Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 32D2163600	(X3) Date Survey Completed 02/05/2020
Name of Provider or Supplier New Mexico Foot & Ankle Institute	**Street Address, City, State** 4343 Pan American Freeway Ne #234, Albuquerque, 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	The following deficiency was cited as the result of an initial survey completed on 02/05/2020 for 42 CFR part 493 Laboratory Requirements.
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 interviews with laboratory staff, review of patient records, laboratory policy, application, validation records and quality assessment records, the laboratory failed to verify the accuracy of the TaqMan assay testing performed on the Applied Biosystems QuantStudio 12K at least twice per year. The laboratory reported performing 132,000 tests per year. Findings are: A. Review of the laboratory's application for a CLIA Certificate of Compliance to perform non-waived testing indicated an effective date of 02/01/19. The application was approved and entered into the CLIA database on 03/18/19. B. Review of 2020 application, 2019 patient test records and validation records indicated the laboratory used Applied Biosystems QuantStudio 12K Flex TaqMan Array Card Platform (a method using genetic material) to detect fungi (22 species) in nail samples and bacteria (22 species) from wounds. Staphylococcus aureus Acremonium strictum Enterococcus faecalis Aspergillus fumigatus Staphylococcus epidermidis Aspergillus niger Streptococcus pyogenes (Group A Aspergillus terreus Streptococcus agalactiae (Group B Strep) Aspergillus versicolor Escherichia coli Candida albicans Bacteroides fragilis Candida krusei Klebsiella pneumoniae Candida glabrata Proteus mirabilis Candida tropicalis Pseudomonas aeruginosa Epidermophyton floccosum Candida albicans Microsporum audouinii Candida glabrata Microsporum gypseum Candida parpsilosis Microsporum nanum Candida dubliniensis Sarcoptes scabiei Candida tropicalis Scopulariopsis brevicaulis C.

	Review of laboratory policy QA0002.V01 Quality Assurance Program, dated 05/28 /2019, indicated: "For those tests which are not covered by an outside proficiency testing program, a system will be established by the department supervisor/manager for verifying the accuracy and reliability of test results at least twice within a twelve month period." D. During interview on 02/05/2020 at 10:22 am, the Technical Supervisor stated: 1. The laboratory had not participated in proficiency yet due to issues with obtaining samples commercially. 2. The laboratory anticipated a start date for the proficiency testing program to be no later than March 2020. 3. The laboratory had performed split sample testing with another laboratory but it was difficult to obtain positive samples for all organisms tested. 4. A written report had not been created for the split sample testing for the current calendar year. E. Review of split sample testing raw data for 01/31/2020 and 02/03/2020 confirmed that the only positive patient samples were for Trichophyton Rubrum (T. rubrum, a species of fungus) and Bacillus atrophaeus (a species of bacteria).