

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 44D0869618	(X3) Date Survey Completed 10/09/2023
Name of Provider or Supplier Rheumatology And Dermatology Associates Pc	Street Address, City, State 8143 Walnut Grove Road, Cordova, TN	
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
D2006	<p>TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)</p> <p>The laboratory must examine or test, as applicable, the proficiency testing samples it receives from the proficiency testing program in the same manner as it tests patient specimens. This testing must be conducted in conformance with paragraph (b)(4) of this section. If the laboratory's patient specimen testing procedures would normally require reflex, distributive, or confirmatory testing at another laboratory, the laboratory should test the proficiency testing sample as it would a patient specimen up until the point it would refer a patient specimen to a second laboratory for any form of further testing.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's Wisconsin State Laboratory of Hygiene (WSLH) proficiency testing records, the laboratory procedure manual, patient test reports and interview with the laboratory director, the laboratory failed to report their proficiency testing results to the proficiency testing program in the same manner as it reported patients in 2021, 2022, and 2023. The findings include: 1. Review of the laboratory's WSLH proficiency testing records from 2021, 2022 and 2023 revealed positive results for mycology cultures were reported to the proficiency testing program as 'present.' 2. Review of the laboratory's procedure manual revealed the following under section 9.1.3 "Fungus is reported to the "Species level." 3. Review of patient test reports revealed the following: Laboratory records and letters issued to patients revealed reporting of cultures to the genus and species level as follows: Culture date= 03/02 /2021, Batch #1150928, left 1st toenail, read out on 03/31/2021 as "positive for T. rubrum." A letter was issued to the patient on 03/31/2021 with a comment of "The results show a fungus called Trichophyton rubrum." Culture date=01/27/2022, batch #1152747, scalp, read out on 02/09/2022 as "Positive for Trichophyton tonsurans." A letter was issued to the patient on 02/09/2022 with a comment of "The results show a fungus called Tricophyton tonsurans." Culture date=01/19/2023, batch #1153622, Lt.</p>

	<p>2nd toenail, read out as positive for multiple Candida. A letter was issued to the patient on 02/23/2023 with a comment of "The results show a fungus called Candida albicans." 4. Interview with the laboratory director on 10/09/23 at 11:30 am confirmed the laboratory failed to report fungal culture results to the WSLH proficiency testing program in the same manner as it reported patient results in 2021, 2022 and 2023.</p>
<p>D2038</p>	<p>MYCOLOGY CFR(s): 493.827(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on observation of the laboratory, review of the Centers for Medicare and Medicaid Casper Report 0155D (CMS 155), the laboratory's proficiency testing records and interview with the laboratory director, the laboratory failed to maintain satisfactory participation in mycology for 2023 event two. The findings include: 1. Observation of the laboratory on 10/09/23 at 8 am revealed multiple patient samples for fungal culture being incubated at ambient room temperature. 2. Review of the CMS 155 revealed an overall event score of 75% for 2023 event two for mycology. 3. Review of the laboratory's proficiency testing records revealed an overall event score of 75% for 2023 event two for mycology. 4. Interview with the lab director on 10/09/23 at 11:30 am confirmed the laboratory failed to maintain satisfactory performance for mycology for 2023 event two.</p>
<p>D2044</p>	<p>MYCOLOGY CFR(s): 493.827(d)</p> <p>(1) For any unsatisfactory testing event for reasons other than a failure to participate, the laboratory must undertake appropriate training and employ the technical assistance necessary to correct problems associated with a proficiency testing failure. (2) Remedial action must be taken and documented, and the documentation must be maintained by the laboratory for two years from the date of participation in the proficiency testing event.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing records and interview with the laboratory director, the laboratory failed to perform corrective action for the unsatisfactory event score for 2023 event two for mycology. The findings include: 1. Review of the laboratory's proficiency testing records revealed an overall event score of 75% for mycology with no corrective action performed. 2. Interview with the lab director on 10/09/23 at 11:30 am confirmed the laboratory failed to perform corrective action for the unsatisfactory proficiency testing event for 2023 event two for mycology.</p>
<p>D5006</p>	<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>

This CONDITION is not met as evidenced by:
Based on review of the laboratory's proficiency testing records, interview with the laboratory director, review of the laboratory procedure manual, lack of records, and observations, the laboratory failed to evaluate non-graded proficiency testing scores (Refer to D5215), failed to document review and evaluation of proficiency testing scores (Refer to D5221), failed to have a procedure that matched the laboratory's testing and reporting protocol (Refer to D5403), and failed to perform quality control for each batch of media received (Refer to D5477).

D5215

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(b)(2)

The laboratory must verify the accuracy of any analyte, specialty or subspecialty assigned a proficiency testing score that does not reflect laboratory test performance (that is, when the proficiency testing program does not obtain the agreement required for scoring as specified in subpart I of this part, or the laboratory receives a zero score for nonparticipation, or late return or results).

This STANDARD is not met as evidenced by:
Based on review of the laboratory's WSLH proficiency testing performance evaluation reports and interview with the laboratory director, the laboratory failed to evaluate non-graded proficiency testing scores for two of two proficiency testing samples that were not scored in 2022 and 2023. The findings include: 1. Review of the laboratory's proficiency testing performance evaluation reports revealed the following events with ungraded scores with no documentation of assessment to determine the laboratory's accuracy: 2022 event three sample number MY-11 with a status of *** and a note on the proficiency testing report that self-assessment was needed. 2023 event one sample number MY-1 with a status of *** and a note on the proficiency testing report that self-assessment was needed. 2. Interview with the laboratory director on 10/09/23 at 11:30 am confirmed the laboratory failed to evaluate non-graded proficiency testing scores for 2022 event three, sample MY-11 and 2023 event one, sample MY-1.

D5221

EVALUATION OF PROFICIENCY TESTING PERFORMANCE
CFR(s): 493.1236(d)

All proficiency testing evaluation and verification activities must be documented.

This STANDARD is not met as evidenced by:
Based on review of the laboratory's WSLH proficiency testing records and interview with the laboratory director, the laboratory failed to ensure seven of eight PT reports from 2021, 2022 and 2023 had been reviewed and evaluated. The findings include: 1. Review of the laboratory's WSLH proficiency testing performance evaluation reports revealed the following events with no documented review: 2021 event one, 2021 event three, 2022 event one, 2022 event two, 2022 event three, 2023 event one, 2023 event two. 2. Interview with the laboratory director on 10/09/23 at 11:30 am confirmed the laboratory's proficiency testing reports for the events from 2021, 2022 and 2023 did not have documentation of review and evaluation.

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 observation of the laboratory, review of the laboratory procedure manual, and phone interview with the lab director, the laboratory procedure manual failed to include step-by-step instructions for identification of organisms isolated from fungal cultures, included references to medium not used by the laboratory, failed to include the use of lactophenol cotton blue in the procedures, and failed to have a reporting protocol to use when identification of the organism to the genus or species level was not possible or appropriate. The findings include: 1. Observation of the laboratory on 10/09/23 at 8 am revealed incubation of patient cultures for fungal culture. Also observed was lactophenol cotton blue stain, mycosel agar, potato dextrose agar, sabouraud dextrose agar and Tween agar. No dermatophyte testing medium was observed. 2. Review of the laboratory procedure titled "Laboratory Procedure Manual Fungal Culture" revealed references to the use of dermatophyte testing medium. The use of lactophenol cotton blue or the steps to arrive at identification of the organism was not included in the procedure. The procedure did not include protocol for reporting when identification of the organism to the genus or species level was not possible or appropriate. It also did not specify what type of agar to use for plating patient specimens. 3. During a phone interview with the lab director on 10/19/23 at 2: 30 pm the laboratory director stated the following: He had not used dermatophyte testing medium in over 30 years. He had not used any agar other than mycosel for patient testing in approximately the last five years. He confirmed that the current procedure did not include the use of lactophenol cotton blue, which specific type(s) of agar to use, step-by-step procedures for identifying organisms isolated from patient fungal cultures, reporting protocol to use when identification to the species level is not possible or appropriate, and included the use of dermatophyte testing medium which was not used by the laboratory.

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 observation of the laboratory, lack of records, and interview with the laboratory director, the laboratory failed to perform quality control on media used for performing patient fungal cultures in 2021, 2022, and 2023. The findings include: 1. Observation of the laboratory on 10/09/23 at 8 am revealed mycosel, sabourad dextrose, and potato dextrose agar used for performing patient fungal culture. 2. There was no documentation that end user media quality control was performed by the laboratory for the last two years (2021, 2022, or 2023). 3. Interview with the laboratory director on 10/09/23 at 11:30 am confirmed the laboratory did not perform quality control checks when new batches of media used for performing patient fungal cultures were received in 2021, 2022 and 2023.

D6092

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(4)(iv)

The laboratory director must ensure an approved corrective action plan is followed when any proficiency testing result is found to be unacceptable or unsatisfactory.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's WSLH proficiency testing records and interview with the laboratory director, the laboratory director failed to perform corrective action for two of two proficiency testing samples with unacceptable scores. The findings include: 1. Review of the laboratory' proficiency testing records revealed the following events/samples with unacceptable results with no corrective action performed: 2021 Event two Sample MY-7 2023 Event two sample MY-7 2. Interview with the laboratory director on 10/09/23 at 11:30 am confirmed the laboratory director failed to perform corrective action for unacceptable proficiency testing scores in 2021 and 2023 (two of two proficiency testing samples with unacceptable scores).