Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	21D2027439	10/21/2022
Name of Provider or Supplier	**Street Address, City, State**	
Lauring Dermatology Llc	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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on review of testing logs and interview with the practice manager (PM), the laboratory failed to maintain the testing logs for at least two years. Findings: 1. The laboratory performed Tzanck smear testing. 2. A log titled "Fungal Tzanck Stain Log" was used to record the date of testing, the stain lot number and expiration date, the stain quality control results, and the patient results. 3. The log only had results from testing performed in 2022. 4. During the survey on 10/21/2022 at 10:00 AM, the PM confirmed that the log sheet for testing performed in 2021 had been removed and could not be located.
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 review of the procedure manual and interview with the practice manager (PM), the laboratory's testing procedure failed to include instructions for using the testing log and for interpreting test results for Tzanck smear testing. Findings: 1. The laboratory performed Tzanck smear testing. 2. A log titled "Fungal Tzanck Stain Log" (log) was used to record the date of testing, the stain lot number and expiration date, the stain quality control (QC) results, and the patient results. 3. The testing procedure gave instructions for preparing and staining the slides and stated to log findings electronically into the patient chart. 4. The procedure did not provide instructions for documenting the test date, stain lot number and expiration date, stain QC results, or patient results on the log. 5. The log had a column for documenting if the stain reaction was consistent with what was expected, but the procedure did not define expected stain characteristics for acceptable stain QC. 6. The procedure did not provide instructions, images, or references for interpretation of patient results. 7. During the survey on 10/21/2022 at 10:00 AM, the PM confirmed that the procedure did not have instructions for interpreting patient results.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview with the practice manager (PM), the laboratory director (LD) failed to approve, sign, and date the procedures prior to use. Findings: 1. The laboratory had two procedures and neither procedure was approved, signed, and dated by the LD. 2. During the survey on 10/21/2022 at 10: 00 AM, the PM confirmed that the procedures were not approved, signed, and dated by the LD prior to use.