

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 45D1069391	<b>(X3) Date Survey Completed</b> 08/30/2022
<b>Name of Provider or Supplier</b> Vitalogy Skincare DbA (Georgetown)	<b>Street Address, City, State</b> 4513 Williams Drive, Georgetown, 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>	A recertification survey was performed on The laboratory was found out of compliance with the CLIA regulations. The condition not met was: D6000 - 42 C.F.R. 493.1403 Condition: Laboratories performing moderate complexity testing; laboratory director. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference.
<b>D5217</b>	<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 verify the accuracy of KOH (potassium hydroxide) for fungal elements and Scabies at least twice annually for 1 of 2 years (2 of 4 events) reviewed in 2020 and 2021. Findings follow. A. Review of accuracy assessments from 2020 and 2021 for KOH for fungal elements and Scabies showed none for 2021 (and none to date for 2022). Accuracy assessments were requested but not provided on August 30, 2022, at 1040 hours. B. Review of the KOH Test Accession Logs from 2021 - 2022 showed 17 patients were tested for fungal elements and 6 patients were tested for Scabies. C. Interview with the Clinic Manager on August 30, 2022, at 1040 hours in the conference room acknowledged accuracy assessments were done in 2020 only. Follow up interview with the Clinic Manager on August 30, 2022, at 1230 hours in the conference room confirmed there were no procedures for accuracy assessments for KOH and Scabies.</p>
<b>D6000</b>	<p>MODERATE COMPLEXITY LABORATORY DIRECTOR CFR(s): 493.1403</p>

	<p>The laboratory must have a director who meets the qualification requirements of 493.1405 of this subpart and provides overall management and direction in accordance with 493.1407 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on review of accuracy assessments, competency evaluations, patient testing logs, and interview the laboratory director failed to provide overall management and direction of the laboratory (see D6014 and D6030).</p>
<p><b>D6014</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(3)(iii)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(3) Ensure that-- (e)(3)(iii) Laboratory personnel are performing the test methods as required for accurate and reliable results.</p> <p>This STANDARD is not met as evidenced by: Based on review of accuracy assessments, patient testing logs, and interview, the Laboratory Director failed to ensure accuracy assessments of KOH (potassium hydroxide) for fungal elements and Scabies were performed at least twice annually for 1 of 2 years (2 of 4 events) reviewed in 2020 and 2021 (see D5217).</p>
<p><b>D6030</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1407(e)(12)</p> <p>The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(12) Ensure that policies and procedures are established for monitoring individuals who conduct preanalytical, analytical, and postanalytical phases of testing to assure that they are competent and maintain their competency to process specimens, perform test procedures and report test results promptly and proficiently, and whenever necessary, identify needs for remedial training or continuing education to improve skills;</p> <p>This STANDARD is not met as evidenced by: Based on review of competency evaluations, patient testing logs, and interview, the Laboratory Director failed to ensure competency evaluations were performed for individuals performing KOH (potassium hydroxide) for fungal elements and Scabies at least annually after the first year the individual tested patient specimens for three of three testing personnel for 1 of 2 years reviewed (refer to D6054).</p>
<p><b>D6054</b></p>	<p><b>TECHNICAL CONSULTANT RESPONSIBILITIES</b> CFR(s): 493.1413(b)(9)</p> <p>The technical consultant is responsible for evaluating and documenting the</p>

performance of individuals responsible for moderate complexity testing at least annually, after the first year.

This STANDARD is not met as evidenced by:

Based on review of competency evaluations, patient testing logs, and interview, the technical consultant failed to document the performance of individuals performing KOH (potassium hydroxide) for fungal elements and Scabies at least annually after the first year the individual tested patient specimens for three of three testing personnel for 1 of 2 years reviewed. Findings follow. A. Review of competency evaluations from 2020 and 2021 for KOH for fungal elements and Scabies showed none for 2021 (and none to date in 2022). Competency evaluations were requested but not provided on August 30, 2022, at 1015 hours. B. Review of the KOH Test Accession Logs from 2021 - 2022 showed 17 patients were tested for fungal elements and 6 patients were tested for Scabies. C. Interview with the Clinic Manager on August 30, 2022 at 1015 hours in the conference room acknowledged competency evaluations were done in 2020 only. Follow up interview with the Clinic Manager on August 30, 2022, at 1230 hours in the conference room confirmed there were no procedures for competency evaluations for KOH and Scabies.