>This CONDITION is not met as evidenced by: Based on an off-site Proficiency Testing (PT) desk review of the laboratory's College of American Pathologists PT records (2020 First Event, 2020 Second Event) and email interview, the laboratory failed to attain a score of at least eighty percent of</p>

acceptable responses for Fibrinogen in two consecutive 2020 Hematology testing events resulting in unsuccessful PT performance. See 2123.

**D2123**

HEMATOLOGY  
CFR(s): 493.851(c)

Failure to participate in a testing event is unsatisfactory performance and results in a score of 0 for the testing event. Consideration may be given to those laboratories failing to participate in a testing event only if-- (1) Patient testing was suspended during the time frame allotted for testing and reporting proficiency testing results; (2) The laboratory notifies the inspecting agency and the proficiency testing program within the time frame for submitting proficiency testing results of the suspension of patient testing and the circumstances associated with failure to perform tests on proficiency testing samples; and (3) The laboratory participated in the previous two proficiency testing events.

This STANDARD is not met as evidenced by:

Based on an off-site desk review of the laboratory's College of American Pathologists (CAP) proficiency testing (PT) records, CASPER Report 0155D, and email interview, the laboratory failed to participate in two (2) consecutive Fibrinogen testing events in 2020. Findings include: 1. Review of the laboratory's CAP 2020 1st Event and 2020 2nd Event PT records, a total of two (2) events, revealed the following statements: Fibrinogen 2020 1st Event - "Per your reporting preferences, this analyte is currently identified as being tested by your laboratory. A score of zero has been given due to the lack of response."; Fibrinogen 2020 2nd Event, "Per your reporting preferences, this analyte is currently identified as being tested by your laboratory. A score of zero has been given due to the lack of response." The score of zero for the events resulted in unsuccessful PT performance. 2. Review of the laboratory's CASPER Report 0155D revealed the following 2020 Fibrinogen events with results of less than 80%: 2020 1st Event=0%; and 2020 2nd Event=0%; resulting in unsatisfactory performance. 3. In a email from the Technical Consultant (TC) on August 12, 2020 at 11:00 AM, the TC confirmed the findings and stated they were not performing Fibrinogen testing in 2020.