

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 23D0859548	(X3) Date Survey Completed 05/03/2018
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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 document review and interview, the laboratory failed to meet the subspecialty of mycology requirements as specified in 493.1230 through 493.1256, 493.1263, and 493.1281 through 493.1299. Findings include: 1. The laboratory failed to have a written request for the mycology patient testing from an authorized person. Refer to D5301. 2. The laboratory failed to follow the "Fungal Culture " procedure for interpreting mycology dermatophyte cultures. Refer to D5401. 3. The laboratory failed to use the mycology dermatophyte testing medium (DTM) before the manufacturer's expiration date. Refer to D5417. 4. The laboratory failed to perform and document media checks for the Healthlink Dermatophyte Test Medium (DTM). Refer to D5477. 5. The laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems in the analytic laboratory systems. Refer to D5791. 6. The laboratory failed to establish a system to ensure the manually entered patient final test results were entered into the patient's paper chart. Refer to D5801.</p>
D5301	<p>TEST REQUEST CFR(s): 493.1241(a)</p> <p>The laboratory must have a written or electronic request for patient testing from an authorized person.</p>

This STANDARD is not met as evidenced by:
. Based on document review and interview, the laboratory failed to have a written request for the mycology patient testing from an authorized person for one (#3) of nine patient charts audited. Findings include: 1. On May 3, 2018 at 10:35 AM, document review for one (#3) of nine patient charts audited did not have a written request for the mycology testing by an authorized person in the patient's paper chart. 2. During the interview on May 3, 2018 at approximately 11:45 AM, the laboratory director as listed on the CMS-209 confirmed a written request for the mycology testing was not present in the patients chart.

D5401

PROCEDURE MANUAL
CFR(s): 493.1251(a)

A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.

This STANDARD is not met as evidenced by:
. Based on record review and interview, the laboratory failed to follow the "Fungal Culture " procedure for interpreting mycology dermatophyte cultures within 10-14 days of inoculation or did not include a date of interpretation for eight (#2-#9) of nine patient charts audited. Findings include: 1. On May 3, 2018 at 10:35 AM, record review for eight (#2 - #9) of nine patient charts audited revealed the final day of recording the test results exceeded the 14 days as stated in the "Fungal Cultures" policy or did not include a date of reading as follows: a. #2 - final result read on day 21 b. #3-#9 - no date documented in the patient's paper chart for final reading 2. During the interview on May 3, 2018 at approximately 11:45 AM, the laboratory director as listed on the CMS-209 confirmed the final interpretation of the mycology testing exceeded the 14 days or was not recorded in the patient's chart.

D5417

TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT
CFR(s): 493.1252(d)

Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality.

This STANDARD is not met as evidenced by:
. Based on procedure review, record review, and interview, the laboratory failed to use the mycology dermatophyte testing medium (DTM) before the manufacturer's expiration date for one (#3) of nine patient charts audited. Findings include: 1. On May 3, 2018 at approximately 9:30 AM, review of a black binder revealed in the "Quality Control Program" section media should not be used when they have "exceeded their expiration dates, have deteriorated or are of substandard quality". 2. On May 3, 2018 at 10:35 AM, record review for one (#3) of nine patient charts audited revealed the patient specimen was inoculated on December 8, 2016 onto expired DTM (November 17, 2016) . 3. During the interview on May 3, 2018 at approximately 11:45 PM, the laboratory director as listed on the CMS-209 confirmed DTM was used past the manufacturer's stated expiration date. ***Repeat Deficiency from April 26, 2012 and January 26, 2016 surveys

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 procedure review, record review, and interview, the laboratory failed to perform and document media checks for the Healthlink Dermatophyte Test Medium (DTM) with each new batch, lot, or shipment including: the sterility, the ability to support growth, and selectivity/inhibition of growth, and the physical characteristics for 24 (May 2016 to May 2018) of 24 months reviewed. Findings include: 1. On May 3, 2018 at 09:20 AM, procedure manual review revealed "Quality Control" section 6.1.1 "When a new lot of DTM is received into laboratory, two bottles will be taken as new control. One is to be inoculated from positive control and the other to remain as is. This is to be recorded in log book as follows: Media lot number & expiration date Sterility = yes or no Physical characteristics DTM + & - control plated Biochemical response of controls plated" 2. On May 3, 2018 at 10:22 AM, record review of the log book revealed for 24 (May 2016 to May 2018) of 24 months there was no documentation to show the media checks for each new batch, lot, or shipment for sterility, the ability to support growth, selectivity/inhibition of growth, and the physical characteristics. 2. During the interview on May 3, 2018 at approximately 11:45 AM, the laboratory director as listed on the CMS-209 confirmed the media checks were not performed and documented. ***Repeat Deficiency from January 26, 2012 survey***

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 review of the laboratory's quality assurance policy and interview, the laboratory failed to follow written policies and procedures for an ongoing mechanism to monitor, assess, and correct problems as specified in 493.1251 through 493.1283 in the analytic laboratory systems for two (May 2016 to May 2018) of two years. Findings include: 1. The surveyor reviewed the laboratory's quality assurance program that stated the laboratory would monitor, assess, and correct problems when indicated for the analytic laboratory system. 2. There was no documentation to show the laboratory had performed six chart reviews every January and June from 2016 to 2018 as stated in the Quality Control 6.2 section. 3. During the interview on May 6, 2018 at approximately 11:45 AM, the laboratory director as listed on the CMS-209 confirmed the above findings. ***Repeat Deficiency from January 26, 2012 survey***

D5801

TEST REPORT

CFR(s): 493.1291(a)

The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

. Based on record review and interview, the laboratory failed to establish a system to ensure the manually entered patient final test results were entered into the patient's paper chart for five (#3 - #7) of nine patient charts audited. Findings include: 1. On May 3, 2018 at 10:35 AM, record review for five (#3 - #7) of nine patient charts audited revealed the final patient test result for the fungal dermatophyte testing was not included in the patient's paper chart. 2. On May 3, 2018 at approximately 11:45 AM when queried, the laboratory director as listed on the CMS-209 was unable to provide the surveyor the final patient test result in the patient's paper chart. 3. During the interview on May 3, 2018 at approximately 11:45 AM, the laboratory director confirmed the final fungal dermatophyte testing results were not included in the patient's paper chart.