

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D2001026	<b>(X3) Date Survey Completed</b> 07/31/2023
<b>Name of Provider or Supplier</b> Vitalogy Skincare DbA (Bastrop)	<b>Street Address, City, State</b> 208 W Sh 71, Bastrop, TX	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D0000</b>	The laboratory was surveyed and found to be in compliance with the Conditions of the CLIA regulations found at 42 CFR 493.1 through 493.1780, and recertification is recommended.
<b>D5417</b>	<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 chemical log, patient testing logs, and interview, the laboratory failed to ensure chemicals and stains used in the Hematoxylin and Eosin (H&amp;E) stain used to process Mohs specimens had not exceeded their expiration date by one month out of 14 months reviewed for Eosin. Findings follow. A. Review of the H&amp;E Linear Stainline Log showed at the bottom of the page where chemicals were documented when opened and showed in January 2022 Eosin-y, Lot number 108396, expiration 12/22 was opened, and not logged again until February 2023, Eosin, Lot number 111055, expiration 04/23. B. Review of the Mohs log showed 42 cases, SBA23-001 - SBA23-042 had been processed and tested with Eosin from 01/04/2023 - 01/23/2023. C. Interview with the Laboratory Manager on July 31, 2023 at 1520 hours confirmed there was no documentation showing Eosin had been opened prior to February 2023 showing Eosin wasn't expired.</p>
<b>D5805</b>	<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</p>

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 patient test reports and interview, the laboratory failed to include the correct name and address of the facility where the Mohs testing was performed for one of 11 reports reviewed. Findings follow. A. Review of 11 test reports showed one had the following name and address for the Mohs testing performed at- Vitalogy Skincare GT, 4513 Williams Drive, Georgetown, TX 78633: 1. MRN: 105865 on June 27, 2023. B. Interview with the Laboratory Manager on August 1, 2023 at 1530 hours confirmed the findings. KEY: MRN - Medical Record Number