Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2210494	09/29/2023
Name of Provider or Supplier	**Street Address, City, State**	
Foot Health Center, Llc	3106 Houma Blvd, Metairie, LA	

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	A Certification survey was performed at Foot Health Center, LLC, CLIA ID # 19D2210494, on September 28, 2023 through September 29, 2023. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard deficiencies were cited.
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 policies, procedures, and interview with personnel, the laboratory failed to establish complete policies for Bacteriology testing. Findings: 1. Review of the laboratory's policies and procedures revealed the

	laboratory did not include the following: a) Quality control procedures for culture media to include, but not limited to, sterility, ability to support growth, visual inspections, and frequency of performance b) Defined frequency of Quality control performance for colony counts, spot indole, Staphaurex and catalase test c) Quality control procedures for culture identification and antimicrobial susceptibility testing (AST) on the Sensititre instrument, to include, but not limited to corrective actions for results outside of acceptable limits d) Culture identification and AST on the Sensititre instrument to include written procedures for manual reads of plates, to include, but not limited to, criteria and limitations of performance e) Detailed written procedure for purity checks, including, but not limited to frequency of performance and acceptability criteria f) Quality control acceptability criteria for wound and nail panel testing on the Quant Studio 12 K g) Interpretation of results for antimicrobial susceptibility testing (AST) on the Sensititre instrument 2. In interview on September 28. 2023 at 12:03 pm, the Compliance personnel confirmed the laboratory did not include the identified procedures.
D5477	CONTROL PROCEDURES CFR(s): 493.1256(e)(4)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e)(4) Before, or concurrent with the initial use-- (e)(4)(i) Check each batch of media for sterility if sterility is required for testing; (e)(4)(ii) Check each batch of media for its ability to support growth and, as appropriate, select or inhibit specific organisms or produce a biochemical response; and (e)(4)(iii) Document the physical characteristics of the media when compromised and report any deterioration in the media to the manufacturer. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on observation by surveyor, review of the laboratory's policies, records, and interview with personnel, the laboratory failed to document visual inspections of media used for Bacteriology testing. Findings: 1. Observation by surveyor during the laboratory tour on September 28, 2023 at 9:50 am revealed the laboratory utilizes the following media for Bacteriology testing: Blood Agar (TSA with 5% Sheep Blood), Spectra UTI, and Mueller-Hinton broth. 2. Review of the laboratory's policies revealed the laboratory did not have a written policy for quality control procedures for media. 3. Review of the laboratory's media logs revealed the laboratory did not document the visual inspection of new lots/shipments of media. 4. In interview on September 29, 2023 at 9:21 am, the Testing Personnel stated she performs visual inspections as part of the sterility checks on new lots of media. The Testing Personnel confirmed the laboratory did not have a written policy or documentation that visual inspections were performed on the identified media.
D5481	CONTROL PROCEDURES CFR(s): 493.1256(f)(g) (f) Results of control materials must meet the laboratory's and, as applicable, the manufacturer's test system criteria for acceptability before reporting patient test results. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedures, records, and interview with personnel,

	the laboratory failed to document performance of purity checks for Bacteriology testing. Findings: 1. Review of the laboratory's control procedures under the "Purity Check" section revealed "For each testing isolate, streak 1 uL from the positive control well or remaining broth directly on to a blood agar plate and incubate over night." 2. In interview on September 28, 2023 at 11:00 am, the Testing Personnel stated purity checks are performed every time a culture is set-up. 3. Review of random selection of patient test records revealed the laboratory did not document performance of purity checks. 4. In further interview on September 29, 2023 at 3:48 pm, the Testing Personnel stated the purity checks are not documented. The Testing Personnel stated approximately 20-25 patients have had culture identification testing since patient testing began in August 2023.
D5793	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c) (b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assurance (QA) policies, quality assurance records, and interview with personnel, the laboratory failed to ensure assessment activities were performed for one (1) of five (5) months reviewed in 2022. Findings: 1. Review of the laboratory's "Quality Assurance and Performance Verification" policy revealed the following monthly monitors: "Reagent Integrity, Maintenance, Calibration/Calibration Verification, Quality Control, Waived Testing, QC Review. 2. Review of random selection of the laboratory's 2022 QA records for five (5) months revealed the laboratory did not perform a monthly QA assessment for December 2022. 3. In interview on September 28, 2023 at 10:56 am, the Compliance personnel stated the laboratory did not perform patient testing December 24, 2022 through January 16, 2023 due to change in personnel. The Compliance personnel confirmed the laboratory did not have documentation of the performance of monthly QA for the dates in December 2022 that included testing.
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 review of the laboratory's test menu, records, manufacturer's guide, patient final test reports, and interview with personnel, the laboratory failed to include

	interpretation of the results for antimicrobial susceptibility testing. Findings: 1. Review of the laboratory's test menu revealed the laboratory performs antimicrobial susceptibility testing on the Thermo Scientific Sensititre instrument. 2. Review of the laboratory's validation and procedures revealed the laboratory did not include interpretation of results. 3. Review of random selection of patient final test reports revealed the laboratory reports "S, NI, or R" next to the antibiotics. 4. Review of the manufacturer's guide, laboratory's procedures, and patient test reports revealed "NI" was not defined. 5. In interview on September 28, 2023 at 1:02 pm, the Compliance personnel stated "NI" stood for no interpretation; however on September 28, 2023 at 2: 38 pm, the Compliance personnel stated "NI" stood for not indicated. 6. In interview on September 28, 2023 at 3:10 pm, the Compliance personnel confirmed the laboratory's procedures and patient reports did not include interpretation of results for antimicrobial susceptibility testing.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 record review and interview with personnel, the Laboratory Director failed to ensure that a quality control program was established to assure the quality of laboratory testing. 1. The laboratory failed to document visual inspections of media used for Bacteriology testing. Refer to D5477. 2. The laboratory failed to document performance of purity checks for Bacteriology testing. Refer to D5481.
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 record review and interview with personnel, the Laboratory Director failed to ensure that a quality assessment (QA) program was maintained to assure the quality of laboratory services provided. Refer to D5793.
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 record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel. Refer to D5403.

D8103	BASIC INSPECTION REQUIREMENTS CFR(s): 493.1773(b)(c)(d) (b) General Requirements. As part of the inspection process, CMS or a CMS agent may require the laboratory to do the following: (b)(1) Test samples, including proficiency testing samples, or perform procedures. (b)(2) Permit interviews of all personnel concerning the laboratory's compliance with the applicable requirements of this part. (b)(3) Permit laboratory personnel to be observed performing all phases of the total testing process preanalytic, analytic, and postanalytic). (b)(4) Permit CMS or a CMS agent access to all areas encompassed under the certificate including, but not limited to, the following: (b)(4)(i) Specimen procurement and processing areas. (b)(4)(ii) Storage facilities for specimens, reagents, supplies, records, and reports. (b)(4)(iii) Testing and reporting areas. (b)(5) Provide CMS or a CMS agent with copies or exact duplicates of all records and data it requires. (c) Accessible records and data. A laboratory must have all records and data accessible and retrievable within a reasonable time frame during the course of the inspection. (d) Requirement to provide information and data. A laboratory must provide, upon request, all information and data needed by CMS or a CMS agent to make a determination of the laboratory's compliance with the applicable requirements of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory's records and interview with personnel, the laboratory failed to have the raw data for Bacteriology specimen stability studies accessible at the time of the survey. Findings: 1. Review of the laboratory's test menu revealed the laboratory performs Bacteriology and Mycology testing. 2. Review of the laboratory's records revealed the laboratory had a summary document titled "COPAN eSwab Transport System Stability Validation;" however the laboratory did not have the raw data for the stability study. 3. The surveyor requested the raw data for the specimen stability study on September 28, 2023 at 12:37 pm, September 29, 2023 at 9:00 am, and September 29, 2023 at 10:25 am. 4. In interview on September 28, 2023 at 12:37 pm, the Compliance personnel stated the files would have to be requested from personnel located in Indiana. 5. In interview on September 29, 2023 at 9:00 am, the Compliance personnel stated she would need to reach out to the personnel located in Indiana again to have the files added to the laboratory's drop box; however he was in meetings. 6. In interview on September 29, 2023 at 10:47 am, the Compliance personnel confirmed the laboratory did not have the raw data associated with the specimen stability studies accessible at the time of the survey.