Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D0661154	09/04/2024
Name of Provider or Supplier	**Street Address, City, State**	
Virginia Physicians, Inc Laboratory Services	4900 Cox Road Suite 180, Glen Allen, 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 Virginia Physicians, Inc-Laboratory Services on September 3-4, 2024 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiencies cited are as follows:
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on a review of policies, system maintenance logs, lack of documentation, and interviews, the laboratory failed to document performance of daily checks of their Evoqua Water System's resistivity per their policy for thirteen (13) of one hundred seventy-three days reviewed in eight (8) months randomly selected for review (timeframe of January 2023 to September 4, 2024). Findings include: 1. Review of the policy manual revealed a policy (title: Water Quality) that outlined the following protocol to be performed daily: observe and document resistivity (range =>10). 2. Review of 8 randomly selected monthly logs (2023: May, June, July, August, September, October and 2024: April, May) revealed the following dates with no water resistivity checks documented: 5/17/23, 6/15/23, 6/16/23, 8/16/23, 8/17/23, 9/15/23, 9/22/23, 10/24-10/27/23, 4/25/24, and 4/26/24. 3. Interviews on 9/4/24 with the Technical Supervisor at 12 PM and Technical Consultant at 3:30 PM confirmed the above findings.

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: Based on a review of instrument validation records, manufacturer's operations manual, immunoassay analyzer maintenance records, lack of documentation, and interviews, the laboratory failed to document performance of required monthly maintenance for eight (8) of 8 months reviewed (timeframe: January 2024 to the last date of the recertification inspection on September 4, 2024). Findings include: 1. Review of laboratory instrument validation records revealed that a new immunoassay analyzer was installed on 11/1/2023 (OC-Auto Sensor io, Serial Number 021UL1490). The inspector noted that the laboratory started testing patients on the new analyzer on January 4, 2024. 2. Review of the OC-Auto Sensor io instruction manual revealed manufacturer's instruction (under Section 11 "Maintenance") to perform the following monthly cleaning protocols: Clean Deionized Water and Wash Solution Bottles, Clean the Drain Tank, and Clean Sample Racks. 3. Review of monthly maintenance logs (January 2024 to 9/4/24) for the analyzer outlined above revealed that the laboratory failed to document performance of two of the three-monthly protocols (clean water and wash bottles, clean drain tank) for 8 of the 8 months reviewed. The inspector noted that the laboratory failed to document the third monthly protocol to clean sample racks in January, March, April, and June of 2024; four of 8 months reviewed lacked documentation that the sample racks were cleaned. The inspector requested to review documentation that the monthly maintenance tasks outlined above were performed per manufacturer's guide. No additional records were available. 4. Interviews on 9/4/24 with the Technical Supervisor at 1:30 PM and Technical Consultant at 3:30 PM confirmed the above findings.