Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0870975	03/20/2024
Name of Provider or Supplier	**Street Address, City, State**	
Feitz Foot Clinic Pa	2424 Frankford Ave, Panama City, FL	

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	An announced CLIA recertification survey was conducted at Feitz Foot Clinic PA on 02/12/2024 - 03/20/2024. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Conditions were cited: D5200-General Laboratory Systems 493.1230 D5300-Preanalytic Systems 493.1240 D5400-Analytic Systems 493.1250 D6000- Moderate Complexity Laboratory Director 493.1403
D5200	GENERAL LABORATORY SYSTEMS CFR(s): 493.1230 Each laboratory that performs nonwaived testing must meet the applicable general laboratory systems requirements in 493.1231 through 493.1236, 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 general laboratory systems and correct identified problems specified in 493.1239 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with the Office Manager, the laboratory failed to verify Dermatophyte Test Medium (DTM) test accuracy twice a year for 2 of 2 (2022-2023) years reviewed (Refer to D5217) and failed to establish and follow a written Quality Assessment plan for 2 out of 2 (2022-2023) years reviewed (Refer to D5291).
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 laboratory records and interview with the Office Manager (OM), the laboratory failed to verify Dermatophyte Test Medium (DTM) test accuracy twice a year for 2 of 2 years reviewed in the subspecialty of Mycology. This repeat deficient practice was cited during the recertification survey completed on 04/01/2022. Findings included: -Review of laboratory records revealed DTM verification for years 2022 and 2023 was not perform. There was no documentation of any DTM verification. -On 02/12/24 at 11:00 a.m., interview with OM confirmed that DTM verification was not performed. - The corrective action documented in the recertification survey completed 04/01/22 (signed by the Laboratory Director 01/18 /2023), stated "Proficiency test performed by the lab techs. Test results kept in lab area. Will be doing double reads when testing is resumed." The plan also states "Lab Director will be the one to monitor" and had a completion date of 03/17/2023.
D5291	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. This STANDARD is not met as evidenced by: Based on review of laboratory records and interview with the Office Manager (OM), the laboratory failed to establish and follow a written Quality Assessment (QA) plan for 2 of 2 years reviewed (2022-2023). This repeat deficient practice was cited during the recertification survey completed on 04/01/2022. Findings included: -Review of records revealed the laboratory did not have a QA plan detailing patient confidentiality, specimen integrity, complaint investigations, communications, personnel competency, and proficiency testing. - The policy for reviewing patient samples for accuracy is not signed or dated by the Laboratory Director. Refer to D5891. -Interview on 02/12/2024 at 10:40 a.m. the OM confirmed the laboratory did not have a QA policy to follow. -The corrective action documented in the recertification survey conducted 04/01/22 (signed by the Laboratory Director 01/18 /2023) stated "Policy and procedures manual updated and system requirements specified. Quality control training and refresher training performed every 6 months for new employees and every year for tenured staff. Documentation kept in Lab Manual in lab area." The plan also states "Lab Director will be the one to monitor" and had a completion date of 03/17/2023.
D5300	PREANALYTIC SYSTEMS CFR(s): 493.1240 Each laboratory that performs nonwaived testing must meet the applicable preanalytic system(s) requirements in 493.1241 and 493.1242, 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 preanalytic systems and correct identified problems as specified in 493. 1249 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by:

	Based on DTM package insert, patient test log, and interview with the Office Manager (OM), the laboratory failed to read Dermatophyte Test Medium (DTM) cultures by manufacturer's instructions for 121 out of 675 patient test results reviewed (Refer to D5311). This repeat deficient practice was cited during the recertification survey completed on 04/01/2022.
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 DTM package insert, patient test log, and interview with the Office Manager (OM), the laboratory failed to read Dermatophyte Test Medium (DTM) cultures by manufacturer's instructions for 121 out of 675 patient test results reviewed. This repeat deficient practice was cited during the recertification survey completed on 04/01/2022. Findings included: -Review of Remel DTM package insert revealed that DTM cultures must be read between 1-14 days after inoculation. -Review of patient test records from 06/01/23 to 02/08/24, revealed 121 DTM cultures that were read after 14 days. Patient specimen (PS) #1 was cultured on 06/01/23 and read 13 days past the manufacturer's instructions. PS#2 was cultured on 06/01/23 and read 13 days past the manufacturer's instructions. PS#3 was cultured on 06/01/23 and read 13 days past the manufacturer's instructions. PS#4 was cultured on 06/01/23 and read 13 days past the manufacturer's instructions. PS#5 was cultured on 06/01/23 and read 13 days past the manufacturer's instructions. PS#6 was cultured on 06/01/23 and read 13 days past the manufacturer's instructions. PS#7 was cultured on 06/01/23 and read 13 days past the manufacturer's instructions. PS#8 was cultured on 06/01/23 and read 13 days past the manufacturer's instructions. PS#9 was cultured on 06/01/23 and read 13 days past the manufacturer's instructions. PS#10 was cultured on 06/01/23 and read 13 days past the manufacturer's instructions. PS#11 was cultured on 06/01/23 and read 13 days past the manufacturer's instructions. PS#12 was cultured on 06/01/23 and read 13 days past the manufacturer's instructions. PS#13 was cultured on 06/05/23 and read 9 days past the manufacturer's instructions. PS#14 was cultured on 06/05/23 and read 9 days past the manufacturer's instructions. PS#15 was cultured on 06/05/23 and read 9 days past the manufacturer's instructions. PS#16 was cultured on 06/05/23 and read 9 days past the manufacturer's instructions. PS#17 was cultured on 06/05/23 and read 9 days past the manufacturer's instructions. PS#18 was cultured on 06/05/23 and read 9 days past the manufacturer's instructions. PS#19 was cultured on 06/05/23 and read 9 days past the manufacturer's instructions. PS#20 was cultured on 06/05/23 and read 9 days past the manufacturer's instructions. PS#21 was cultured on 06/06/23 and read 8 days past the manufacturer's instructions. PS#22 was cultured on 06/06/23 and read 8 days past the manufacturer's instructions. PS#23 was cultured on 06/06/23 and read 8 days past the manufacturer's instructions. PS#24 was cultured on 06/06/23 and read 8 days past the manufacturer's instructions. PS#25 was cultured on 06/13/23 and read 1 day past the manufacturer's instructions. PS#26 was cultured on 06/13/23 and read 1 day past the manufacturer's instructions. PS#27 was cultured on 06/13/23 and read 1 day past the manufacturer's instructions. PS#28 was cultured on 06/13/23 and read 1 day past the

manufacturer's instructions. PS#29 was cultured on 06/13/23 and read 1 day past the manufacturer's instructions. PS#30 was cultured on 06/13/23 and read 1 day past the manufacturer's instructions. PS#31 was cultured on 06/13/23 and read 1 day past the manufacturer's instructions. PS#32 was cultured on 06/13/23 and read 1 day past the manufacturer's instructions. PS#33 was cultured on 06/13/23 and read 1 day past the manufacturer's instructions. PS#34 was cultured on 06/12/23 and read 9 days past the manufacturer's instructions. PS#35 was cultured on 06/12/23 and read 9 days past the manufacturer's instructions. PS#36 was cultured on 06/12/23 and read 9 days past the manufacturer's instructions. PS#37 was cultured on 06/12/23 and read 9 days past the manufacturer's instructions. PS#38 was cultured on 06/12/23 and read 9 days past the manufacturer's instructions. PS#39 was cultured on 06/12/23 and read 9 days past the manufacturer's instructions. PS#40 was cultured on 06/12/23 and read 9 days past the manufacturer's instructions. PS#41 was cultured on 06/12/23 and read 9 days past the manufacturer's instructions. PS#42 was cultured on 06/12/23 and read 9 days past the manufacturer's instructions. PS#43 was cultured on 06/12/23 and read 9 days past the manufacturer's instructions. PS#44 was cultured on 06/12/23 and read 9 days past the manufacturer's instructions. PS#45 was cultured on 06/12/23 and read 9 days past the manufacturer's instructions. PS#46 was cultured on 06/12/23 and read 9 days past the manufacturer's instructions. PS#47 was cultured on 06/12/23 and read 9 days past the manufacturer's instructions. PS#48 was cultured on 06/15/23 and read 6 days past the manufacturer's instructions. PS#49 was cultured on 06/15/23 and read 6 days past the manufacturer's instructions. PS#50 was cultured on 06/15/23 and read 6 days past the manufacturer's instructions. PS#51 was cultured on 06/15/23 and read 6 days past the manufacturer's instructions. PS#52 was cultured on 06/15/23 and read 6 days past the manufacturer's instructions. PS#53 was cultured on 06/15/23 and read 6 days past the manufacturer's instructions. PS#54 was cultured on 06/15/23 and read 6 days past the manufacturer's instructions. PS#55 was cultured on 06/15/23 and read 6 days past the manufacturer's instructions. PS#56 was cultured on 06/15/23 and read 6 days past the manufacturer's instructions. PS#57 was cultured on 06/15/23 and read 6 days past the manufacturer's instructions. PS#58 was cultured on 06/15/23 and read 6 days past the manufacturer's instructions. PS#59 was cultured on 06/15/23 and read 6 days past the manufacturer's instructions. PS#60 was cultured on 06/15/23 and read 6 days past the manufacturer's instructions. PS#61 was cultured on 06/15/23 and read 6 days past the manufacturer's instructions. PS#62 was cultured on 06/15/23 and read 6 days past the manufacturer's instructions. PS#63 was cultured on 06/15/23 and read 6 days past the manufacturer's instructions. PS#64 was cultured on 06/15/23 and read 6 days past the manufacturer's instructions. PS#65 was cultured on 06/19/23 and read 2 days past the manufacturer's instructions. PS#66 was cultured on 06/19/23 and read 2 days past the manufacturer's instructions. PS#67 was cultured on 06/19/23 and read 2 days past the manufacturer's instructions. PS#68 was cultured on 06/19/23 and read 2 days past the manufacturer's instructions. PS#69 was cultured on 06/19/23 and read 2 days past the manufacturer's instructions. PS#70 was cultured on 06/19/23 and read 2 days past the manufacturer's instructions. PS#71 was cultured on 06/19/23 and read 2 days past the manufacturer's instructions. PS#72 was cultured on 06/19/23 and read 2 days past the manufacturer's instructions. PS#73 was cultured on 06/19/23 and read 2 days past the manufacturer's instructions. PS#74 was cultured on 06/19/23 and read 2 days past the manufacturer's instructions. PS#75 was cultured on 06/19/23 and read 2 days past the manufacturer's instructions. PS#76 was cultured on 06/19/23 and read 2 days past the manufacturer's instructions. PS#77 was cultured on 06/19/23 and read 2 days past the manufacturer's instructions. PS#78 was cultured on 06/19/23 and read 2 days past the manufacturer's instructions. PS#79 was cultured on 06/19/23 and read 2 days past the manufacturer's instructions. PS#80 was cultured on 06/19/23 and read 2 days past the manufacturer's instructions. PS#81 was cultured on 06/19/23 and read 2 days past the

	manufacturer's instructions. PS#82 was cultured on 06/19/23 and read 2 days past the manufacturer's instructions. PS#83 was cultured on 06/19/23 and read 2 days past the manufacturer's instructions. PS#84 was cultured on 06/19/23 and read 2 days past the manufacturer's instructions. PS#85 was cultured on 06/19/23 and read 2 days past the manufacturer's instructions. PS#86 was cultured on 06/19/23 and read 2 days past the manufacturer's instructions. PS#87 was cultured on 07/31/23 and read 1 day past the manufacturer's instructions. PS#88 was cultured on 07/31/23 and read 1 day past the manufacturer's instructions. PS#89 was cultured on 07/31/23 and read 1 day past the manufacturer's instructions. PS#90 was cultured on 07/31/23 and read 1 day past the manufacturer's instructions. PS#91 was cultured on 07/31/23 and read 1 day past the manufacturer's instructions. PS#92 was cultured on 07/31/23 and read 1 day past the manufacturer's instructions. PS#93 was cultured on 08/01/23 and read 1 day past the manufacturer's instructions. PS#94 was cultured on 08/01/23 and read 1 day past the manufacturer's instructions. PS#95 was cultured on 08/01/23 and read 1 day past the manufacturer's instructions. PS#96 was cultured on 08/01/23 and read 1 day past the manufacturer's instructions. PS#97 was cultured on 08/01/23 and read 1 day past the manufacturer's instructions. PS#98 was cultured on 08/01/23 and read 1 day past the manufacturer's instructions. PS#99 was cultured on 08/01/23 and read 1 day past the manufacturer's instructions. PS#100 was cultured on 08/01/23 and read 1 day past the manufacturer's instructions. PS#101 was cultured on 08/01/23 and read 1 day past the manufacturer's instructions. PS#102 was cultured on 08/01/23 and read 1 day past the manufacturer's instructions. PS#103 was cultured on 08/07/23 and read 1 day past the manufacturer's instructions. PS#104 was cultured on 08/07/23 and read 1 day past the manufacturer's instructions. PS#105 was cultured on 08/07/23 and read 1 day past the manufacturer's instructions. PS#106 was cultured on 08/07/23 and read 1 day past the manufacturer's instructions. PS#107 was cultured on 08/07/23 and read 1 day past the manufacturer's instructions. PS#108 was cultured on 08/07/23 and read 1 day past the manufacturer's instructions. PS#109 was cultured on 08/07/23 and read 1 day past the manufacturer's instructions. PS#110 was cultured on 08/07/23 and read 1 day past the manufacturer's instructions. PS#111 was cultured on 08/07/23 and read 1 day past the manufacturer's instructions. PS#112 was cultured on 08/07/23 and read 1 day past the manufacturer's instructions. PS#113 was cultured on 08/07/23 and read 1 day past the manufacturer's instructions. PS#114 was cultured on 08/07/23 and read 1 day past the manufacturer's instructions. PS#115 was cultured on 08/07/23 and read 1 day past the manufacturer's instructions. PS#116 was cultured on 08/21/23 and read 1 day past the manufacturer's instructions. PS#117 was cultured on 08/21/23 and read 1 day past the manufacturer's instructions. PS#118 was cultured on 08/21/23 and read 1 day past the manufacturer's instructions. PS#119 was cultured on 08/21/23 and read 1 day past the manufacturer's instructions. PS#120 was cultured on 08/21/23 and read 1 day past the manufacturer's instructions. PS#121 was cultured on 08/21/23 and read 1 day past the manufacturer's instructions. -Interview with the OM on 02/12/24 at 11:55 a.m., confirmed DTM cultures were read past the manufacturer's instructions (reading up to 14 days after inoculation). -The corrective action documented in the recertification survey conducted 04/01/22 (signed by the Laboratory Director 01/18/2023) stated "All requirements and guidelines updated and reviewed by Director of Laboratory ensuring all lab personnel understand perform and continue to follow specific guidelines ensuring all requirements are met" and "Lab Director will monitor" with a completion date of 03/17/2023.
D5391	PREANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1249(a) The laboratory must establish and follow written policies and procedures for an

	ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the preanalytic systems specified at 493.1241 through 493.1242. This STANDARD is not met as evidenced by: Based on Dermatophyte Test Medium (DTM) manufacturer's instructions and patient result log, and interview the laboratory failed to implement a quality assessment policy for monitoring, assessing, and correcting problems identified in preanalytic systems. This repeat deficient practice was cited during the recertification survey completed on 04/01/2022. Findings included: -The laboratory failed to identify and correct culture reads past 14 days of inoculation. Refer to D5311. -Interview on 02/12 /2024 at 10:50 a.m. the Office Manager confirmed that the laboratory did not have a quality assessment plan in place. -The corrective action documented in the recertification survey completed 04/01/2022 (signed by the Lab Director 01/18/2023) stated that "A policy was written for specimen labeling, rejection policy for DTM test and QA" and that "Lab Director will monitor" with a completion date of 03/17/2023.
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 Laboratory records, the laboratory failed to meet the requirements of analytic systems. The laboratory failed to ensure the Dermatophyte Test Medium (DTM) Procedure was reviewed, signed, and dated by the Laboratory Director (Refer to D5407). The laboratory failed to monitor and document DTM culture incubation temperature for 2 of 2 (2022-2023) years reviewed (Refer to D5413). The laboratory failed to document sterility and perform DTM quality control (QC) for 2 of 2 (2022-2023)years reviewed (Refer to D5477). This repeat deficient practice was cited during the recertification survey completed on 04/01/2022.
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 review of Procedure Manual and interview, the laboratory failed to ensure the Dermatophyte Test Medium (DTM) culture procedure and the Specimen Collection Procedure were reviewed, signed, and dated by the Laboratory Director. This is a repeat deficient practice cited during the recertification survey completed on 04/01/2022. Findings include: -Review of laboratory records revealed the laboratory director did not sign and date the DTM culture procedure or the Specimen Collection procedure. -Interview on 02/13/2024 the Office Manager confirmed that the

	Laboratory Director did not sign the procedure manual. -The corrective action documented on the recertification survey completed 04/01/22 (signed by the Laboratory Director 01/18/2023) states the "A policy and procedure manual created." The plan also stated "Lab Director will monitor" with a completion date of 03/17 /2023.
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 record review and interview with the Office Manager (OM) and Laboratory Director (LD), the laboratory failed to monitor and document DTM culture incubation temperature and DTM storage for 2 of 2 years (2022-2023) reviewed. This repeat deficient practice was cited during the recertification survey completed on 04/01 /2022. Findings included: -Review of laboratory records revealed there were no refrigerator or DTM culture cabinet temperature logs. -Remel DTM manufacturer's indicated temperature for stored media as 2-8 degrees Celsius. -Remel DTM manufacturer's indicated inoculated DTM incubation temperature as 25-30 degrees Celsius. -Interview with the OM on 02/12/24 at 11:50 a.m., confirmed the lack of DTM incubation cabinet and refrigerator temperature logs. -Interview conducted with LD via email on 02/26/24 at 8:30 p.m., confirmed the lack of DTM incubation cabinet and refrigerator temperature logs. -The corrective action documented in the recertification survey completed 04/01/22 stated "New temp log for room temp and humidity. New temp log for refrigerator temp. Will be monitored everyday we're open and testing. Lab Director will monitor." This plan had a completion date of 03/17 /2023.
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 record review and interview with the Office Manager (OM) and Laboratory Director (LD), the laboratory failed to perform quality control (QC) measures for Dermatophyte Test Medium (DTM) used to test patients for 2 of 2 years (2022-2023). This is a repeat deficient practice cited during the recertification survey completed on

	04/01/2022. Findings included: -Review of laboratory records revealed a lack of documentation for DTM sterility, DTM QC (its ability to support growth, select or inhibit specific organisms), and DTM visual inspection. -Review of Remel DTM package insert states control organisms should be tested in accordance with established laboratory quality control procedures. - Interview with the OM on 02/12 /24 at 11:45 a.m., confirmed that sterility was not performed or documented and DTM QC and visual exam was not performed or documented. -Interview conducted with the LD via email on 02/26/24 at 8:30 p.m., confirmed that sterility was not performed or documented and DTM QC and visual exam was not performed or documented. -The corrective action documented in the recertification survey completed 04/01/22 stated that "Controls were ordered. Will be done with each new box as well as a visual inspection of the media. Lab Director will monitor." This plan had a completion date of 03/17/2023.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on Dermatophyte Test Medium (DTM) manufacturer's instructions, patient result logs, and interview, the laboratory failed to implement a quality assessment (QA) policy for monitoring, assessing, and correcting problems identified in analytic systems for 2 of 2 (2022-2023) years reviewed. This repeat deficient practice was cited during the recertification survey completed on 04/01/2022. Findings included: - The laboratory failed to monitor and document sterility and DTM incubation temperature. Refer to D5413. -The laboratory failed to ensure the DTM procedure was signed and dated by the Lab Director. Refer to D5407. -The laboratory failed to perform quality control for DTM. Refer to 5477. -There were no QA policy or records to review. -Interview of 02/12/2024 at 10:50 a.m. the Office Manager confirmed there were no QA policies or records to review. -The corrective action documented in the recertification survey completed 04/01/2022 stated that "New QA procedure that will be followed and documented. Lab Director will monitor." This plan had a complete date of 03/17/2023.
D6000	MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403 The laboratory must have a director who meets the qualification requirements of 493. 1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart. This CONDITION is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to effectively oversee the laboratory and identify failures in the quality of laboratory (Refer to D6007) and failed to ensure testing was performed as required by the manufacturer for Dermatophyte Test Medium (DTM) testing (Refer to D6014). This repeat deficient practice was cited during the recertification survey completed on 04/01/2022.

D6007	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (E) The laboratory director must-- (E)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing; This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director (LD) failed to ensure that test systems developed and used for the tests performed in the laboratory provide quality laboratory services for all aspects of test performance for 2 out of 2 (2022-2023) years reviewed. This repeat deficient practice was cited during the recertification survey completed on 04/01/2022. Findings included: -The LD failed to implement a quality assessment policy for monitoring, assessing, and correcting problems when identified. Refer to D5791. -The LD failed to review, sign and date Dermatophyte Test Medium (DTM) testing procedure. Refer to D5407. -The LD failed to monitor and document refrigerator temperatures for DTM storage and incubation temperature for DTM cultures for 2 of 2 years (2022-2023) reviewed. Refer to D5413. -The LD failed to ensure twice a year accuracy testing were performed for 2 of 2 years (2022-2023) reviewed while conducting patient testing. Refer to D5217. -The LD failed to ensure that quality control was performed daily or that an Individualized Quality Control Plan was in place. Refer to D5477. -Interview on 02/12/2024 at 12:00 p.m. the Office Manager confirmed that the aforementioned were not completed. -The corrective action plan for the recertification survey completed 04/01/2024 (signed by the Laboratory director on 01/18/2023) stated the "Lab Director will monitor" with a completion date of 03/17/2023.
D6014	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(3)(iii) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results. This STANDARD is not met as evidenced by: Based on patient test logs, manufacturer's instructions, and interviews with the Office Manager (OM) and Laboratory Director (LD), the Laboratory Director (LD) failed to ensure that Testing Personnel (TP) performed the Dermatophyte Test Medium (DTM) test as required by the manufacturer for 121 out of 675 patient test results. Findings included: - The LD failed to ensure that DTM cultures were read per manufacturer's instructions for 121 out of 675 patient test results. Refer to D5311. -The LD failed to approve (review, sign and date) the DTM culture procedure. Refer to D5407. -Interview with the OM on 02/12/24 at 11:55 a.m., confirmed DTM TP#A read

	cultures past the manufacturer's instructions of reading up to 14 days after inoculation and did not sign the DTM culture procedure. -Interview conducted with the LD via email 02/26/24 at 8:30 p.m., confirmed that the TP#A was not competency assessed.
D6046	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8) (b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently. This STANDARD is not met as evidenced by: Based on record review and interview with the Office Manager (OM), the Technical Consultant (TC) failed to perform competency assessment (CA) for 1 of 1 Testing Personnel (TP#A) responsible for reading the Dermatophyte Test Medium inoculations. This repeat deficient practice was cited during the recertification survey completed on 04/01/2022. Findings included: -TC did not ensure that TP# received annual CA. Record review on 02/12/24 revealed no documentation for annual CA for TP#A. - Interview with the OM on 02/12/24 confirmed that TP#A did not perform annual competency assessment. -Interview with the LD via email on 02/26/24 at 8:30 p.m., confirmed that the TC did not ensure TP#A was competency assessed. -Record review of CMS Form 209 shows that the TC is the LD. -The corrective action documented in the recertification survey conducted on 04/01/2022 (signed by the Laboratory Director 01/18/2023) stated that "Competency were performed on all three testing people. Competency will be evaluated every yr. Lab Director will monitor for comp." This plan had a completion date of 03/17/2023.