

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D0661154	<b>(X3) Date Survey Completed</b> 01/29/2021
<b>Name of Provider or Supplier</b> Virginia Physicians, Inc Laboratory Services	<b>Street Address, City, State</b> 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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	An announced CLIA recertification survey was conducted for Virginia Physicians, Inc-Laboratory Services on January 28-29, 2021 by the Virginia Department of Health's Office of Licensure and Certification. The survey also included an entrance telephone interview with initial virtual record review conducted on 1/27/2021. The inspector noted that the laboratory performs COVID-19 testing and was in compliance with the applicable SARS-CoV-2 reporting requirements. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. Specific deficiency cited is as follows:
<b>D5413</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a review of policies, system maintenance logs, and interviews, the laboratory failed to document performance of their Evoqua Water System's water culture monitoring for six (6) of eight (8) quarters reviewed (review timeframe 1/1/19 to 1/29/21). Findings include: 1. Review of the policy manual revealed two (2) water quality policies: Quality Assurance protocol ("Water Quality") that stated: "Once per quarter, a water sample is to be collected and cultured. A colony count must be determined. The maximum CFU/ml is 10. If results exceed the limit, a retest will be performed. If retest exceeds limits, Evoqua must be called to troubleshoot the water system."; Quality Assurance protocol ("Bacterial Testing of Laboratory Water") that</p>

stated: "Ideally, Clinical Lab Reagent Water (CLRW) should be bacteria free. Virginia Physicians Core Lab will verify CLRW on a quarterly basis". 2. Review of the Evoqua Water System maintenance logs and attached culture results from January 2019 to the date of the survey, on 1/28/21, revealed that water culture reports were completed and reviewed by the general supervisor on the following dates: 06/01/19; 02/17/20; 03/09/20 -noted water system line dropped for DXC 700 and AU, system decontaminated. The inspector requested to review additional quarterly water maintenance reports performed in 2019 and 2020. No records were available for review. The chemistry general supervisor stated on 1/29/21 at approximately 11 AM: "Yes, we got the water check done only once in 2019. The reference lab that we sent our water samples to for the culture counts notified us that they had discontinued doing the tests. It has taken me a while to get another protocol of quarterly water bacteria colony count checks in place". 3. The technical supervisor confirmed the above findings on 1/29/21 at approximately 1:00 PM.