

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0693457	(X3) Date Survey Completed 06/06/2024
Name of Provider or Supplier Ronald E Reece Md	Street Address, City, State 2701 Old Eureka Way Ste 2a, Redding, CA	
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
D5401	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor observation and review of laboratory's policy & procedure test results and interview with the laboratory staff on June 6, 2024, at 2:20 pm, the laboratory failed to follow its test procedure of DTM culture for 1 patient out of 4 patients, reviewed. The findings include: 1. The laboratory used a selective medium, Acu-DTM to detect dermatophytes in the patient's sample. According to the procedure a positive test results will turn the culture medium color from yellow to red with the growth of the micoorganisms within 14 days of culture. However, the patient's, initialed as PM sample was cultured on April 30, 2024, and read the result 21 days later May 21, 2024, as positive. A small growth was observed but no color change occurred. The result should have been read as negative instead of positive as instructed in the procedure. Also, the result reading exceeded the 14-day time limit stated in the procedure. On the other had, the same patient's KOH test result was negative on April 30, 2024. Therefore, the accuracy of the laboratory's reported positive result cannot be assured and may have potentially harmed patients. 2. The laboratory staff on June 6, 2024, at 2:20 pm, affirmed that the patient's (PM) sample was read positive and waiting for the doctor to verify. The doctor was out of office. 3. It was determined that the laboratory performed approximately 60 DTM tests, annually based on the surveyor review of the laboratory's test records.</p>
D6004	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(a)(b)</p>

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. (a) The laboratory director, if qualified, may perform the duties of the technical consultant, clinical consultant, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications of 493.1409, 493.1415, and 493.1421, respectively. (b) If the laboratory director reappoints performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's policy & procedure test results and interview with the laboratory staff on June 6, 2024, at 2:20 pm, the laboratory director failed to assure laboratory's compliance with the applicable regulations and may have potentially harmed patients. The findings include: See D5401 and D6070.

D6014

LABORATORY DIRECTOR RESPONSIBILITIES
CFR(s): 493.1407(e)(3)(iii)

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)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.

This STANDARD is not met as evidenced by:
Based on Surveyor review of laboratory's policy & procedure, test results and interview with the laboratory's staff on June, 2024, at 2:20 pm, the laboratory director failed to ensure that the laboratory personnel are performing the test methods as required for accurate and reliable results. The findings include: The laboratory testing personnel did not follow its test procedure for DTM culture. See D5401.

D6070

TESTING PERSONNEL RESPONSIBILITIES
CFR(s): 493.1425(b)(1)

Each individual performing moderate complexity testing must follow the laboratory's procedures for specimen handling and processing, test analyses, reporting and maintaining records of patient test results.

This STANDARD is not met as evidenced by:
Based on Surveyor observation and review of laboratory's policy & procedure, test results and interview with the laboratory staff on June 6, 2024, at 2:20 pm, the laboratory testing personnel failed to follow the laboratory's procedures for test analyses. The findings include: The laboratory testing person #1 did not follow its test procedure for DTM culture. See D5401.