

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D1056890	<b>(X3) Date Survey Completed</b> 07/06/2022
<b>Name of Provider or Supplier</b> Vitalogy Skincare DbA (Burnet)	<b>Street Address, City, State</b> 200 Cr 340 A, Bldg 4 Suite B, Burnet, 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>	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.
<b>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on review of competency records, pre-survey paperwork, and interview, the laboratory failed to ensure the competency of 2 of 2 Technical Supervisors/General Supervisors performing Mohs testing. Findings follow. 1. Review of competency evaluations revealed no competency evaluations were performed for personnel acting in the capacity of Technical Supervisors (TS) and General Supervisors (GS) in Mohs testing. 2. Review of the pre-survey paperwork, showed TS/GS #1, as listed on the CMS form 209, began Mohs testing at the facility on 09/01/2020, and TS/GS #2 began Mohs testing at the facility on 11/20/2020. 3. Interview with the Laboratory Manager on July 6, 2022 at 1055 hours in the office acknowledged they never qualified Mohs surgeons (outside the LD) as TS/GS.</p>
<b>D5217</b>	<p><b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b> 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>

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 11 of 11 months reviewed. Findings follow. 1. Accuracy assessments for the dermatopathology interpretations of Frozen sections were requested on July 6, 2022 at 1225 hours but not provided. 2. Review of the Frozen Section Accession Log showed from 08/11/2021 - 07/06/2022 there were 2 cases/patients reported. 3. Interview with the Laboratory Manager on July 6, 2022 at 1235 hours in the office confirmed accuracy assessments for Frozen sections were not performed.

**D5805**

**TEST REPORT**  
CFR(s): 493.1291(c)

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 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 the patient test reports, slides, and interview, the laboratory failed to report the results of the Immunohistochemical (IHC) stains for two of nine Mohs test reports reviewed. Findings follow. 1. Review of nine Mohs cases with IHC stains, showed the patient reports for Mohs case PB22-238 was missing the result of the Mart-1 stain, and Mohs case PB21-466 was missing the result of the CK5 (Cytokeratin 5) stain. 2. Review of the case slides showed the slides for both IHC stains. 3. Interview with the Laboratory Manager on July 6, 2022 at 1245 hours in the office confirmed the results of the IHC stain were not in the reports.