

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 14D0877152	(X3) Date Survey Completed 10/04/2018
Name of Provider or Supplier Hospital Plaza Foot & Ankle Sc	Street Address, City, State 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	<p>MYCOLOGY CFR(s): 493.1203</p> <p>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.</p> <p>This CONDITION is not met as evidenced by: Based on review of laboratory records and interview with the laboratory director (LD); the laboratory failed to meet the requirements specified in 493.1230 through 493.1256, 493.1263, and 493.1281 through 493.1299. Findings Include: 1. The laboratory failed to ensure the manufacturer's instructions were followed. Dermatophyte test medium (DTM) cultures were reported after incubations longer than 14 days. See D5411. 2. The laboratory failed to check each batch of dermatophyte test media (DTM) for sterility, growth, inhibition, and biochemical response with initial use. See D5477.</p>
D5411	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a)</p> <p>Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253.</p> <p>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 follow manufacturer's instructions for Dermatophyte Test Medium (DTM) cultures by reporting results of cultures which were incubated</p>

longer than 14 days. Findings Include: 1. Review of manufacturer's instructions for "Dermatophyte Test Medium" (DTM) identified the following under the subsection "X. Procedure", "incubate the inoculated plate at 22-25C for up to 14 days." Additionally, under the section, "XII. Laboratory Results" the instructions state, "disregard any color changes in the medium after 14 days of incubation." 2. Review of patient test reports for 5 of 5 DTM culture results found the cultures were incubated and resulted beyond the 14 day time point as well as reporting the color change of the media. Patient Identifier Culture Inoculated Culture Read P1 09-10-2018 10-02-2018 P2 06-17-2018 07-19-2018 P3 05-08-2018 05-23-2018 P4 11-14-2017 01-02-2018 P5 06-26-2017 07-31-2017 3. Additionally, review of the laboratory's "specimen record sheets", which provide the culture inoculation date and the date when the culture is read, found for June of 2018 31 of 47 cultures were read beyond the 14 day time point. 4. On survey date 10-4-2018, at 11:00 am, the LD confirmed that DTM cultures identified were incubated beyond the manufacturer's instructions of 14 days.

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 review of laboratory records and interview with the laboratory director (LD); the laboratory failed to check each batch of dermatophyte test medium (DTM) for sterility, ability to support growth, inhibit specific organisms, and the ability to selectively induce a biochemical response. Findings include: 1. Review of the laboratory procedure, "Handling Procedures for D.T.M. Vials", under the section, "User Quality Control", states the following: "Incubate 2 samples at 71.6-88 degrees F for 14 days and examine for sterility Based on CLIA test lot samples of media with stock cultures know for positive and negative results. Full color changes in 3-6 days. Candida Albicans: Growth, not color change Trichoplyton Mentagrophutes: Growth, color change to red E. Coli: (- G/ -CC)" 2. Review of "D.T.M. Purchase Record Sheet" logs for 2017 through the date of survey 2018 (10-4-2018) identified 7 lots of media received by the laboratory for use in patient testing. DTM Lot #s 1632207 1623005 1704514 1707409 1810013 1812906 1812916 3. "D.T.M. Purchase Record Sheet" logs for 2017 through the date of survey 2018 (10-04-2018) documented quality control testing for 7 of 7 lots for E. coli and T. rubrum. 4. "D.T.M. Purchase Record Sheet" logs failed to document quality control testing for 7 of 7 DTM lots for sterility, Candida Albicans, and Trichophyton Mentagrophytes, as outlined in the laboratory procedure, "Handling Procedures for D.T.M. Vials". 5. Review of "Specimen Record sheet" logs for 2018 documented 248 DTM cultures have been performed when quality controls for DTM culture media failed to follow the laboratory's procedure. 6. On survey date 10-04-2018, at 11:00 am, the survey findings were confirmed by the LD.

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 the test report date for 3 of 5 dermatophyte test medium (DTM) patient test reports reviewed. Findings Include: 1. Review of 3 of 5 patient test reports for dermatophyte test medium (DTM) cultures failed to indicate the test report date. Patient Test Report Identification P2 P4 P5 2. During survey date 10-04-2018, at 11:00 am, the above findings were confirmed by the LD.