Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2133895	06/16/2022
Name of Provider or Supplier	**Street Address, City, State**	
Inova Lab At Isci	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA recertification survey was conducted at Inova Lab at ISCI on June 16, 2022 by the Virginia Department of Health's Office of Licensure and Certification. The inspector noted that the laboratory is performing COVID-19 testing and is in compliance with the applicable COVID-19 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Requirements. Specific deficiencies cited are as follows:
D5429	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer. This STANDARD is not met as evidenced by: A. Based on review of procedures, available maintenance records, lack of documentation, and an interview, the laboratory failed to document required weekly maintenance protocols for the Abbott iSTAT chemistry analyzer for twenty-seven (27) of thirty-nine (39) weeks reviewed (timeframe of review: analyzer installation date September 21, 2021 to the date of the inspection on June 16, 2022). Findings include: 1. Review of the laboratory's procedures and maintenance guidelines revealed the following Abbott iSTAT maintenance protocol outlined in Procedure 10137027 "Pleural Fluid pH with iSTAT": Weekly - External Electronic Simulator Procedure: "Perform weekly on each analyzer. After performing the electronic simulator test, when PASS is displayed, press key to display thermal probe result. Record the thermal probe delta result." 2. Review of the laboratory's available iSTAT Electronic Simulator log records from September 2021 to 6/16/22 revealed documentation of the maintenance outlined above on the following dates: 9/21/21, 9/27/21, 9/29/21, 9/30 /21, 10/12/21, 10/14/21, 10/19/21, 12/3/21, 12/14/21, 1/11/22, 1/28/22, 2/8/22, 3/1/22, 6/7/22. The inspector requested to review additional documentation of the weekly

	external simulator protocol maintenance. No additional records or corrective action documentation was available. 3. An exit interview with the laboratory supervisor on 6 /16/22 at approximately 3:00 PM confirmed the above findings. B. Based on review of analyzer's maintenance logs, lack of documentation, and an interview, the laboratory failed to document required monthly preventative maintenance protocols for the Beckman Architect ci4100 chemistry analyzer for two (2) of twelve (12) months reviewed in calendar year 2021. Findings include: 1. Review of the laboratory's ci4100 maintenance log records for calendar year 2021 (review timeframe: January 2021 through December 2021) revealed lack of documentation in February and November for the following delineated monthly tasks: "Check Dispensers, Clean Cuvette with Nozzle, Clean Syringes/Valves, Perform System Backup, Clean ICT Drain Tip". The inspector requested to review additional documentation of the monthly maintenance tasks outlined above in calendar year 2021. No records or corrective action documentation was available for review. 2. An exit interview with the laboratory supervisor on 6/16/22 at approximately 3:00 PM confirmed the above findings. C. Based on review of procedures, equipment guide, maintenance records, lack of documentation, and interviews, the laboratory failed to document their hematology Hematek 3000 Stainer's quarterly preventative maintenance according to manufacturer and laboratory log protocol during six (6) of eight (8) quarters of the twenty-four (24) months reviewed (timeframe: June 2020 to the date of the inspection on June 16, 2022). Findings include: 1. Review of the laboratory's procedures and maintenance guidelines revealed the following required Hematek 3000 maintenance protocol outlined in Procedure 9720498 "Hematek 3000 Stainer Procedure": "Replace Tubing -see Hematek Instruction Manual" 2. Review of instruction guide revealed instruction, "Tubing should be replaced after three stain packs and at minimum quarterly". 3. Review of the laboratory's Hematek maintenance logs revealed indicator "Quarterly- Replace Tubing". The inspector noted documentation that the tubing was replaced in June and October of calendar year 2021. The inspector requested additional documentation of the quarterly tubing replacement maintenance. The laboratory supervisor stated on 6/16/22 at approximately 1:30 PM, "The tubing should have been changed more often than is documented because I have ordered replacement tubing. I am not sure why it is not documented on the logs". 4. An exit interview with the laboratory supervisor on 6/16 /22 at approximately 3:00 PM confirmed the above findings.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on a tour, review of procedures, maintenance logs, lack of documentation, and interview, the laboratory failed to document function checks for revolutions per minute (RPM) for two (2) centrifuges (ThermoFisher urinalysis and ELITech Cytofuge) in 2 of 2 years reviewed (timeframe-calendar years 2020 and 2021).

	Findings include: 1. During an entrance interview/tour with the laboratory supervisor on 6/16/22 at approximately 10:00 AM, the inspector noted a ThermoFisher Sorvall ST16 centrifuge serial number (SN) 42338552 in use for urine microscopy specimen processing and a ELITech Group Cytofuge SN 762218334 in use for body fluid cell count procedures. 2. Review of the laboratory procedures revealed the following polices: Policy #9926239 - Microscopic Examination of Urine Sediment: "Centrifuge urine specimen at 1500 RPM for 5 minutes." Policy #11814179 - Cell Count Procedure: "Ensure the cyto centrifuge settings are on rotation 700 RPM for 5 minutes." Policy #11556622 - Centrifuge Cleaning and Maintenance Procedure: "Biomedical Preventative Maintenance-Inova Technical Dyanamics will complete all annual centrifuge maintenance. Operating speed (RPM) will be verified annually and documented. Records will be maintained electronically by Inova Technical Dynamics". 3. Review of the laboratory's 2020 and 2021 centrifuge maintenance documentation revealed no record of RPM verifications for the 2 centrifuges outlined above (ThermoFisher Sorvall ST16 and ELITech Cytofuge). The inspector inquired regarding the RPM verification. The laboratory supervisor stated on 6/16/22 at approximately 2:00 PM, "We do have all of the centrifuges checked at least once per year. The service tech places stickers on the equipment." The laboratory supervisor reached out by email and contacted Technical Dynamics Services for the additional records. The following documents were provided: 12/30/20 - Sorvall ST16 SN 42338552 PM with service note "Completed-No Correction"; 11/29/21 - Sorvall ST16 SN 42338552 PM with service note "Completed-No Correction"; 07/14/20 - Cytofuge SN 762218334 with service note "Completed-No Correction"; 07/29/21 - Cytofuge SN 762218334 with service note "Speed verified by tachometer -1000 RPM (999.8), 1200 RPM (1200.0), 2000 RPM (1999), 5 min." The inspector noted no 1500 RPM verification for the Sorvall ST16 or 700 RPM for the Cytofuge on the records provided -outlined above. No additional RPM verification documentation was available on the date of the survey, 6/16/22. 4. An exit interview with the laboratory supervisor on 6/16/22 at approximately 3:00 PM confirmed the above findings.