Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D2278413	04/09/2025
Name of Provider or Supplier	**Street Address, City, State**	
Potomac Podiatry Group Pllc	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA recertification survey was conducted at Potomac Podiatry Group, PLLC on April 8-9, 2025 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. The deficiencies cited are as follows:
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) (a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: A. Based on a review of the laboratory's policies and procedures, reagent and quality control (QC) records, interviews and lack of documentation, the laboratory failed to follow their established policy to document new lot number acceptable performance of the Thermo MasterMix and Lighthouse panel plates for the seventeen (17) months from November 2023 until April 2025. The findings include: 1. Review of the laboratory's policies and procedures revealed the following policy and instructions, "Reagent Receiving and QC Testing" and "Lot Verification Log" with the following instructions, "On the Log Verification sheet, enter the required information (Item Name, Vendor, Catalog Number, Lot Number, Expiration Date, Storage Temperature, the number of items received in the Count column, the batch/name that the item was tested in the In-Use Batch column, Pass/Fail status of all controls, Corrective Action as applicable (N/A if does not apply), initials of the tech performing the PCR for that batch, and the initials of the Technical Supervisor)." 2. Review of the laboratory's "Lot Verification Log" revealed an empty spreadsheet from November 2023 until April 2025. The logs lacked documentation of the verification for the 7 lot numbers listed below: Mastermix lot # Expiration date 2665652 06/22/2024 2309036 04/05

	/2024 2965079 03/31/2026 Wound Panel Plate Lot # Expiration date 8103483 06/22 /2024 8342049 07/17/2025 Nail Panel Plate Lot # Expiration date 8121028 07/11 /2024 8335297 07/10/2025 3. In an exit interview with the Technical Supervisor and Testing Personnel on April 9, 2025 at 12:00 PM, the above findings were confirmed. B. Based on a review of the laboratory's policies and procedures, "Molecular Wipe Testing" records, lack of documentation and interviews, the laboratory failed to follow their established policy to perform and document "Molecular Wipe Testing" quarterly in one of six quarters from November 2023 until April 2025. The findings include: 1. Review the laboratory's policies and procedures revealed a policy, "Molecular Wipe Testing", with the following statements, "2. Scope: Applies to all surfaces used regularly for testing. Testing is performed quarterly, when molecular microbiology specimens have been processed within the quarter, as needed to rule out contamination, or at the Lab Director's discretion at a more frequent interval...9. Results Review and Reporting...9.5 The Wipe Test Specimen Information Form and copies of the final reports are to be submitted by lab personnel via DocSign to the Lab Director for review and signature. 9.6 The signed copy will need to filed onsite in the maintenance binder." Further review of the "Molecular Wipe Testing" policy revealed the following Wipe Test Schedule: April-Pipettes, Hood Interior, QuantStudio Exterior, Accessioning Station, Chairs. June-KingFisher Exterior, Lab Bench (es) used for testing, Light switches, Fridge/freezer handles, Centrifuge. September-Door Handles, Faucets, Keyboards, Post-sterilized tube racks, Pipettes. December-Door Handles, Lab Branch (es) used for testing, Accessioning Station, Light Switches, Chairs. 2. Review of the available the "Wipe Test Specimen Information" forms from November 2023 until April 2025 revealed the following dates when the "Molecular Wipe Testing" was performed: 9/2023, 4/2024, 6/2024, and 12/2024. The surveyor requested to review the "Wipe Test Specimen Information" forms for 12/2023 and 9 /2024. The laboratory provided no documentation to review. In an interview on April 9, 2025 at 10:30 AM, the Technical Supervisor stated the 9/2024 Wipe Test was not completed due to a laboratory move in August 2024. They stated no patient testing was performed from 7/23/2024 until 11/14/2024. 3. In an exit interview with the Technical Supervisor and Testing Personnel on April 9, 2025 at 12:00 PM, the above findings were confirmed.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) (d)(10) Establish or verify the criteria for acceptability of all control materials. (d)(10)(i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (d)(10)(ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (d)(10)(iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and procedures, quality control (QC) records, interviews and lack of documentation, the laboratory failed to follow their established policy to document new QC lot verification prior to putting QC into use for eight (8) of eight lot numbers of QC from November 2023 until April 2025. The findings include: 1. Review of the laboratory's policies and procedure revealed a

	policy, "Reagent Receiving and QC Testing", with the following statements, "5.3 Performing New Lot QC Testing 5.3.1. Document the use of a new QC lot by entering the date put into use and the batch number into the Lot Verification log...5.3.3. Verify that the QC performs within acceptance criteria outlined in the technical SOP. 5.3.4. When testing performance is successfully verified, go back to the Lot Verification Log and record that the new lot of QC passed and initial. 5.3.5. The new lot of QC is now ready for clinical use." 2. Review of the laboratory's "Lot Verification Log" from November 2023 until April 2024 records revealed a lack of documentation of the Lighthouse Lab Services (LLS) QC Lot verification, in use date, batch number, if QC passed and initial for the following lot numbers of LLS Wound positive (+) control and LLS Nail positive (+) control received and put into use from November 2023 until April 2024: Wound + control lot# Expiration date 232828 04/30/2024 23353C 06 /30/2024 24113A 10/31/2024 M24264B 03/31/2025 M25041A 08/30/2025 Nail + control Lot # Expiration date 23314A 05/31/2024 24128A 11/30/2024 M24281A 04 /30/2025 A total of 8 lot numbers of QC in use from November 2023 until April 2025. The surveyor requested to review the completed "Lot verification Log" from November 2023 until April 2025. The laboratory provided no documentation for review. 3. In an exit interview with the Technical Supervisor and Testing Personnel on April 9, 2025 at 12:00 PM, the above findings were confirmed.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on the review of the laboratory's policies and procedures, reagent and quality control (QC) verification records, Wipe Testing records, Quality Assessment Policy and forms, lack of documentation and interviews, the laboratory's Quality Assessment plan failed to identify and address analytic issues within the specialties of Microbiology (see D5401A & B and D5469) from November 2023 until April 2025 (17 months). The findings include: 1. Review of the laboratory's Quality Assessment (QA) policies and procedures, reagent and quality control verification records revealed the analytic issues listed below. The laboratory failed to follow their established policy to: -document the verification of reagents upon receipt during the 17 months reviewed (D5401A). -perform and document the quarterly Wipe Testing for December 2023 (see D5401B). -document the verification of new lot numbers of QC during the 17 months reviewed (D5469). 2. Review of the laboratory's Quality Assessment Policy and forms revealed the following statements, "Quality Assessment Reviews are conducted at the frequency specified. The calendar indicates which monitors will be reviewed each month. The Quality Assessment Forms associated with the monitor are completed. If a problem is identified, corrective action is implemented, and a follow-up review is conducted to assure that the corrective actions have resolved the problem. The QA Review forms are signed by the reviewer and laboratory director and retained in the Quality Assessment folder for a minimum of two years (3 years for California)." 3. Review of the Quality Assessment forms used to document QA reviews revealed a lack of documentation of the analytic issues specified above for the 17 months reviewed from November 2023 until April 2025.

	The forms were signed by the Technical Supervisor and Laboratory Director for the above mentioned timeframe. 4. In an exit interview with the Technical Supervisor and Testing Personnel on April 9, 2025 at 12:00 PM, the above findings were confirmed.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur; This STANDARD is not met as evidenced by: Based on a review of the laboratory's Quality Assessment (QA) policy and forms, Quality Control records and Wipe testing records, lack of documentation and interviews, the Laboratory Director failed to ensure the laboratory's established policy for QA was maintained from November 2023 until April 2025 (see D5793).