

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D2133895	<b>(X3) Date Survey Completed</b> 01/14/2020
<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 announced CLIA recertification survey was conducted at INOVA Laboratories at INOVA Schar Cancer Institute on January 14, 2019 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The specific deficiency is as follows:
<b>D5545</b>	<p>HEMATOLOGY CFR(s): 493.1269(b)(d)</p> <p>(b) For all nonmanual coagulation test systems, the laboratory must include two levels of control material each 8 hours of operation and each time a reagent is changed. (d) The laboratory must document all control procedures performed, as specified in this section.</p> <p>This STANDARD is not met as evidenced by: A. Based on the review of the laboratory's procedures, quality control (QC) records, lack of documentation and interviews, the laboratory failed to follow their procedure and perform ProThrombin Time and Internal Normalized Ratio (PT/INR) coagulation QC materials every 8 hours of operation for twenty-two (22) days in June 2019 and twenty-six (26) days in July 2019 while reporting two-hundred sixty seven (267) patients. Findings include: 1. Review of the laboratory's procedure manual revealed a procedure, "IL at Inova Schar Cancer Institute STAGO Compact Operation", which stated "QUALITY CONTROL-Two levels of controls will be run with each test at eight hour intervals." 2. An interview with General Supervisor at approximately 11:00 AM revealed the laboratory is open for approximately 13 hours and there is one (1) STAGO Compact/STA coagulation instrument utilized for PT/INR patient testing. 3. Review of the Compact/STA PT/INR QC records from June 2019 until December 2019 revealed 22 days in June 2019 and 26 days in July 2019 with no documentation of PT/INR QC being assayed every 8 hours on the STAGO Compact while reporting 267 patients. The surveyor requested documentation of the PT/INR QC material being assayed every 8 hours for 22 days in June 2019 and 26 days in July 2019. The</p>

laboratory provided no documentation of the QC material being assayed. 4. An interview with the Technical Supervisor, General Supervisor and Lab Director at approximately 2:30 PM, the above listed findings were confirmed. B. Based on the review of the laboratory's procedures, quality control (QC) records, lack of documentation and interviews, the laboratory failed to follow their procedure and perform Activated Partial Thromboplastin Time (APTT) coagulation QC materials every 8 hours of operation for sixteen (16) days in June 2019 and sixteen (16) days in July 2019 while reporting sixty-five (65) patients. Findings include: 1. Review of the laboratory's procedure manual revealed a procedure, "IL at Inova Schar Cancer Institute STAGO Compact Operation", which stated "QUALITY CONTROL-Two levels of controls will be run with each test at eight hour intervals." 2. An interview with General Supervisor at approximately 11:00 AM revealed the laboratory is open for approximately 13 hours and there is one (1) STAGO Compact/STA coagulation instrument utilized for APTT patient testing. 3. Review of the Compact/STA APTT QC records from June 2019 until December 2019 revealed 16 days in June 2019 and 16 days in July 2019 with no documentation of APTT QC being assayed every 8 hours on the STAGO Compact while reporting 65 patients. The surveyor requested documentation of the PT/INR QC material being assayed every 8 hours for 16 days in June 2019 and 16 days in July 2019. The laboratory provided no documentation of the QC material being assayed. 4. An interview with the Technical Supervisor, General Supervisor and Lab Director at approximately 2:30 PM, the above listed findings were confirmed.