

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1081803	(X3) Date Survey Completed 07/07/2022
Name of Provider or Supplier Vitalogy Skincare DbA (San Marcos)	Street Address, City, State 1320 Wonder World Dr Suite 108, San Marcos, 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	Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
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 accuracy assessments, patient testing logs, and interview, the laboratory failed to perform twice a year accuracy assessment of its Frozen sections for the dermatopathology interpretations (diagnosis) for 1 of 2 events reviewed. Findings follow. 1. Review of the accuracy assessments from 06/10/2021 - 07/07/2022 showed 1 event performed on 07/07/2022. Additional accuracy assessments were requested on July 7, 2022 at 1130 hours but not provided. 2. Review of the Frozen Section Accession Log for 2021 showed the laboratory reported frozens as early as 06/10/2021, (previous logs were not reviewed). 3. Interview with the Laboratory Manager on July 7, 2022 at 1130 hours in the office confirmed accuracy assessments for Frozens were not performed in 2021.</p>
D5473	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The</p>

laboratory must document all control procedures performed.

This STANDARD is not met as evidenced by:

Based on review of the laboratory's policies and procedures, patient testing logs, quality control (QC) records, and interview, the laboratory failed to document the reactivity of the Hematoxylin and Eosin stain to ensure predictable staining characteristics for their quality control used in Mohs testing for 2 out of 46 events reviewed. Findings follow. 1. Review of the laboratory's policy and procedure titled Professional Competency, revised 08/22/2018, stated, "In the field of Histopathology, we run controls on a daily basis with the patient slides to identify the presence /absence of the analyte: Eosin/Three shades of pink: red blood cells - dark reddish orange, collagen - lighter pastel pink and smooth muscle- bright pink. All daily/batch control information is documented by the surgeon on the H&E (Hematoxylin and Eosin Control Slide assessment). ... The control slide is verified for accuracy prior to case diagnosis with the date." 2. Review of the Mohs Accession Log showed from Feb - May 2022 there were 46 days of Mohs patient testing. 3. Review of the H&E Control Slide QC log showed QC was not documented on 05/19/2022 and 04/14 /2022. 4. Interview with the Laboratory Manager on July 7, 2022 at 1200 hours in the office confirmed quality control was not documented on days of patient testing.