

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D2133895	<b>(X3) Date Survey Completed</b> 03/05/2024
<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 Lab at ISCI on March 4-5, 2024 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 cited is as follows:
<b>D5415</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use.</p> <p>This STANDARD is not met as evidenced by: A. Based on a tour of the laboratory, review of the laboratory's policy and procedures, manufacturer's package insert and interviews, the laboratory failed to label two (2) of 2 StatSensor Creatinine Control Solution quality control (QC) solutions with an expiration date as described in the policies and procedures on the date of the survey on March 5, 2024. The findings include: 1. During a tour of the Magnetic Resonance Imaging (MRI) department on March 5, 2024, at approximately 10:15 AM, the surveyor noted 2 boxes of StatSensor Creatinine Control Solution. Box 1 contained a vial labeled as StatSensor Creatinine Control Solution Level 1 (lot number 5023130241 with manufacturer's expiration date of 5/10/2025) and a handwritten "Discard Date" of "5/10/2025", greater than 90 days. Box 2 contained a vial labeled as StatSensor Creatinine Control Solution Level 3 (lot number 5022103243 with manufacturer's expiration date of 4/13/2024) and a handwritten "Discard Date" of "5/10/2025", past manufacturer's expiration date and greater than 90 days. 2. Review of the laboratory's policies and procedures revealed a policy, "ILS StatSensor Creatinine POCT Procedure", with the following statements, "EQUIPMENT, REAGENTS &amp;</p>

SUPPLIES-StatSensor Creatinine Control Solutions: Levels 1 and 3... Once opened the control is stable for up to 90 days or until the expiration date, whichever comes first. Bottles should be marked with new expiration date upon opening." 3. Review of the StatSensor Creatinine Control Solution QC package insert revealed the following statement, "Precautions: Use only for 90 days after first opening. When you open a new vial of control solution, count forward 90 days and write that date on the control solution vial." 4. In an exit interview with the Laboratory Director, Technical Supervisor, and Technical Consultant on March 5, 2024, at approximately 12:15 PM, the above findings were confirmed. B. Based on a tour of the laboratory, review of the laboratory's policy and procedures, manufacturer's package insert and interview, the laboratory failed to label one (1) of 1 Nova StatSensor Creatinine Test Strips with an expiration date as described in the policies and procedures on the date of the survey on March 5, 2024. The findings include: 1. During a tour of the Magnetic Resonance Imaging (MRI) department on March 5, 2024, at approximately 10:15 AM, the surveyor noted 1 container of Nova StatSensor Creatinine Test Strips (lot number 4923177129 manufacturer's expiration date 6/26/2024) with a handwritten "Open Date" of "2/5/2024". The reagent test strip vial lacked a handwritten date in the "Discard Date" space. 2. Review of the laboratory's policies and procedures revealed a policy, "ILS StatSensor Creatinine POCT Procedure", with the following statements, "EQUIPMENT, REAGENTS & SUPPLIES StatSensor Creatinine Test Strips... Once opened the StatSensor test strips are stable for 90 days at room temperature 15 to 40C (59 to 104F), or the expiration date, whichever comes first. Bottles should be marked with new expiration date upon opening." 3. Review of the StatSensor Creatinine Test Strip's package insert revealed the following statement, "Expiration: The expiration date is printed on the vial of test strips. Once opened, the StatSensor Test Strips are stable for up to 90 days at room temperature or until the expiration date, whichever comes first." 4. In an exit interview with the Laboratory Director, Technical Supervisor, and Technical Consultant on March 5, 2024, at approximately 12:15 PM, the above findings were confirmed.