Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	19D2210494	03/23/2026
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 Recertification survey was performed at Foot Health Center, LLC, CLIA ID 19D0464754, on March 23, 2026. Foot Health Center, LLC was found not in compliance with the following CONDITION LEVEL DEFICIENCIES: 42 CFR 493.1250: CONDITION: Analytic systems 42 CFR 493.1441: CONDITION: Laboratories performing high complexity testing; Laboratory Director 42 CFR 493.1447: CONDITION: Laboratories performing high complexity testing; Technical Supervisor
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, record review, and interview with personnel, the laboratory failed to ensure quality of testing within the analytic systems. Findings: 1. The laboratory failed to have complete performance specification verification studies following the laboratory's relocation per the laboratory's policies. Refer to D5423. 2. The laboratory failed to perform corrective actions when the positive control for the nail panel was unacceptable for Mycology testing for one (1) of five (5) random dates reviewed. Refer to D5783.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2)

	(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: (b)(2)(i) Accuracy. (b)(2)(ii) Precision. (b)(2)(iii) Analytical sensitivity. (b)(2)(iv) Analytical specificity to include interfering substances. (b)(2)(v) Reportable range of test results for the test system. (b)(2)(vi) Reference intervals (normal values). (b)(2)(vii) Any other performance characteristic required for test performance. This STANDARD is not met as evidenced by: Based on observation, review of the laboratory's policies, performance verification studies, and interview with personnel, the laboratory failed to have complete performance specification verification studies following the laboratory's relocation per the laboratory's policies. Findings: 1. Observation on March 23, 2026 at 9:52 am revealed the laboratory utilizes the QuantStudio 12 K Flex for nail and wound panel testing. 2. In interview on March 23, 2026 at 10:21 am, the Testing Personnel stated the laboratory relocated to a different address in October 2024. The Testing Personnel further stated following the relocation preventative maintenance was performed on the instrument and previously analyzed patient samples were tested. 3. Review of the laboratory's "Correlation Report-Laboratory Relocation" policy revealed "All equipment was powered down, transported according to manufacturer guidelines, and reinstalled in the new facility. Environmental conditions (temperature, humidity, electrical supply) were verified prior to instrument startup. Correlation testing was performed to compare pre-move and post-move instrument performance using the following methods: Pre-Move Baseline: Historical quality control (QC) data were collected for each instrument, Calibration records and maintenance logs were reviewed, acceptable performance ranges were established based on manufacturer specifications and internal QC standards. Post- Move Verification: Instruments were recalibrated where required, QC samples (normal, abnormal, and control standards) were run in replicate, and results were compared against pre-move baseline data. Acceptance Criteria: Results must fall within established QC ranges, variance between pre- and post-move results must not exceed +/- 10% (or lab-defined acceptable limits) and no systematic bias or drift should be observed. Results Summary: All instruments were successfully reinstalled and calibrated. QC results were within acceptable limits. No significant deviations or performance issues were identified." The Laboratory Director approved the study November 1, 2024. 4. Review of the laboratory's relocation performance specification verification records revealed the laboratory only included the post-move raw data. The post-move data for the nail panel included four (4) patients, two (2) previously analyzed proficiency samples, and positive/negative controls. The post-move data for the wound panel included two (2) patients, four (4) previously analyzed proficiency samples, and positive/negative controls. The laboratory did not include the pre-move raw data, results from the previously analyzed patients and comparison of the pre- and post-move results. 5. In interview on March 23, 2026 at 1:40 pm, the Testing Personnel confirmed the laboratory did not have complete performance specification verification studies following their relocation.
D5783	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(2)

	(b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results. This STANDARD is not met as evidenced by: Based on observation, review of policies, instrument data, and interview with personnel, the laboratory failed to perform corrective actions when the positive control for the nail panel was unacceptable for Mycology testing for one (1) of five (5) random dates reviewed. Findings: 1. Observation on March 23, 2026 at 9:52 am revealed the laboratory utilizes the QuantStudio 12 K Flex for nail and wound panel testing. 2. Review of the laboratory's "Reviewing Results and Acceptance of Data" policy revealed "Positive Amplification Control: All targets must have a CRT value below 35, an Amplification Score above 1.2 (or validated Amp Score Threshold), and a Cq Confidence Score above 0.8 9 or validated Cq Conf Score Threshold). If Amplification Control fails, the entire run must be re-amplified." 3. Review of the raw instrument data for the nail panel run from July 25, 2024 revealed the positive control was unacceptable for the following fungi: A. strictum (Undetermined), A. fumigatus (35.284, 35.111), A. versicolor (35.802, 35.675), C. krusei (35.269), E. floccosum (Undetermined), M. audouinii (35.221), M. gypseum (35.285, 35.395), T. rubrum (35.741, Undetermined), T. violaceum (35.817, 35.617), Trichospor64542 (35.417), A. niger (35.345), C. tropicalis (35.150), S. scabiei (Undetermined, 35.414), T. soudanense (Undetermined) , and T. tonsurans (Undetermined). The samples were tested in replicate. 4. Further review of the raw instrument data for the nail panel run from July 25, 2024 revealed six (6) patients had results reported. 5. In interview on March 23, 3026 at 2:00 pm, the Testing Personnel stated the amp and confidence scores are also reviewed and any questionable results are deferred to the scientific specialist. The Testing Personnel confirmed corrective actions were not performed for the identified unacceptable positive control.
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 observation, record review, and interview with personnel, the Laboratory Director failed to provide overall management and direction for the laboratory. Findings: 1. The Laboratory Director failed to ensure performance specification studies were complete. Refer to D6086. 2. The Laboratory Director failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D6096. 3. The Laboratory Director failed to ensure one (1) of two (2) Technical Supervisors had the appropriate state of Louisiana license. Refer to D6102.
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii)

	(e)(3)(ii) Verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method; and This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure performance specification studies were complete. Refer to D5423.
D6096	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(7) (e)(7) Ensure that all necessary remedial actions are taken and documented whenever significant deviations from the laboratorys established performance characteristics are identified, and This STANDARD is not met as evidenced by: Based on observation, record review, and interview with personnel, the Laboratory Director failed to ensure corrective actions were taken and documented when deviations from the laboratory's policies occurred. Refer to D5783.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) 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 review of personnel record and interview with personnel, the Laboratory Director failed to ensure one (1) of two (2) Technical Supervisors had the appropriate state of Louisiana license. Refer to D6111.
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 record review and interview with personnel, the Technical Supervisor failed to provide technical oversight for high complexity testing. Refer to D61111.
D6111	TECHNICAL SUPERVISOR QUALIFICATIONS CFR(s): 493.1449 (a) The technical supervisor must possess a current license issued by the State in

which the laboratory is located, if such licensing is required; and (b) The laboratory may perform anatomic and clinical laboratory procedures and tests in all specialties and subspecialties of services except histocompatibility and clinical cytogenetics services provided the individual functioning as the technical supervisor-- (b)(1) Is a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (b)(2) Is certified in both anatomic and clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology. (c) Bacteriology, Mycobacteriology, Mycology, Parasitology or Virology- If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of bacteriology, mycobacteriology, mycology, parasitology, or virology, the individual functioning as the technical supervisor must- (c)(1)(i) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (c)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (c)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (c)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable microbiology subspecialty; or (c)(3)(i)(A) Have an earned doctoral degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (c)(3)(i)(B) Meet the requirements in 493.1443(b)(3)(i)(B); and(c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months experience in high complexity testing within the subspecialty of bacteriology; or (c)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable subspecialty; or (c)(4)(i)(A) Have earned a master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (c)(4)(i)(B)(1) Meet bachelor's degree equivalency; and (c)(4)(i)(B)(2) Have at least 16 semester hours of additional graduate level coursework in chemical, biological, clinical or medical laboratory science, or medical technology; or (c)(4)(i)(C)(1) Meet bachelor's degree equivalency; and (c)(4)(i)(C)(2) Have at least 16 semester hours in a combination of graduate level coursework in biology, chemistry, medical technology, or clinical or medical laboratory science coursework and an approved thesis or research project related to laboratory testing for the diagnosis, prevention, or treatment of any disease or impairment of, or the assessment of the health of, human beings; and (c)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable subspecialty; or (c)(5)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (c)(5)(i)(B) Have at least 120 semester hours, or equivalent, from an accredited institution that, at a minimum, includes either- (c)(5)(i)(B)(1) 48 semester hours of medical laboratory technology courses; or (c)(5)(i)(B)(2) 48 semester hours of science courses that include- (c)(5)(i)(B)(2)(i) 12 semester hours of chemistry, which must include general chemistry and biochemistry or organic chemistry; (c)(5)(i)(B)(2)(ii) 12 semester hours of biology, which must include general biology and molecular biology, cell biology or genetics; and (c)(5)(i)(B)(2)(iii) 24 semester hours of chemistry, biology, or medical laboratory science or technology in any combination; and (c)(5)(ii) Have at least 4 years of laboratory training or experience,

or both, in high complexity testing within the specialty of microbiology with a minimum of 6 months of experience in high complexity testing within the applicable subspecialty. (d) Diagnostic Immunology, Chemistry, Hematology, Radiobioassay, or Immunohematology - If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the specialty of diagnostic immunology, chemistry, hematology, radiobioassay, or immunohematology, the individual functioning as the technical supervisor must- (d)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (d)(1)(ii) Be certified in clinical pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (d)(2)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (d)(2)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing for the applicable specialty; or (d)(3)(i)(A) Have an earned doctoral degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (d)(3)(i)(B) Meet the education requirement at 493.1443(b)(3)(i)(B); and (d)(3)(ii) Have at least 1 year of laboratory training or experience, or both, in high complexity testing within the applicable specialty; or (d)(4)(i)(A) Have earned a master's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (d)(4)(i)(B) Meet the education requirement at paragraphs (c)(4)(i)(B) or (C) of this section; and (d)(4)(ii) Have at least 2 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty; or (d)(5)(i)(A) Have earned a bachelor's degree in a chemical, biological, clinical or medical laboratory science, or medical technology from an accredited institution; or (d)(5)(i)(B) Meet the education requirement at paragraph (c)(5)(i)(B) of this section; and (d)(5)(ii) Have at least 4 years of laboratory training or experience, or both, in high complexity testing for the applicable specialty. (e) Cytology- If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of cytology, the individual functioning as the technical supervisor must- (e)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (e)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (e)(2) An individual qualified under paragraph (b) or (e)(1) of this section may delegate some of the cytology technical supervisor responsibilities to an individual who is in the final year of full-time training leading to certification specified in paragraph (b) or (e)(1)(ii) of this section provided the technical supervisor qualified under paragraph (b) or (e)(1) of this section remains ultimately responsible for ensuring that all of the responsibilities of the cytology technical supervisor are met. (f) Histopathology - If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of histopathology, the individual functioning as the technical supervisor must- (f)(1) Meet one of the following requirements: (f)(1)(i)(A) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (f)(1)(i)(B) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (f)(1)(ii) An individual qualified under paragraph (b) or (f)(1) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (f)(1)(i)(B) of this section, the responsibility for examination and interpretation of histopathology specimens. (f)(2) For tests in dermatopathology, meet one of the following requirements: (f)(2)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (f)

(2)(i)(B) Meet one of the following requirements: (f)(2)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (f)(2)(i)(B)(2) Be certified in dermatopathology by the American Board of Dermatology and the American Board of Pathology; or (f)(2)(i)(B)(3) Be certified in dermatology by the American Board of Dermatology; or (f)(2)(ii) An individual qualified under paragraph (b) or (f)(2)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (f)(2)(i)(B) of this section, the responsibility for examination and interpretation of dermatopathology specimens. (f)(3) For tests in ophthalmic pathology, meet one of the following requirements: (f)(3)(i)(A) Be a doctor of medicine or doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (f)(3)(i)(B) Must meet one of the following requirements: (f)(3)(i)(B)(1) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (f)(3)(i)(B)(2) Be certified by the American Board of Ophthalmology and have successfully completed at least 1 year of formal post-residency fellowship training in ophthalmic pathology; or (f)(3)(ii) An individual qualified under paragraph (b) or (f)(3)(i) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (f)(3)(i)(B) of this section, the responsibility for examination and interpretation of ophthalmic specimens; or (g) Oral Pathology- If the requirements of paragraph (b) of this section are not met and the laboratory performs tests in the subspecialty of oral pathology, the individual functioning as the technical supervisor must meet one of the following requirements: (g)(1)(i) Be a doctor of medicine or a doctor of osteopathy licensed to practice medicine or osteopathy in the State in which the laboratory is located; and (g)(1)(ii) Be certified in anatomic pathology by the American Board of Pathology or the American Osteopathic Board of Pathology; or (g)(2) Be certified in oral pathology by the American Board of Oral Pathology; or (g)(3) An individual qualified under paragraph (b) or (g)(1) or (2) of this section may delegate to an individual who is a resident in a training program leading to certification specified in paragraph (b) or (g)(1) or (2) of this section, the responsibility for examination and interpretation of oral pathology specimens. (h) Histocompatibility - If the laboratory performs tests in the specialty of histocompatibility, the individual functioning as the technical supervisor must either- (h)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (h)(1)(ii) Have training or experience that meets one of the following requirements: (h)(1)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (h)(1)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (h)(1)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility; or (h)(2)(i) Have an earned doctoral degree in a biological, clinical or medical laboratory science, or medical technology from an accredited institution; or meet the education requirement at 493.1443(b)(3)(i)(B); and (h)(2)(ii) Have training or experience that meets one of the following requirements: (h)(2)(ii)(A) Have 4 years of laboratory training or experience, or both, within the specialty of histocompatibility; or (h)(2)(ii)(B)(1) Have 2 years of laboratory training or experience, or both, in the specialty of general immunology; and (h)(2)(ii)(B)(2) Have 2 years of laboratory training or experience, or both, in the specialty of histocompatibility. (i) Clinical cytogenetics- If the laboratory performs tests in the specialty of clinical cytogenetics, the individual functioning as the technical supervisor must- (i)(1)(i) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located; and (i)(1)(ii) Have 4 years of laboratory

	training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics; or (i)(2)(i) Hold an earned doctoral degree in a biological science, including biochemistry, clinical or medical laboratory science, or medical technology from an accredited institution; or meet the education requirement at 493.1443(b)(3)(i)(B); and (i)(2)(ii) Have 4 years of laboratory training or experience, or both, in genetics, 2 of which have been in clinical cytogenetics. (j) Notwithstanding any other provision of this section, an individual is considered qualified as a technical supervisor under this section if they were qualified and serving as a technical supervisor for high complexity testing in a CLIA-certified laboratory as of December 28, 2024, and have done so continuously since December 28, 2024. This STANDARD is not met as evidenced by: Based on review of the laboratory's CMS-209 form, personnel records, Louisiana State Board of Medical Examiners (LSBME) website, and interview with personnel, the laboratory failed to ensure one (1) of two (2) personnel functioning as the Technical Supervisor met the state of Louisiana licensure requirement. Findings: 1. Review of the CMS 209 (Laboratory Personnel Report) submitted via email on March 21, 2026 at 12:26 pm, revealed the laboratory did not indicate who served as Technical Supervisor. 2. In interview on March 23, 2026 at 2:00 pm the Chief Executive Officer stated she served as the laboratory's Technical Supervisor for 2024 and 2025. The Chief Executive Officer stated her Louisiana State Board of Medical Examiners license was not renewed. The Chief Executive Officer stated the Laboratory Director serves as the current Technical Supervisor. 3. Review of the personnel records for the Chief Executive Officer revealed a "Technical Supervisor /Consultant Evaluation" was performed in 2024 and 2025. The Laboratory Director signed the identified competencies on October 13, 2024 and October 9, 2025. The Chief Executive Officer's resume under the licensure section did not include documentation of a state of Louisiana license for laboratory testing. 4. Review of the LSBME website revealed the Chief Executive Officer did not have an active laboratory license for 2024 and 2025. The status was listed as "CLOSED/No License."