Department of Health & Human Services
Centers for Medicare & Medicaid Services

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Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2094070	(X3) Date Survey Completed 03/01/2019
Name of Provider or Supplier Foot & Ankle Specialists Of The Mid Atlantic, Llc	**Street Address, City, State** 1600 E Gude Drive, Suite 205, Rockville, MD	
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 the "FASMA Molecular NGS Assay Blind Sample Policy" and interview with the technical supervisor, the laboratory's written procedure did not define how many samples would be sent for culture comparison, and did not define acceptable limits of the comparison and remedial actions to be taken when results are not within acceptable limits. Findings: During the exit interview on 03/01/19 at 11:00 AM the technical supervisor confirmed that the "FASMA Molecular NGS Assay Blind Sample Policy" did not include how many samples would be sent for culture comparison, and did not define acceptable limits of the comparison and remedial actions to be taken when results are not within acceptable limits.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or

	control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual for deoxyribonucleic acid (DNA) sequencing testing after the exit of 03/01/19, the laboratory's procedure manual did not include written instructions for labeling the "Collection Tubes." Findings: 1. Review of the "Section 5. DNA Sequencing 1. Wound DNA Extraction" procedure showed that step "6." states: "Label the Collection Tubes properly." The procedure does not define exactly what should be written on the "Collection Tubes." 2. The procedure "Section 5. DNA Sequencing" includes additional sections labeled "2. Quantification of DNA by Qubit Assay", "3. IonExpress Library Prep", and "4. Ion Chef and ISS XL." There procedures do not clearly define how to label the specimen through each step in the process.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on review of the computer records, worksheets and interview with the testing person, the laboratory's record system did not include the identity of the testing person who performed each of the different steps in the deoxyribonucleic acid (DNA) sequencing testing. Findings: 1. Review of the laboratory computer records and worksheets on 02/04/19 showed that there were no initials of the testing personnel listed. 2. The testing person explained that each of the four steps in the DNA sequencing testing could be performed by the same person or one of three different testing personnel. The laboratory records did not differentiate between the three testing personnel listed on the "Laboratory Personnel Report (CLIA) (CMS-209). 3. During the exit interview on 03/01/19 at 11:00 AM the technical supervisor confirmed that the laboratory records did not include the initials of the testing person who performed each step in the testing process.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

	This STANDARD is not met as evidenced by: Based on review of the policy and procedure manual and interview with the technical supervisor, the laboratory director did not ensure that a quality assessment (QA) plan was established to maintain the quality of the laboratory services, identify failures as the occur and implement corrective actions as needed. Findings: 1. Review of the policy and procedure manual showed that there was no written QA program to monitor patient test management, testing methods, quality control, proficiency testing, comparison of test results, relationship of patient information to patient test results, personnel assessment, communication, complaint investigation and quality assessment reviews. 2. During the exit interview on 03/01/19 at 11:00 AM the technical supervisor confirmed that the laboratory did not have a written QA program to monitor quality of the laboratory services.