Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	14D0877152	10/01/2024
Name of Provider or Supplier	**Street Address, City, State**	
Hospital Plaza Foot & Ankle Sc	1228 Ogden Ave, Downers Grove, IL	

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
D5006	MYCOLOGY CFR(s): 493.1203 If the laboratory provides services in the subspecialty of Mycology, the laboratory must meet the requirements specified in 493.1230 through 493.1256, 493.1263, and 493.1281 through 493.1299. This CONDITION is not met as evidenced by: Based on review of the laboratory's policy and procedure manual, laboratory records, patient test logs, quality control records, and interview with the laboratory director (LD); the laboratory failed to outline the required components of a test procedure for dermatophyte test medium (DTM) (See D5403); the laboratory failed to ensure the procedures for dermatophyte testing in the sub-specialty of mycology were approved, signed, and dated by the current LD before use. (See D5407); the laboratory failed to monitor and document manufacturer's required conditions for proper storage of DTM (See D5413); the laboratory failed to verify the criteria for acceptability of control materials for eight of eight lots of dermatophyte test medium (DTM) (See D5469); and the laboratory failed to include all the required components of a laboratory test report for patient test reports for testing using DTM (See D5805).
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 and interview with the laboratory director (LD), the laboratory failed to outline 8 of 14 required components of the Dermatophyte Test Medium (DTM) test procedure for the specialty microbiology. Findings Include: 1. Review of the laboratory's procedure manual identified the procedure for DTM testing titled, "Handling Procedures for D.T.M. Vials", which failed to have the following required components of a 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. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (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. (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 imminent life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. 2. During survey date 10/1/2024, at 11:40 am, the LD confirmed the DTM test procedure failed to include all the required components identified above.
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 the laboratory's procedure manual and interview with the laboratory director (LD), the laboratory failed to ensure the procedures for dermatophyte testing in the sub-specialty of mycology were approved, signed, and dated by the current LD before use. Findings Include: 1. Review of the laboratory documents identified the procedure titled, "Handling procedures for D.T.M Vials" that was not approved and signed by the current laboratory director prior to use. The document was last revised on 08-05-21. 2. During survey date 10-01-24, at 11:40 am, the LD confirmed the Dermatophyte Test Medium procedure failed to be approved, signed, and dated prior to use by the current LD.
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 review of quality control documentation, lack of documentation, manufacturers package insert and an interview with the laboratory director (LD), the laboratory failed to monitor and document manufacturer's required conditions for proper storage of Dermatophyte Test Medium (DTM) for eight of eight lots in use from 12-29-22 through date of survey, 10-01-2024. Findings include: 1. Review of laboratory quality control documentation identified eight lots of DTM used by the laboratory for patient testing: 1. Lot number: 3161 Date received: 09-03-2024 2. Lot number: 3115 Date received: 05-21-2024 3. Lot number: 3012 Date received: 04-01-2024 4. Lot number: 2994 Date received: 12-09-2023 5. Lot number: 2886 Date received: 08-07-2023 6. Lot number: D1468-0722 Date received: 05-31-2023 7. Lot number: D1453-7625 Date received: 03-16-2023 8. Lot number: D1415-6651 Date received: 12-29-2022 2. Review of the manufacturer's package insert instructions stated: "Storage instructions: On receipt, store tubes in the dark at 2-8 C." 3. The laboratory failed to provide the surveyors with temperature monitoring documentation for the reagent storage location for eight of eight lots of DTM received since 2022. 4. On survey date 10-1-2024, at 01:07 pm, the LD confirmed the laboratory failed to monitor and document refrigeration temperature for DTM test media storage location.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(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--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of laboratory records, review of patient records and interview with laboratory director (LD), the laboratory failed to verify the criteria for acceptability of control materials for eight of eight lots of dermatophyte test medium (DTM) in use from 12-29-2022 through date of survey, 10-01-2024. Findings include: 1.Review of laboratory quality control (QC) records identified a document titled "Quality Control Process (Each DTM Lot)" which states: "1. Record patient and patient vial number as

	control for Candida QC test (+G/-CC) patient first name/ Last initial_____ Patient DTM vial# _____ Results/Findings: _____ 2. Record patient and patient vial number as control for T. rubrum QC test (+G/+CC) patient first name/ Last initial_____ Patient DTM vial # _____ Results/Findings: _____ 3. Record patient and patient vial number as control for E. coli QC test (-G/-CC) patient first name/ Last initial_____ Patient DTM vial # _____ Results/Findings: _____" 2. Review of the laboratory document titled "Specimen Record Sheet" identified patient samples were used as the control materials for eight of eight lots of DTM. 1. DTM Lot #: D1415-6651 Date: 12-29-22 a. Patient name: P-CC Vial #: 312 findings: +G/-CC Test report reading date:12-23-22 b. Patient name: P-MD Vial #: 314 findings: +G/+CC Test report reading date:12-23-22 c. Patient name: P-PK Vial #: 317 findings: -G/-CC Test report reading date:12-23-22 2. DTM Lot # D1453-7625 Date: 03-16-23 a. Patient name: P-TR Vial #: 68 findings: +G/-CC Test report reading date: 03-04-23 b. Patient name: P-AC Vial #: 63 findings: +G /+CC Test report reading date:03-01-23 c. Patient name: P-DH Vial # :64 findings: -G/-CC Test report reading date: 03-01-23 3. DTM Lot # D1468-0722 Date: 05-31-23 a. Patient name: P-AB Vial #:201 findings: +G/-CC Test report reading date:05-31-23 b. Patient name: P-GB Vial #: 204 findings: +G/+CC Test report reading date: 06-03-23 c. Patient name: P-ML Vial #: 166 findings: -G/-CC Test report reading date: 05-06-23 4. DTM Lot# 2886 Date: 08-07-23 a. Patient name: P-SS Vial #:282 findings: +G/-CC Test report reading date: 07-20-23 b. Patient name: P-DS Vial #: 286 findings: +G/+CC Test report reading date: 07-20-23 c. Patient name: P-WZ Vial #: 305 findings: -G/-CC Test report reading date: 08-05-23 5. DTM Lot# 2994 Date: 12-09-23 a. Patient name: P-LW Vial #: 422 findings: +G/-CC Test report reading date: 11-16-23 b. Patient name: P-RH Vial #: 420 findings: +G/+CC Test report reading date: 11-12-23 c. Patient name: P-FB Vial #: 437 findings: -G/-CC Test report reading date: 12-05-23 6. DTM Lot# 3012 Date: 04-01-24 a. Patient name: P-GF Vial #: 11 findings: +G/-CC Test report reading date: 01-18-24 b. Patient name: P-CJ Vial #: 9 findings: +G/+CC Test report reading date: 01-14-24 c. Patient name: P-JK Vial #: 70 findings: -G/-CC Test report reading date: 03-16-24 7. DTM Lot# 3115 Date: 05-21-24 a. Patient name: P-LN Vial #:137 findings: +G/-CC Test report reading date:05-21-24 b. Patient name: P-BD Vial #: 136 findings: +G/+CC Test report reading date: 05-21-24 c. Patient name: P-T8 Vial #: 145 findings: -G/-CC Test report reading date: 05-24-24 8. DTM Lot# 3163 Date: 09-03-24 a. Patient name: P-SA Vial #:285 findings: +G/-CC Test report reading date: 09-07-24 b. Patient name: P-SJ Vial #: 288 findings: +G/+CC Test report reading date: 09-08-24 c. Patient name: P-CA Vial #: 257 findings: -G/-CC Test report reading date: 08-15-24 4. Review of laboratory records found the laboratory failed to verify the acceptability of the patient controls used for DTM quality control for eight of eight DTM lots. 5. On survey date 10-01-24, at 12: 09 pm, the LD confirmed the above findings that patient samples were used as the known control materials for Candida QC test, T. Rubrum QC test, and E. Coli QC test without verifying the acceptability of the control materials.
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 laboratory records and interview with the laboratory director (LD); the laboratory failed to include all the required components of a laboratory test report for five of five patient test reports reviewed for testing using the dermatophyte test medium (DTM) process. Findings Include: 1. Review of five of five patient test reports (P-VM, P-RC, P-WJ, P-FR, and P-BC) for DTM testing found the laboratory failed to indicate the test performed and the test result /interpretation, on the laboratory's test report. 2. On survey date 10-01-24, at 12:09 pm, the LD confirmed the patient test reports failed to identify the test performed and the test result /interpretation on the patient test reports.
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 review of laboratory documents, lack of documentation, and interview with the laboratory director (LD); the LD failed to establish and maintain a quality assurance program (See D6021) and the LD failed to provide an approved procedure manual outline all testing performed by the laboratory (See D6031).
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) 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)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on lack of laboratory records and interview with the laboratory director (LD); the laboratory director failed to establish and follow written policies and procedures for monitoring, assessing, and correcting problems for the specialty of mycology. Findings Include: 1. No documentation of a written quality assessment plan was available for review on date of survey, 10-01-2024. 2. Interview with LD on date 10-01-2024, at 11:40 am the LD confirmed that no quality assessment plan or procedure existed.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) 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 surveyor review of laboratory procedure manual, lack of documentation, and interview with laboratory director (LD); the laboratory director failed to provide an approved procedure manual outlining all testing performed by the laboratory for Dermatophyte Test Media (DTM) testing. Findings Include: 1. Procedure manual titled "Handling Procedures for D.T.M. Vials" failed have the required components and did not have signed approval from the LD. See D5403.