

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D1097978	<b>(X3) Date Survey Completed</b> 02/27/2024
<b>Name of Provider or Supplier</b> Vitalogy Skincare DbA (Cedar Park)	<b>Street Address, City, State</b> 1610 East Whitestone, Cedar Park, 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 reagent 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 two out of seven months reviewed for Hematoxylin. Findings follow. A. Review of the Chemical Tracker Log showed Stat Lab Hematoxylin, Lot # 147706, expiration 10/31/2023 was opened on 09/27/2023, and the next entry was on 01/31/2024 for FisherFinest Hematoxylin, Lot #131008, expiration date 12/01/2024 received and opened on 01/31/2024 revealing an elapsed expiration of two months. B. Review of the Mohs Accession Log from 07/26/2023 - 01/31/2024 showed one out of six days of Mohs testing with expired Hematoxylin on 11/20/2023 with 11 cases reported: HC23-031 - HC23-041. C. Interview with the Laboratory Manager on February 27, 2024 at 1445 hours confirmed the findings.</p>
<b>D5801</b>	<p>TEST REPORT CFR(s): 493.1291(a)</p> <p>The laboratory must have an adequate manual or electronic system(s) in place to ensure test results and other patient-specific data are accurately and reliably sent from</p>

the point of data entry (whether interfaced or entered manually) to final report destination, in a timely manner. This includes the following: (a)(1) Results reported from calculated data. (a)(2) Results and patient-specific data electronically reported to network or interfaced systems. (a)(3) Manually transcribed or electronically transmitted results and patient-specific information reported directly or upon receipt from outside referral laboratories, satellite or point-of-care testing locations.

This STANDARD is not met as evidenced by:

Based on review of the Mohs map and interview, the laboratory failed to accurately transcribe the date of birth on the Mohs map for one out of seven cases reviewed from 07/26/2023 - 01/31/2024. Findings follow. A. Random review of seven Mohs cases from 07/26/2023 - 01/31/2024 showed one Mohs map compared to the chart notes with a different date of birth, as listed by case number and date of service: HC24-006 on 01/31/2024. B. Interview with the Clinic Manager on February 27, 2024 at 1520 hours verified the date of birth on the Mohs map was incorrect.