Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D2286002	02/27/2024
Name of Provider or Supplier	**Street Address, City, State**	
Four Corners Foot And Ankle Pc	2700 N Farmington Ave Suite C-1, Farmington, NM	

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 onsite initial survey conducted at Four Corners Foot and Ankle PC on February 27, 2024, found the laboratory to be out of compliance with the CLIA regulations found at 42 CFR, Part 493 Laboratory Requirements, with the following conditions not met: 493.1250 Analytic Systems 493.1441 Laboratory Director, high complexity
D5213	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(b)(1) The laboratory must verify the accuracy of any analyte or subspecialty without analytes listed in subpart I of this part that is not evaluated or scored by a CMS-approved proficiency testing program. This STANDARD is not met as evidenced by: Based on review of American Proficiency Institute (API) proficiency testing (PT) records and interview, the laboratory failed to evaluate the performance of ungraded analytes in Microbiology for 1 of 2 PT events in 2023. Findings included: 1. Review of API PT performance records for the 1st event in Microbiology - Mycology and Microbiology - Other list the following tested analytes as ungraded. 1. Microbiology - Mycology: Molecular Mycology Urine i. QuantStudio / Candida Tropicalis: - UTI -01 = Ungraded 2. Microbiology - Other: Molecular Resist. Gene Urine: i. QuantStudio / Resistance Gene CTX-M: - UTI -01 = Ungraded - UTI -03 = Ungraded - UTI -04 = Ungraded ii. QuantStudio / Resistance Gene IMP: - UTI -01 = Ungraded - UTI -03 = Ungraded - UTI -04 = Ungraded iii. QuantStudio / Resistance Gene mecA: - UTI -01 = Ungraded - UTI -02 = Ungraded - UTI -03 = Ungraded - UTI -05 = Ungraded iv. QuantStudio / Resistance Gene NDM: - UTI -01 = Ungraded - UTI -03 = Ungraded - UTI -04 = Ungraded v. QuantStudio / Resistance Gene qnrA: - UTI -01 = Ungraded - UTI -03 = Ungraded - UTI -04 = Ungraded 2. Laboratory was asked to provided documentation of ungraded analytes being evaluated. None were provided. 3. Interview on 2/27/2024 at 9:45 am with the general supervisor confirmed the findings.

D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: The laboratory failed to meet analytic systems requirements as evidenced by: 1. The laboratory failed to verify the performance of the QuantStudio 12 Flex following the relocation of the laboratory for 6 of 6 months in 2023. Refer to D5421. 2. The laboratory failed to establish specimen stability for 2 of 2 laboratory developed assays in 2023. Refer to D5423.
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 direct observation, review of the MagMAX Viral/Pathogen Ultra Enzyme Mix manufacturer's instructions, maintenance log, and interview the laboratory failed to ensure proper storage conditions for the MagMAX Viral/Pathogen Ultra Enzyme Mix for 13 of 37 events in December 2023 through February 2024. Finding included: 1. During a tour of the laboratory on 2/27/2024 4 boxes of MagMAX Viral/Pathogen Ultra Enzyme Mix were found in the storge freezer. 2. Review of MagMAX Viral /Pathogen Ultra Enzyme Mix manufacturer's instructions found on the box listed the storage conditions for the reagent as -15 Celsius (C) through -25 Celsius (C) 3. Review of the maintenance log under "Daily Freezer Temperature" lists the freezer temperature range as -10C through -25C, which is outside manufacturer's specified ranges. 4. Review of the maintenance log from December 2023 through February 2024 found the following days out of manufacturer's specified ranges. 1. 12/1/2023: Freezer temperature -14C 2. 12/5/2023: Freezer temperature -14C 3. 12/11/2023: Freezer temperature -14C 4. 12/13/2023: Freezer temperature -13C 5.12/14/2023: Freezer temperature -14C 6.12/28/2023: Freezer temperature -14C 7. 12/29/2023: Freezer temperature -14C 8. 1/4/2024: Freezer temperature -14C 9. 1/8/2024: Freezer temperature -14C 10. 1/12/2024: Freezer temperature -14C 11.1/16/2024: Freezer temperature -13C 12.1/17/2024: Freezer temperature -14C 13. 2/20/2024: Freezer temperature -14C 5. Interview on 2/27/2024 at 11:07am with the general supervisor confirmed the findings.
D5421	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE

	CFR(s): 493.1253(b)(1) Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the laboratory's studies, Quality Control (QC) logs, test volumes, and staff interview, the laboratory failed to verify the performance of the QuantStudio 12K Flex following the relocation of the laboratory for 6 of 6 months in 2023. Findings included: 1. Review of the laboratory's "A Supplemental Validation and Correlation Study Performed on the QuantStudio 12K Flex and Kingfisher" revealed the validation study was approved by the Laboratory Director on 01/02/2024. 2. Review of the laboratory's "Stability Study for Fungal and Wound Panels in Transport Medium, Time Refrigerated, and Time Frozen" revealed the establishment study was approved by the Laboratory Director on 01/02/2024. The QuantStudio was approved for use on 01/02/2024. 3. Review of the laboratory's QC logs revealed the following dates when studies were performed: a. 11-06-2023 Wound transport study and nail transport study b. 12-04-2023 Wound stability study freezer and nail stability study freezer 4. Review of the laboratory's QuantStudio 12K Flex test volumes in 2023 revealed: a. July - 84 total tests b. August - 96 total tests c. September - 101 total tests d. October - 84 total tests e. November - 87 total tests f. December - 88 total tests Patient testing on the QuantStudio began July 2023, but was not approved for use until 01/02/2024. 5. During an interview on 02/27/2024 at 11:30 am, the general supervisor stated the laboratory was relocated in July 2023. After review of the above records, the findings were confirmed.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on a review of laboratory's test menu, TaqMan Array Stability Study, procedure, test volume, and staff interview, the laboratory failed to establish specimen stability for 2 of 2 laboratory developed assays in 2023. 1. Review of the laboratory's test menu revealed the following laboratory developed assays were performed: a. Thermo Fisher TaqMan Fungal Assay Panel b. Thermo Fisher TaqMan Wound Assay

	Panel 2. Review of the laboratory's "Stability Study for Fungal and Wound Panels in Transport Medium, Time Refrigerated, and Time Frozen" establishment study stated, "Genomic DNA was placed into transport medium and either refrigerated or held at room temperature for 3 and 5 days." 3. Review of the laboratory's "Laboratory Operations Manual for DNA/RNA Based Pathogen Testing" procedure stated, "Specimens can be refrigerated at 4-8C for 7 days. The laboratory failed to establish refrigerated storage at 7 days. 4. During an interview on 02/27/2024 at 11:30 am, after review of the above records, the general supervisor confirmed the findings. Word Key: C = Degrees celsius DNA = Deoxyribonucleic acid RNA = Ribonucleic acid
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory records, laboratory procedure, and staff interview, the Laboratory Director failed to provide overall management and direction as evidenced by: 1. The Laboratory Director failed to ensure verification procedures were adequate prior to performing patient testing. Refer to D6086.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on review of the laboratory's studies, Quality Control (QC) logs, test volumes, test menu , laboratory procedure, and staff interview, the Laboratory Director failed to ensure verification procedures were adequate as evidenced by: 1. The Laboratory Director failed to ensure instrument test systems were verified after relocating the laboratory prior to performing patient testing. Refer to D5421. 2. The Laboratory Director failed to ensure specimen refrigerated stability conditions were established for the TaqMan Fungal and Wound Assays. Refer to D5423.