

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1097978	(X3) Date Survey Completed 08/12/2025
Name of Provider or Supplier Vitalogy Skincare DbA (Cedar Park)	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	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. Standard level deficiencies were cited.
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure, accuracy assessments and interview, the laboratory failed to verify the accuracy of KOH (potassium hydroxide) for fungal elements at least twice annually for 1 of 2 years (2 of 4 events) reviewed in 2023 and 2024. Findings follow. A. Review of the laboratory's policy and procedure titled KOH Prep, 09/2022, under Accuracy Assessment stated, "A provider will review the slides to confirm the initial diagnosis from the original clinician for positive or negative results; this should be reviewed within 1 hour of the test being performed. The provider reviewing the slide must complete a KOH/Scabies Bi-Annual Accuracy Assessment Form. If no slide is available for review by May or November of each year, an Accuracy Assessment Test will be given to the provider to be completed." B. Review of accuracy assessments from 2023 and 2024 for KOH for fungal elements showed none for 2024. Accuracy assessments were requested but not provided on August 12, 2024 at 0950 hours. C. Interview with the Clinic Manager on August 12, 2024 at 0950 hours in the office verified there were no accuracy assessments in 2024 for KOH.</p>
D5417	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)</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.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, reagent log, patient testing logs, interview, and pre-survey paperwork, the laboratory failed to ensure chemicals and stains used in the Hematoxylin and Eosin (H&E) stain used to process Mohs specimens had not exceeded their expiration date by 271 out of 730 days reviewed. Findings follow. A. Review of the laboratory's policies and procedures titled Chemical Hygiene/Chemical Exposure Plan, approved 03/31/2025, stated at 5.10 "All commercially purchased chemicals/reagents, stock solutions and working solutions must be used prior to their indicated expiration dates: 1) The SharePoint Chemical Tracker will be used by technicians to document technician initials, 2) the clinic location of the chemical, 3) the manufacturer, 4) the full chemical name and concentration, 5) the chemical lot number, 4) the open date, 7) the expiration date, and 8) the date waste removed from patient testing prior to the expiration date of the chemical and the technical removing the chemical from the testing process and 8) dispose expired chemicals according to the SharePoint Safety Material Data Sheet and local and federal regulations. Do not use expired chemicals." B. Review of the SharePoint Chemical Tracker showed: 1. Hematoxylin a. Lot #147706, expiration date 10/31/2023, was opened on 9/27/2023 and the next entry was Lot # 131008, expiration date 12/01/2024, was opened on 01/31/2024 revealing an elapsed expiration of 92 days. b. Lot #131008, expiration date 12/01/2024, was opened on 01/31/2024 and the next entry was Lot # 144470, expiration 01/01/2026, was opened on 02/19/2025 revealing an elapsed expiration of 80 days. 2. Eosin a. Lot # 129232, expiration 10/01/2024 was opened on 09/27/2023 and the next entry was Lot #143922, expiration date 12/01/2025 was opened on 01/08/2025 revealing an elapsed expiration of 99 days. C. Review of the Mohs Accession Log: 1. a. From 10/31/2023 - 01/31/2024 showed 1 day of Mohs testing on 11/20/2023 with expired Hematoxylin and 11 cases reported (HC23-031 - HC23-041). b. From 12/01/2024 - 02/19/2025 showed 2 days of Mohs testing on 01/08/2025 and 01/15/2025 with expired Hematoxylin and 21 cases reported (HC25-001 - HC25-021). 2. From 10/01/2024 - 01/08/2025 showed 1 day of Mohs testing on 10/22/2024 with expired Eosin with 13 cases reported (HC24-114 - HC24-126). D. Interview with the Laboratory Manager on August 12, 2025 at 1005 hours in the office confirmed the findings. E. Review of the CMS Form 116 showed approximately 126 blocks were reported annually.