

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0859303	(X3) Date Survey Completed 02/27/2025
Name of Provider or Supplier Jon A Erickson Md Inc Dermatology Clnc	Street Address, City, State 3257 Professional Dr Ste B, Auburn, 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
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</p> <p>(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.</p> <p>This STANDARD is not met as evidenced by: Based on Surveyor review of laboratory's DTM culture records and reagents, and interview with the laboratory director on February 27, 2025, at 11:30 a.m., the laboratory used expired DTM reagents to perform the test. The findings include: 1. The laboratory performed DTM culture test however, it used an expired DTM reagents (expired on 10/21/2024) to test 1 patient sample on 12/3/2024 and 1 on 2/3/2025. Both patients' test results were negative. Therefore, the accuracy of the patients' test results rendered by the laboratory cannot be assured since it used an expired reagents and may have harmed patient. 2. The laboratory director on February 27, 2025, at 11:30 a.m., affirmed that the laboratory used an expired DTM reagents to test patients' sample. 3. The laboratory's testing declaration form, signed by the laboratory director on 2/27/2025, stated that the laboratory performed approximately 13 DTM tests, annually.</p>
D6007	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(1)</p> <p>(e) The laboratory director must-- (e)(1) Ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing;</p>

This STANDARD is not met as evidenced by:

Based on Surveyor review of laboratory's DTM culture records and reagents, and interview with the laboratory director on February 27, 2025, at 11:30 a.m., it was determined that the laboratory director failed to ensure the quality of the analytical system. The laboratory director's failure to ensure quality laboratory services has a consequence of potential erroneous test result reporting and patient harm. The findings include: The laboratory director failed to ensure the maintenance of an acceptable levels of quality laboratory services in the analytical system. See D5417.