

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 49D2278413	<b>(X3) Date Survey Completed</b> 10/31/2023
<b>Name of Provider or Supplier</b> Potomac Podiatry Group PLLC	<b>Street Address, City, State</b> 46440 Benedict Dr, Suite 209, Sterling, 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 initial survey was conducted at Potomac Podiatry Group on October 30-31, 2023 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>D5411</b>	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>This STANDARD is not met as evidenced by: Based on a laboratory tour, review of the laboratory's temperature and humidity records, instrument environmental/operating requirements, lack of documentation, and interview, the lab failed to monitor and document the room temperatures and relative humidity for seventy-four (74) of one-hundred eighty-four (184) days reviewed from May 1, 2023 to October 31, 2023. The findings include: 1. During a tour of the laboratory on October 30, 2023, at approximately 8:45 AM, the surveyor noted an Applied Biosystems QuantStudio 7 flex real-time instrument and ThermoScientific KingFisher Duo Prime instrument in use for patient testing in the laboratory. 2. Review of the laboratory's policies and procedures revealed a procedure, "GEN 14.1.0 Gen: Good Laboratory Practice" (effective date/signed by the laboratory director on 4/24/2023), with the statements, "5. Instructions, 5.1 Daily Verification Activities, 5.1.1 Lab Personnel-Verify that the temperature and relative humidity of the lab are within the acceptable range, refer to the Environmental Conditions Control &amp; Monitoring System Level Procedure (SLP)." 3. Review of the laboratory's temperature records from May 1, 2023 until October 31, 2023 revealed a lack of documentation of room temperature and relative humidity recordings for the</p>

following days from May 1, 2023 until October 31, 2023: 5/1/2023-5/5/2023, 5/8/2023-5/12/2023, 5/15/2023-5/19/2023, 5/22/2023-5/26/2023, 5/29/2023-6/2/2023, 6/5/2023-6/9/2023, 6/12/2023-6/16/2023, 6/19/2023-6/23/2023, 6/26/2023-6/30/2023, 7/3/2023, 7/5/2023-7/7/2023, 7/10/2023-7/14/2023, 7/17/2023-7/21/2023, 7/24/2023-7/28/2023, 7/31/2023-8/4/2023, 8/7/2023-8/11/2023. Total of 74 days of 184 days reviewed. The surveyor requested to review documentation of the room temperature and relative humidity for the above listed 73 days. The laboratory provided no documentation to review. 4. Review of the Thermo Scientific King Fisher Duo Prime Technical Manual's Operating Conditions revealed the following instrument environmental/operating requirements, "Operating Conditions (indoor use) +4C to +40C (104F); the maximum relative humidity 80% for temperatures up to 31C decreasing linearly to 50% relative humidity at 40C." Review of the Applied Biosystems QuantStudio 6 and 7 flex real-time PCR Manual revealed the following: Environmental requirements-Humidity 15-80% (non-condensing), Temperature 15-30C (60-85F). 5. In an exit interview with the quality technical supervisor and technical supervisor on October 31, 2023, at approximately 1:00 PM, the findings were confirmed.