Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	32D2163600	12/20/2022
Name of Provider or Supplier	**Street Address, City, State**	
New Mexico Foot & Ankle Institute	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 standard deficiences were cited as the results of a recertification survey on 12/20/2022. This facility was found NOT to be in compliance with the CLIA regulations found at 42 CFR for the specialties/subspecialties in which it was surveyed.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(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 qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory policies and procedures for the Quant Studio 12K Flex Real Time PCR System (PCR test system used for testing nail, wound and respiratory samples for fungal or microbial growth), laboratory quality control (QC) records for 2021 and 2022, and confirmed in an interview with the technical supervisor, the laboratory failed to perform a positive and negative external quality control with each day of patient testing for 54 out of 78 batches/runs for 7 of 12 months in 2021 and 35 out of 63 batches/runs for 5 of 11 months in 2022. Findings included: 1. Review of the laboratory's procedure titled "SOP 11 - DNA Based Pathogen Testing", section labeled "Quality Control Logs", stated: "External and internal QC are run each day of testing." Section labeled "External Controls" stated: "Every extraction plate has a No Template Control (NTC), or Negative Control. Negative controls must pass for the extraction plate to be valid. If a negative control fails, the corresponding extraction plate must be re-extracted .... Every amplification plate has a Positive Control, which contains RNA for every target, resulting in a positive amplification for every target.

	The positive control must pass for the amplification on the plate to be valid. If the positive control fails, then only amplification needs to be repeated (assuming the negative controls from the extraction plates are acceptable)." 2. Review of the laboratory's policy "Calibration and Quality Control", signed by the laboratory director on 03/13/2021, under section titled "Routine QC Procedures" stated: "A. Whenever possible, commercially available controls are selected for use in assessing the assays performed in the laboratory. Control values must address both the normal and abnormal range, or positive or negative values for the assay. These control materials are assayed in the same manner as patient samples." ... Section E., titled "Control Frequency" stated: "2. Run appropriate controls with each run associated with testing." 3. Review of the laboratory's quality control logs titled "QC Log - Daily /Weekly, Monthly Reviews" for 7 of 12 months in 2021 and 5 of 11 months in 2022 showed that external quality control was not performed or was missing the Positive control for 54 out of 78 batches/runs in 2021, and 35 out of 63 batches/runs in 2022. A random review of the laboratory's quality control logs, in which the laboratory tested nail samples for fungal growth, for 2021 & 2022 revealed the following: QC log for the month of November 2021 (11-01-21 to 11-30-21) Batch# Date Neg QC Pos QC 498495 11-05-2021 Passed Not performed 507095 11-11-2021 Passed Not performed 507144 11-12-2021 Not performed Not performed 512852 11-17-2021 Passed Not performed 517436 11-19-2021 Passed Not performed 517506 11-19-2021 Not performed Not performed 521480 11-23-2021 Passed Not performed 522081 11-24-2021 Passed Not performed 523819 11-24-2021 Not performed Not performed QC log for the month of July 2022 (7-18-22 to 7-29-22) Batch Date Neg QC Pos QC 835587 7-22-2022 Passed Not performed 838098 7-25-2022 Passed Not performed 838681 7-26-2022 Passed Not performed 838927 7-26-2022 Passed Not performed 840458 7-27-2022 Passed Not performed 841665 7-28-2022 Not performed Not performed 841938 7-28-2022 Passed Not performed 841555 7-28-2022 Not performed Not performed 842142 7-28-2022 Passed Not performed 843116 7-29-2022 Passed Not performed 843332 7-29-2022 Passed Not performed 843555 7-29-2022 Not performed Not performed 4. In an interview on 12/20/2022 at 2:26 pm the technical supervisor confirmed the above findings. Word Key: RNA = Ribonucleic Acid SOP = Standard Operating Procedure PCR = Polymerase Chain Reaction
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on review of the manufacturer's user guide, laboratory policy, laboratory's environmental & maintenance records for 2021 and 2022, and confirmed in an interview with the technical supervisor, the laboratory failed to document corrective actions when humidity was outside of their defined range for 54 out of 81 days in 2021 and 11 out of 22 days in 2022 for the QuantStudio 12K Flex Real-Time PCR

	instrument. Findings included: 1. Review of the QuantStudio 12K Flex Real-Time PCR System User Guide revealed a humidity requirement of 20 - 80%. 2. Review of the laboratory's Policy titled "General Laboratory Maintenance", signed by the laboratory director on 03/13/2021, stated: "When determining acceptable room temperature and humidity, consult each user guide for all equipment and instruments used." 3. A Random review of the laboratory's environmental & maintenance records titled; "Daily/Weekly/Monthly Maintenance" for 2021 (September through December) & 2022 (October through November) showed the laboratory failed to meet the required humidity requirements of 20% - 80% for 54 out of 81 days in 2021 and 11 out of 22 days in 2022. A random review of the laboratory's environmental & maintenance logs revealed the following without documentation of corrective actions when humidity was outside of the defined range: 09/17/2021 = humidity recorded as 17% 09/21/2021 = humidity recorded as 17% 09/23/2021 = humidity recorded as 17% 10/11/2021 = humidity recorded as 12% 10/12/2021 = humidity recorded as 17% 10 /13/2021 = humidity recorded as 12% 10/14/2021 = humidity recorded as 11% 10/15 /2021 = humidity recorded as 10% 10/19/2021 = humidity recorded as 17% 10/20 /2021 = humidity recorded as 12% 10/21/2021 = humidity recorded as 10% 10/22 /2021 = humidity recorded as 10% 10/25/2021 = humidity recorded as 16% 10/26 /2021 = humidity recorded as 12% 10/27/2021 = humidity recorded as 10% 10/28 /2021 = humidity recorded as 12% 10/29/2021 = humidity recorded as 12% 11/01 /2021 = humidity recorded as 16% 11/02/2021 = humidity recorded as 16% 11/03 /2021 = humidity recorded as 12% 11/04/2021 = humidity recorded as 15% 11/05 /2021 = humidity recorded as 15% 11/08/2021 = humidity recorded as 10% 11/09 /2021 = humidity recorded as 10% 11/10/2021 = humidity recorded as 12% 11/11 /2021 = humidity recorded as 10% 11/12/2021 = humidity recorded as 10% 11/15 /2021 = humidity recorded as 10% 11/16/2021 = humidity recorded as 10% 11/17 /2021 = humidity recorded as 10% 11/18/2021 = humidity recorded as 10% 11/19 /2021 = humidity recorded as 10% 11/22/2021 = humidity recorded as 10% 11/23 /2021 = humidity recorded as 10% 11/29/2021 = humidity recorded as 10% 11/30 /2021 = humidity recorded as 10% 12/01/2021 = humidity recorded as 10% 12/02 /2021 = humidity recorded as 10% 12/03/2021 = humidity recorded as 10% 12/06 /2021 = humidity recorded as 10% 12/07/2021 = humidity recorded as 12% 12/08 /2021 = humidity recorded as 12% 12/09/2021 = humidity recorded as 10% 12/10 /2021 = humidity recorded as 10% 12/13/2021 = humidity recorded as 10% 12/14 /2021 = humidity recorded as 10% 12/15/2021 = humidity recorded as 10% 12/16 /2021 = humidity recorded as 10% 12/20/2021 = humidity recorded as 10% 12/21 /2021 = humidity recorded as 10% 12/22/2021 = humidity recorded as 10% 12/27 /2021 = humidity recorded as 10% 12/28/2021 = humidity recorded as 10% 12/29 /2021 = humidity recorded as 12% 10/26/2022 = humidity recorded as 15% 10/28 /2022 = humidity recorded as 15% 10/31/2022 = humidity recorded as 16% 11/01 /2022 = humidity recorded as 17% 11/02/2022 = humidity recorded as 15% 11/16 /2022 = humidity recorded as 10% 11/17/2022 = humidity recorded as 10% 11/18 /2022 = humidity recorded as 10% 11/21/2022 = humidity recorded as 10% 11/22 /2022 = humidity recorded as 10% 11/28/2022 = humidity recorded as 10% 4. During an interview on 12/20/2022 at 2:56 pm the technical supervisor confirmed the above findings. Word Key: PCR = Polymerase Chain Reaction