

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D1069391	<b>(X3) Date Survey Completed</b>  09/25/2024
<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>	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.
<b>D1001</b>	<p>CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e)</p> <p>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.</p> <p>This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions, laboratory's policy and procedure, patient testing log, presurvey paperwork, and interview, the laboratory failed to document the internal controls for the Sekisui OSOM Card Pregnancy Test for one of one testing person interviewed. Findings follow. A. Review of the Sekisui OSOM Card Pregnancy Test package insert, 2012, under Quality Control for Internal Quality Control stated, "Internal procedural controls are incorporated into each OSOM Pregnancy Test for routine quality checks. The same labeled conjugate antibody results in the appearance of both the test and the control bands. The appearance of the control band in the result window is an internal positive procedural control which validates the following: Test System: The appearance of the control band assures that the detection component of both the test line and control line is intact, that adequate sample volume was added and that adequate capillary migration of the sample has occurred. It also verifies proper assembly of the Test Device. Operator: The appearance of the control band indicates that an adequate volume of fluid was added to the sample well for capillary migration to occur. If the control band does not appear at the read time the test is invalid. The clearing of the background in the results area may be documented as a negative procedural control. It also serves as an additional capillary flow control. At the read time, the background should appear white to light</p>

gray and not interfere with the reading of the test. The test is invalid if the background fails to clear and obscures the observation of a distinct control band." B. Review of the laboratory's policy and procedure titled Work Instructions for Performing HCG Testing, effective 05/21/2012, under 5.0 Performing HCG Test at 5.2 Interpreting Results stated "A Positive Result is: Two distinct red lines. One line should be in the control region, the other in the test region. (Refer to the illustration packaged with the HCG test). A Negative result is: One red line appears in the control region. No apparent red or pink line appears in the test region. (Refer to the illustration packaged with the HCG test). An Invalid result is: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failures. Review the procedure and repeat the test with a new test. If the problem persists discontinue use of the test kits immediately and contact technical support at (800)-637-3717 C. Review of the HCG Test Kit Quality Control/Patient Log from 06/20/2024 - 08/08/2024 showed documentation of the results for the Internal Control with Yes/No option. Review of the log showed 23 patient tests were performed from 06/20/2024 - 08/08/2024. D. Review of the CMS Form 116 showed an estimated annual test volume of 142. E. Interview with the Medical Assistant on September 25, 2024 at 1700 hours in the conference room stated she thought the control column meant external controls were performed on the box and was answering Yes for the column under Internal Control.

**D6054**

**TECHNICAL CONSULTANT RESPONSIBILITIES**  
CFR(s): 493.1413(b)(9)

The technical consultant is responsible for evaluating and documenting the 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 the laboratory's policy and procedure, competency evaluations, patient testing logs, and interview, the technical consultant failed to document the performance of individuals performing KOH (potassium hydroxide) for fungal elements at least annually for one of two KOH testing personnel for one of two years reviewed. Findings follow. A. Review of the laboratory's policy and procedure titled KOH Prep, 09/2022, under Accuracy Assessment and Competency Review stated, "This PPM test is a Moderate Complexity procedure and is required to document accuracy assessment and competency reviews at least twice a year." B. Review of competency evaluations from 2022 and 2023 for KOH for fungal elements showed none for 2023 for testing personnel #4 (as listed on the CMS Form 209). C. Review of the KOH Test Accession Logs from 2023 - 2024 revealed testing personnel #4 had reported a KOH on 06/20/2023 (K23-013) and 05/16/2024 (K24-007). D. Interview with the Clinic Manager on September 25, 2024 at 1440 hours in the conference room stated she thought the quiz was substitute for the competency evaluation.