

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 03D1083140	(X3) Date Survey Completed 11/07/2023
Name of Provider or Supplier Roadrunner Foot And Ankle	Street Address, City, State 13660 N 94th Drive Ste A-3, Peoria, AZ	
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
D5203	<p>SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232</p> <p>The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results.</p> <p>This STANDARD is not met as evidenced by: Based on review of patient logs, final test reports maintained in the patient's Electronic Medical Record (EMR), and interview with the testing personnel (TP-1), the laboratory failed to ensure positive identification for 3 out of 5 patient specimens from the time of collection through completion of testing and reporting of test results. Findings include: 1. The laboratory performs Dermatophyte (DTM) testing under the subspecialty of Mycology with an annual test volume of 320. 2. The laboratory maintains a hand-written patient log for DTM testing, which includes a unique patient ID assigned by the facility. The final test result information is then manually transcribed into the patient's EMR. 3. The laboratory failed to ensure positive identification of a patient's specimen from the time of collection through completion of testing and reporting of results for three out of five patients as follows: - The patient log for patient J.L. listed the Patient ID as: LOTJAD0001. The final report in the EMR listed the Patient ID as: HF335547629. - The patient log for patient A.G. listed the Patient ID as: GRAASH0001. The final report in the EMR listed the Patient ID as: HF402636260. - The patient log for patient K.B. listed the Patient ID as: BLOKAT0001. The final report in the EMR listed the Patient ID as HF429766997. 4. The TP-1 interviewed on 11/07/2023 at 1:40 PM acknowledged that the laboratory failed to ensure positive identification of the patient's specimens from the time of collection through completion of testing and reporting of results, as evidenced by the specimen identification errors listed above.</p>

<p>D5291</p>	<p>GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on a lack of established policies and procedures for review and interview with the testing personnel (TP-1), the laboratory failed to establish policies and procedures to monitor, assess and correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236. Findings include: 1. No documentation was presented for review during the survey to indicate the laboratory established policies and procedures for assessing the competency of testing personnel. 2. No documentation was presented for review during the survey to indicate the laboratory established policies and procedures for Proficiency Testing (PT). 3. The TP-1 interviewed on 11/07/2023 at 2:30 PM confirmed the laboratory failed to provide documentation of established policies and procedures to monitor, assess and correct problems identified in the general laboratory systems requirements as indicated above.</p>
<p>D5301</p>	<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> <p>This STANDARD is not met as evidenced by: Based on lack of test requisition documentation for review and interview with the testing personnel (TP-1), the laboratory failed to have a written or electronic request for patient testing for one out of five patient records reviewed during the survey. Findings include: 1. The laboratory performs Dermatophyte (DTM) testing under the subspecialty of Mycology with an annual test volume of 320. 2. No written or electronic request for DTM testing was presented for review for one out of five patient records reviewed during the survey (patient ID: BLOKAT001, tested on 4/25/23). 3. The TP-1 interviewed on 11/07/2023 at 1:40 PM confirmed the laboratory failed to have an electronic or written test requisition for DTM testing performed on the patient indicated above.</p>
<p>D5803</p>	<p>TEST REPORT CFR(s): 493.1291(b)</p> <p>Test report information maintained as part of the patient's chart or medical record must be readily available to the laboratory and to CMS or a CMS agent upon request.</p> <p>This STANDARD is not met as evidenced by: Based on lack of a final test report for review and interview with the testing personnel (TP-1), the laboratory failed to provide the final test report for one out of five patient records reviewed during the survey. Findings include: 1. The laboratory performs Dermatophyte (DTM) testing under the subspecialty of Mycology with an annual test</p>

volume of 320. 2. The laboratory failed to provide evidence of the final DTM test report for one of out five patient records reviewed during the survey (patient ID: BLOKAT001, tested on 4/25/23) . 3. The TP-1 interviewed on 11/07/2023 at 1:45 PM confirmed the laboratory failed to provide evidence of the final DTM test report as indicated above.

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 the laboratory's test procedure, review of patient test reports, and interview with the testing personnel (TP-1), the laboratory failed to follow their test procedure for result reporting for three out of three test reports reviewed during the survey. Findings include: 1. The laboratory performs Dermatophyte (DTM) testing under the subspecialty of Mycology with an annual test volume of 320. 2. The laboratory's "ACU-DTM" test procedure for reporting test results states, "Report as positive or negative for the presence of fungi." 3. The laboratory failed to report DTM test results as positive or negative for three out of three patient records reviewed during the survey. Patient test results reviewed in the Electronic Medical Record (EMR) were reported as follows: Pt. ID: TULNA0001, test result = T. Mentagrophytes; Pt. ID: GRAASH0001, test result = T. Rubrum; and Pt. ID: EURROX0001, test result = T. Mentagrophytes. 4. The TP-1 interviewed on 11/07/2023 at 1:25 PM confirmed the laboratory failed to follow the ACU-DTM test procedure for result reporting for the patients indicated above.