Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 32D2163600	**(X3) Date Survey Completed** 05/06/2019
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 New Mexico Department of Health completed a complaint survey on 05/06/19 for 42 CFR Part 493, Laboratory Requirements. Complaint Intake #NM00036877 was substantiated. The laboratory was found out of compliance with the following conditions: 42 CFR Part 493.801 Proficiency Testing Enrollment 42 CFR Part 493.1250 Analytic Systems 42 CFR Part 493.1441 Laboratory Director, High Complexity 42 CFR Part 493.1447 Technical Supervisor
D2000	ENROLLMENT AND TESTING OF SAMPLES CFR(s): 493.801 Each laboratory must enroll in a proficiency testing (PT) program that meets the criteria in subpart I of this part and is approved by HHS. The laboratory must enroll in an approved program or programs for each of the specialties and subspecialties for which it seeks certification. The laboratory must test the samples in the same manner as patients' specimens. For laboratories subject to 42 CFR part 493 published on March 14, 1990 (55 FR 9538) prior to September 1, 1992, the rules of this subpart are effective on September 1, 1992. For all other laboratories, the rules of this subpart are effective January 1, 1994. This CONDITION is not met as evidenced by: Based on review of 2019 patient test records, laboratory validation records, application for certification and e-mail, the laboratory failed to enroll in proficiency testing for all tests performed in the laboratory. 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 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 in nail samples. C. Review of available documents revealed no enrollment in

	proficiency testing or a written policy for proficiency testing for 2019. D. During interview on 05/01/19 at 01:13 pm, the Office Manager stated that she was not aware of any proficiency testing enrollment.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on the review of laboratory policies, validation records, and interviews with laboratory staff, the laboratory failed to have approved, written policies for 1) specimen preservation 2) specimen storage 3) conditions for specimen transportation. 5 patients (P1-P5) were reported on 04/22/19. Findings are: A. The laboratory failed to perform and document studies to establish protocols for the use of Copan eSwab transport media with the Applied Biosystems QuantStudio 12K and TaqMan assays. See D5423 1. The following patients were tested and results reported on 04/22/19. P1 Collected on 03/20/19 Received by the laboratory on 03/25/19, 5 days after collection. P2 Collected on 03/22/19 Received by the laboratory on 03/25/19, 3 days after collection. P3 Collected on 03/18/19 Received by the laboratory on 03/25/19, 7 days after collection. P4 Collected on 03/19/19 Received by the laboratory on 03/25/19, 6 days after collection. P5 Collected on 03/20/19 Received by the laboratory on 03/25 /19, 5 days after collection. 2. Review of the patient log revealed that the laboratory received 13 samples from 03/20/19 to 03/27/19 which were used for validation studies. At least 1 one of these patient samples, P1, was reported by the laboratory on 04/22/19. 3. Review of the validation records indicated that the validation studies started on 03/27/19 (7 days after collection of sample P1) and ended on 04/04/19. 3. During interview on 05/01/19 at 12:45 pm, the Office Manager stated that only 8 patients had been reported since the laboratory began testing but provided only 5 test reports for review. She further stated that all other patients were tested and the results held until the laboratory resolved technical issues. B. During a telephone interview on 05/01/19 at 10:31 am, the Technical Supervisor stated that sample transport container studies were done and summarized in the validation. C. Review of the undated "draft" validation summary "Summary Report for 'Nail Fungus' Microbiota TaqMan Assays on the Applied Biosystems QuantStudio 12K Flex Taqman Array Card(TAC) Platform revealed no reference to specimen preservation, storage or transportation requirement studies performed by the laboratory. a. Review of Section 2.2.2, "Specimen Collection, Processing and Storage Requirements" revealed the following: "Specimens will be collected via nail clippings. Sample collection and handling shall be performed per lab procedure, 'Specimen collection, handling, transport and submission'-SOP Reference." b. Section 2.2.3, "Specimen Rejection Criteria." revealed the following: "Laboratory procedures for collection of nail clippings were developed based on vendor-supplied extraction protocols. See laboratory procedure 'Specimen collection, handling, transport and submission'-SOP Reference." D. The laboratory failed to provide a copy of the laboratory's specimen collection and handling policy when it was requested by the surveyor on 05/01/19 at 9:15 am.

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: Based on observation, review of temperature records, laboratory policies, validation records, manufacturer instructions, calibration records and interview with laboratory staff, the laboratory failed to meet the Condition of Analytic Systems. 5 (P1-P5) patients were tested then reported on 04/22/19. Findings are: A. The laboratory failed to 1) establish criteria for specimen collection and handling and 2) validate the laboratory information system (LIS). See D5423 B. The laboratory failed to have an approved procedure manual available to testing personnel. See D5407 C. The laboratory failed to establish and follow policies for monitoring temperatures for the refrigerator, freezer and incubator used in the testing process. See D5413
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on the review of laboratory procedures, email, and interview with the Office Manager, the laboratory failed to have an approved procedure manual available to testing personnel. Findings are: A. Review of the following undated "draft" laboratory policies and procedures revealed no indication that the Laboratory Director had reviewed and approved the test procedures prior to beginning patient testing. 1. DNA Extraction, prepared by the current, temporary Testing Person on 09 Oct 18. 2. Quality Management Program, prepared by the previous laboratory consultant. 3. Laboratory Operations Manual, prepared by the Technical Supervisor in January 2019. The laboratory name was left blank. 4. Analytical Validation Plan for "Nail Fungus." B. During interview on 05/01/19 at 09:56 am, the Office Manager confirmed that the procedures had not been finalized. C. Review of an email sent by the Office Manager on 05/02/19 confirmed the Laboratory Director had not reviewed and approved the procedures prior to patient testing.
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 observation, review of temperature records, manufacturer instructions, calibration records and interview with laboratory staff, the laboratory failed to establish and follow policies for monitoring temperatures for the refrigerator, freezer and incubator used in the testing process. Findings are: A. Observation of the laboratory on 05/01/19 at 09:19 am revealed that the laboratory did not have a dedicated thermometer to monitor the room temperature. 1. During interview on 05/01 /19 at 9:19 am, the Office Manager confirmed the observation and further stated that the laboratory had not created temperature logs for recording the refrigerator and freezer temperatures. The Office Manager stated that the temperatures were recorded on a sheet of paper. B. Review of the manufacturer instructions for the use of the Applied Biosystems QuantStudio 12K Flex Real-Time instrument indicated: "Calibrate the QuantStudiio 12K Flex Real-Time PCR instrument at the same ambient temperature at which you will run experiments. Extreme variations in ambient temperature can affect the heating and cooling of the QuantStudio 12K Flex Real-Time PCR instrument, and in extreme cases, influence experimental results." C. Review of the calibration and temperature records indicated calibration was performed on 03/07/19 but the room temperature was not documented. D. Review of the manufacturer's instructions for the MagMax Viral Pathogen Ultra Total Nucleic Acid Extraction kit indicated that processed/prepared samples must be tested immediately, within 1-2 days if refrigerated, or frozen if not tested within 2 days. The instructions also indicated that the Enzyme mix must be frozen at -15 to -25 degrees Celsius. E. Review of the available temperature records indicated: 1. Freezer temperatures (the year is not documented on the record nor is the units of measurement) 5 of 10 days were unacceptable for the storage of the Enzyme mix. 04 /15 = -13.0 04/15 = -14.1 04/18 = -13.7 04/19 = -13.6 04/22 = -11.5 2. Refrigerator temperatures were documented 04/10 - 04/22 but there was no acceptable range on the log. 3. Incubator temperatures 04/16 - 04/18 but there was no acceptable range on the log. 4. There was no record of temperature monitoring on 05/01/19, the day of the survey.
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 the review of laboratory policies, manufacturer instructions, validation records, and interviews with the laboratory staff, the laboratory failed to 1) establish criteria for specimen collection and handling and 2) validate the laboratory

	information system (LIS). 5 (P1-P5) patients were tested then reported on 04/22/19. Findings are: A. The laboratory failed to establish policies for the specimen collection and handling of fungal specimens using Copan eSwab transport media. 1. Review of manufacturer instructions for the TaqMan reagents indicated "For Research Use Only. Not for use in diagnostic procedures." 2. The laboratory staff could not find a copy of the manufacturer's instructions for the Copan eSwab transport media but an electronic version (49E Rev.05 Date 2014.07) obtained by the surveyor on the Internet revealed: a. "Copan Liquid Amies Elution Swab (ESwab) Collection and Transport System is intended for the collection and transport of clinical specimens containing aerobes, anaerobes and fastidious bacteria from the collection site to the testing laboratory." b. " The use of this product in association with a rapid diagnostic kit or with diagnostic instrumentation should be previously validated by the user." c. There was no reference indicating that the transport media was suitable for the preservation of fungal species. 2. Review of the Ovation (Laboratory Information System) test files and the laboratory's validation records did not identify any studies performed using the laboratory's chosen specimen transport vial, Copan eSwab. 3. During a telephone interview on 05/01/19 at 10:31 am, the Technical Supervisor stated that sample transport container studies were done and summarized in the validation. 4. Review of the "Summary Report for 'Nail Fungus' Microbiota TaqMan Assays on the Applied Biosystems QuantStudio 12K Flex Taqman Array Card (TAC) Platform" a. Section 2.2.2, "Specimen Collection, Processing and Storage Requirements" revealed the following: "Specimens will be collected via nail clippings. Sample collection and handling shall be performed lab procedure, 'Specimen collection, handling, transport and submission'-SOP Reference." b. Section 2.2.3, "Specimen Rejection Criteria." revealed the following: "Laboratory procedures for collection of nail clippings were developed based on vendor-supplied extraction protocols. See laboratory procedure 'Specimen collection, handling, transport and submission'-SOP Reference." 5. Review of the undated "draft" validation summary "Summary Report for 'Nail Fungus' Microbiota TaqMan Assays on the Applied Biosystems QuantStudio 12K Flex Taqman Array Card(TAC) Platform revealed no reference to laboratory performed studies that established criteria for specimen acceptability such as stability over time, use of the transport media, and temperature requirements. 6. During interview on 05 /01/19 at 09:56 am, the Office Manager confirmed that the laboratory had not finalized the summaries and put the laboratory letterhead on the documents. 7. The following patients were reported on 04/22/19. P1 Collected on 03/20/19 Received by the laboratory on 03/25/19, 5 days after collection. P2 Collected on 03/22/19 Received by the laboratory on 03/25/19, 3 days after collection. P3 Collected on 03/18/19 Received by the laboratory on 03/25/19, 7 days after collection. P4 Collected on 03/19 /19 Received by the laboratory on 03/25/19, 6 days after collection. P5 Collected on 03 /20/19 Received by the laboratory on 03/25/19, 5 days after collection. B. The laboratory failed to validate the the Ovation LIS used to analyze and report patient results. 1. Review of test reports for 5 of 5 (P1-P5) patients revealed the reports had the incorrect laboratory name and address. See D5805 2. During interview on 0501/19 at 12:41 pm, the Office Manager stated that she was unaware of any validation studies performed with the LIS and the analyzer. She also stated that she would contact the manufacturer of the LIS for the studies. As of 05/06/19, the Office Manager had not provided documentation of LIS validation studies.
D5805	TEST REPORT CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and

	identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on the review of patient test reports and interview with the Office Manager, the laboratory failed to ensure test reports included the name and address of the laboratory and the test methodology used by the laboratory. Findings are: A. Review of patient test reports revealed 5 of 5 (P1-P5) patient reports and a sample printout that had the name, address, laboratory director, and CLIA number of a laboratory located in California. B. During interview on 05/01/19 at 12:41 pm, the Office Manager stated that she had not noticed the error on the reports. She also confirmed that the report printouts were the same as what was available to the providers. C. Review of the same 5 patient reports indicated that a different methodology, Luminex xMAP multiplex technology, was used to perform patient testing. The laboratory used the Applied Biosystems QuantStudio 12K Flex Taqman Array Platform.
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 the review of laboratory policies, personnel records, email, test reports, validation records, and interviews with the laboratory staff, the Laboratory Director failed to provide overall management and direction of the laboratory. The laboratory reported performing 8 patients tests in April 2019. Findings are: A. The Laboratory Director failed to ensure that establishment studies and validation procedures were completed prior to patient testing. See D6086 B. The Laboratory Director failed to ensure that the laboratory was enrolled in a CLIA approved proficiency testing program. See D6088 C. The Laboratory Director failed to approve the procedure manual prior to patient testing. See D6106 D. The Laboratory Director failed to ensure that testing personnel had the appropriate education and training prior to patient testing. See D6102 E. The Laboratory Director failed to specify, in writing, the duties and responsibilities for all laboratory personnel. See D6107
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 the review of laboratory policies, email, test reports, validation records, and

	interviews with the laboratory staff, the laboratory director failed to ensure that establishment studies and validation procedures were completed prior to patient testing. The laboratory reported performing 8 patients tests. Findings are: A. The laboratory failed to establish specimen collection and handling of fungal specimens using Copan eSwab transport media. See D5243 A B. The laboratory failed to validate the laboratory information system (LIS). See S5243 B and D5805
D6088	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(4) The laboratory director must ensure that the laboratory is enrolled in an HHS-approved proficiency testing program for the testing performed. This STANDARD is not met as evidenced by: Based on the review of laboratory policies, and email from the Office Manager, the Laboratory Director failed to ensure that the laboratory was enrolled in a CLIA approved proficiency testing program. Findings are: A. Reveiw of the laboratory's policies revealed no policy or record of enrollment in proficiency testing for fungal testing. See D2000 B. Review of an email dated 05/08/19 from the Office Manager confirmed the laboratory did not have an approved proficiency testing policy.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by: Based on interviews with laboratory staff, the Laboratory Director failed to ensure that testing personnel had the appropriate education and training prior to patient testing. Findings are: A. During interview on 05/01/19 at 09:50 am, the Office Manager stated that she did not have a copy of a diploma or transcript for the current, temporary testing person. The Testing Person showed the surveyor a copy of his Bachelor of Science degree earned in 2015 as a file on his cell phone. B. During interview on 05/01/19 at 09:45 am, the Testing Person stated that he did not get any training at this laboratory other than with the Laboratory Information System. He also stated that he had previous experience with similar instrumentation.
D6106	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(14) The laboratory director must ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process. This STANDARD is not met as evidenced by: Based on the review of laboratory procedures, email, and interview with the Office Manager, the Laboratory Director failed to approve the procedure manual prior to

	patient testing. Findings are: Review of the following undated "draft" laboratory policies and procedures revealed no indication that the Laboratory Director had reviewed and approved the test procedures prior to beginning patient testing. 1. DNA Extraction, prepared by the current, temporary Testing Person on 09 Oct 18. 2. Quality Management Program, prepared by the previous laboratory consultant. 3. Laboratory Operations Manual, prepared by the Technical Supervisor in January 2019. The laboratory name was left blank. 4. Analytical Validation Plan for "Nail Fungus." See D5407
D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on the review of personnel records and email from the Office Manager, the Laboratory Director failed to specify, in writing, the duties and responsibilities for all laboratory personnel. Findings are: A. The laboratory did not have job descriptions available for all staff on 05/01/19, the day of the survey. B. The Office Manager provided a copy of the Medical Laboratory Technologist job description on the afternoon of 05/01/19 but it was not dated or signed by the laboratory director. C. The Office Manager sent job descriptions for the General Supervisor, Laboratory Technologist, and Technical Supervisor via email on 05/06/19 at 02/25 pm but they were not signed by the Laboratory Director.
D6108	LABORATORY TECHNICAL SUPERVISOR CFR(s): 493.1447 The laboratory must have a technical supervisor who meets the qualification requirements of 493.1449 of this subpart and provides technical supervision in accordance with 493.1451 of this subpart. This CONDITION is not met as evidenced by: Based on the review of laboratory policies, laboratory policies, email, test reports, validation records, and interviews with the laboratory staff, the Technical Supervisor failed to provide technical oversight of the laboratory. Findings are: A. The Technical Supervisor failed to ensure that the laboratory was enrolled in a CLIA approved proficiency testing program. See D6116 B. The Technical Supervisor failed to ensure that all establishment and validation studies were completed prior to patient testing. See D6115
D6115	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(2) The technical supervisor is responsible for verification of the test procedures

	performed and establishment of the laboratory's test performance characteristics, including the precision and accuracy of each test and test system. This STANDARD is not met as evidenced by: Based on the review of laboratory policies, email, test reports, validation records, and interviews with the laboratory staff, the Technical Supervisor failed to ensure that all establishment and validation studies were completed prior to patient testing. The laboratory reported testing 8 patients in April 2019. Findings are: The Technical Supervisor failed to ensure that establishment studies and validation procedures were completed prior to patient testing. A. The laboratory failed to establish specimen collection and handling of fungal specimens using Copan eSwab transport media. See D5243 A B. The laboratory failed to validate the laboratory information system (LIS). See S5243 B and D5805
D6116	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(3) The technical supervisor is responsible for enrollment and participation in an HHS approved proficiency testing program commensurate with the services offered. This STANDARD is not met as evidenced by: Based on the review of laboratory policies, and email from the Office Manager, the Technical Supervisor failed to ensure that the laboratory was enrolled in a CLIA approved proficiency testing program. Findings are: A. Review of the undated "draft" laboratory's policies revealed no policy or record of enrollment in proficiency testing for fungal testing. See D2000 B. Review of an email dated 05/08/19 from the Office Manager indicated the laboratory did not currently have an approved proficiency testing policy.