Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	42D2099909	12/05/2024
Name of Provider or Supplier	**Street Address, City, State**	
Physicians Footcare Lab	1815 Back Creek Drive, Charlotte, NC	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of validation records, review of laboratory test list, the absence of documentation, interview with laboratory director (LD) 12/05/24, and follow-up phone conference with general supervisor (GS) 12/18/24, the laboratory failed to verify the accuracy of the histopathology staining performed on the Ventana automated stainer at least twice a year since testing began in January of 2023, approximately 24 months. The laboratory also failed to verify accuracy of the pathology testing at least twice a year. 1. The laboratory failed to verify the accuracy of the histopathology staining performed on the Ventana automated stainer at least twice a year since testing began in January of 2023. Findings: Review of validation records revealed the laboratory began testing on the Ventana automated stainer in January of 2023. Review of test list for the Ventana automated stainer revealed the following stains are performed by the laboratory: 1. Anti-Pan Keratin 2. Ber Ep4 (antihuman epithelial antigen) 3. HPV HR (high-risk human papillomavirus) 4. CEA (serial plasma carcinoembryonic antigen) 5. CD 34 (cluster of differentiation 34) 6. CD 68 (cluster of differentiation 68) 7. Cd 138 (Syndecan-1) 8. CK-7 (cytokeratin 7) 9. CK-20 (cytokeratin 20) 10. Desmin 11. EMA (epithelial membrane antigen) 12. Factor XIIIa 13. HMB 45 (human melanoma black 45) 14. HSV I (herpes simplex virus 1) 15. HSV II (herpes simplex virus 2) 16. KI 67 (antigen Kiel 67 mitotic index) 17. P 16 (p 16 protein) 18. Melan A (melanocyte antigen) 19. PGP 9.5 (protein gene product 9.5) 20. P 40 (deltaNp63) 21. SM Actin (smooth muscle actin) 22. S 100 (soluble protein) 23. SOX 10 (SRY-box transcription factor 10) Review of laboratory records revealed no documentation the laboratory had performed a twice a year verification of accuracy for the testing performed on the Ventana automated stainer

	since testing began in January of 2023. Follow-up phone conference with GS on 12/18 /24 confirmed the laboratory had not performed a verification of accuracy for the testing performed on the Ventana automated stainer since testing began in January of 2023. The GS also stated they were unaware of this requirement and many of the stains are rarely performed. 2. The laboratory failed to verify the accuracy of the pathology testing at least twice a year. Findings: Review of laboratory procedure "Professional Competency" revealed "PROCEDURE:...4. A Quality Assurance (QA) comparative table between the pathologist and the consultant pathologist diagnoses and have three types of comparative results: similar diagnosis, minor differences (insignificant), and major differences (significant). 5. The results for all the above will be evaluated and documented. Corrective action taken if it is necessary." Review of 7 laboratory pathology reports presented as documentation of verification of accuracy revealed the cases sent for review included the original pathology report and notes requesting a consultation from a referring pathologist. The cases were not sent as blind samples, a pathology report was not generated from the referring pathologist and there was also no documentation of a comparison of pathology test results. Interview with LD 12/05/24 at approximately 2:30 p.m. confirmed the pathology cases were not sent as blind samples, a pathology report was not generated from the referring pathologist and there was no documentation of a comparison of pathology test results.
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 review of operator's manual, review of laboratory procedure, review of 2022, 2023 and 2024 maintenance logs, review of 2022, 2023 and 2024 analyzer service reports, review of CMS-116 submitted at time of survey and interview with testing personnel (TP #3) on 12/04/24, the laboratory failed to perform and/or document monthly maintenance on the QuantStudio 7 Flex analyzer from June of 2022 until November of 2024, a period of approximatlely 28 months, failed to perform semi-annual maintenance every six months, and failed to ensure maintenance was documented and performed for each facility utilizing the QuantStudio 7 Flex analyzer. 1. The laboratory failed to perform and/or document monthly maintenance on the QuantStudio 7 Flex analyzer from June of 2022 until November of 2024. Findings: Review of operator's manual revealed the following "Calibration and maintenance schedule...The QuantStudio 6 and 7 Flex Systems require regular calibration and maintenance for proper operation. To ensure proper operation of your instrument, perform weekly, monthly and semiannual maintenance as indicated in the following table.....Monthly...Perform a background calibration...Run disk cleanup and disk defragmentation...Perform an instrument self test....". Review of laboratory procedure "APPLIED BIOSYSTEMS QUANTSTUDIO FLEX 7 OPERATING PROCEDURE" revealed a copy of the maintenance table from the operator's manual, with monthly maintenance as stated in the operators manual. Review of 2022, 2023 and 2024 maintenance logs for the QuantStudio 7 Flex analyzer revealed no documentation of monthly maintenance from June of 2022 until November of 2024. 2. The laboratory failed to perform semi-annual maintenance every six months for the QuantStudio 7 Flex analyzer. Findings: Review of operator's manual revealed the following "Calibration and maintenance schedule...The QuantStudio 6 and 7 Flex

	Systems require regular calibration and maintenance for proper operation. To ensure proper operation of your instrument, perform weekly, monthly and semiannual maintenance as indicated in the following table.....Semi-annually (every 6 months).... Perform a ROI calibration...Perform a background calibration...Perform a uniformity calibration...Perform a dye calibration...". Review of laboratory procedure "APPLIED BIOSYSTEMS QUANTSTUDIO FLEX 7 OPERATING PROCEDURE" revealed a copy of the maintenance table from the operator's manual, with semi-annual maintenance as stated in the operators manual. Review of 2022, 2023 and 2024 maintenance logs for the QuantStudio 7 Flex analyzer revealed under the Semi-Annually section of the log "Performed by Service" and "See service report". Review of 2022, 2023 and 2024 service reports for the QuantStudio 7 Flex analyzer revealed semi-annual maintenance was performed 10/06/22 and 03/14/23. Semi-annual maintenance was not performed again until 04/03/24, a period of approximately 13 months. Semi-annual maintenance was due 10/03/24 and had not been completed at time of survey, a period of approximately 8 months. 3. The laboratory failed to ensure maintenance was documented for each facility utilizing the QuantStudio Flex analyzer. Findings: Review of CMS-116 at time of survey listed "Hours of Laboratory Testing" as Monday through Friday, 3:30 p.m. - 4:30 p.m. The other facility who utilizes the analyzer listed different hours of operation Monday through Friday. Review of 2022, 2023 and 2024 maintenance logs for the QuantStudio 7 Flex analyzer revealed only one set of maintenance logs with no distinction as to which facility performed the maintenance. Interview with TP #3 on 12/04/24 at approximately 11:00 a.m. confirmed maintenance was not documented for each facility. TP #3 stated samples from each facility are run at the same time and not on different days or at different hours.
D5453	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(iv)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each test system that has an extraction phase, include two control materials, including one that is capable of detecting errors in the extraction process; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory procedure, review of 2023 and 2024 quality control (QC) records, lack of documentation, review of CMS-116 submitted at time of survey, and interview with TP #3 on 12/04/24, the laboratory failed to perform a positive extraction control (PEC) and negative extraction control (NEC) each day of patient testing and/or for each TaqMan Array Card (test system) and failed to ensure QC was documented and/or performed for each facility utilizing the QuantStudio 7 Flex analyzer. Approximately 3386 patients were tested from January of 2023 until time of survey. The laboratory performs "Wound Infection Panel" and "Periungual Infection Panel" on the QuantStudio 7 Flex Analyzer utilizing a TaqMan Array Card test system. Each TaqMan Array Card can test up to 8 patient samples. 1. The laboratory failed to perform a PEC and NEC each day of patient testing and/or for each TaqMan Array Card (test system). Findings: Review of laboratory procedure "APPLIED BIOSYSTEMS QUANTSTUDIO FLEX 7 OPERATING PROCEDURE" revealed "QUALITY CONTROL (QC): There are several QC materials that are utilized on the Applied Biosystems QuantStudio 7 Flex...Positive Extraction Control (PEC) and

	Negative Extraction Control (NEC) will be performed monthly. NOTE: PEC and NEC may be performed more frequently if deemed necessary for troubleshooting.". Review of 2023 QC records revealed the laboratory performed a NEC each day of patient testing but failed to perform a PEC approximately 152 of 164 days in which patient testing was performed.. Surveyor was unable to determine the number of patients tested each day or the number of TaqMan Array Cards (test systems) ran each day. Review of 2024 QC records revealed the laboratory performed a NEC each day of patient testing but failed to perform a PEC approximately 24 of 32 days in which patient testing was performed. Surveyor was unable to determine the number of patients tested each day or the number of TaqMan Array Cards (test systems) ran each day. Interview with TP #3 on 12/04/24 at approximately 11:00 a.m. confirmed the PEC was not performed each day of patient testing. TP #3 stated the PEC is performed at least monthly and the NEC has been performed weekly since January of 2024 when the laboratory began to batch test patients weekly. TP #3 also confirmed PEC and NEC was not performed for each TaqMan Array Card (test system) used in a daily run. Review of CMS-116 submitted at time of survey revealed the laboratory performs 1693 test panels per year on the QuantStudio 7 Flex analyzer; approximately 3386 patients were tested since January of 2023. 2. The laboratory failed to ensure QC was documented and/or performed for each facility utilizing the QuantStudio 7 Flex analyzer. Findings: Review of CMS-116 at time of survey listed "Hours of Laboratory Testing" as Monday through Friday, 3:30 p.m. - 4:30 p.m. The other facility who utilizes the analyzer listed different hours of operation Monday through Friday. Review of 2023 and 2024 QC logs for the QuantStudio 7 Flex analyzer revealed only one set of QC logs with no distinction as to which facility performed the QC. Interview with TP #3 on 12/04/24 at approximately 11:00 a.m. confirmed QC was not documented for each facility. TP #3 stated samples from each facility are batched together, ran at the same time and not on different days or at different hours.
D6122	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(ii) The procedures for evaluation of the competency of the staff must include, but are not limited to monitoring the recording and reporting of test results. This STANDARD is not met as evidenced by: Based on review of personnel records and interview with the GS 12/05/24, the technical supervisor (TS) failed to ensure testing personnel competency evaluations included all required elements for one of three testing personnel (TP #3). Findings: Review of personnel records for TP #3 revealed the semiannual Molecular: QuantStudio 7 Flex personnel competency assessment signed 03/20/24 did not include documentation that the TS monitored the recording and reporting of test results. During interview on 12/05/24, the GS confirmed that the competency evaluation was incomplete and did not include monitoring the recording and reporting of test results.
D6126	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(8)(vi) The procedures for evaluation of the competency of the staff must include, but are not limted to assessment of problem solving skills. This STANDARD is not met as evidenced by:

	Based on review of personnel records and interview with the GS 12/05/24, the TS failed to ensure testing personnel competency evaluations included all required elements for one of three testing personnel (TP #3). Findings: Review of personnel records for TP #3 revealed the semiannual Molecular: QuantStudio 7 Flex personnel competency assessment signed 03/20/24 did not include documentation that the TS assessed problem solving skills. During interview on 12/05/24, the GS confirmed that the competency evaluation was incomplete and did not include the assessment of problem solving skills.