

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2027439	(X3) Date Survey Completed 03/21/2024
Name of Provider or Supplier Lauring Dermatology Llc	Street Address, City, State 7642 Belair Road, Nottingham, MD	
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>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 review of the "Tzanck Stain Log" and interview with office manager (OM), the laboratory failed to ensure that the expiration dates of the stains used were not used past the expiration date. Findings: 1. The "Tzanck Stain Log" records for 2023 and 2024 were reviewed to ensure documentation of the lot numbers (#) and expiration dates of the stains and solutions used during the staining process. 2. The "Tzanck Stain Log" records showed that the lot # was being recorded, but not the expiration date. 3. During the survey on 03/21/2024 at 10:15 AM, the OM confirmed that the records failed to include the expiration date of the fungal Tzanck stain that was used in the laboratory.</p>
D5805	<p>TEST REPORT CFR(s): 493.1291(c)</p> <p>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.</p>

This STANDARD is not met as evidenced by:
Based on review of final reports and interview with the office manager (OM), the laboratory failed to ensure that the final test report included the result of the Tzanck Stain (herpes simplex virus) result. Findings: 1. Two final test reports were reviewed in the laboratory's electronic medical record (EMR) system. One of the two test reports did not list the reactivity of the fungal Tzanck stain as positive or negative. 2. During the survey on 03/21/2024 at 10:15 AM, the OM confirmed that the EMR records failed to include the positive or negative reactivity of the fungal Tzanck stain on the final report.