

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D1056890	(X3) Date Survey Completed 09/12/2018
Name of Provider or Supplier Vitalogy Skincare DbA (Burnet)	Street Address, City, State 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.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
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 quality assurance records from 2017 through 2018, patient test records for 2017 and 2018 and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for KOH preparations in 2017 and 2018. Findings included: 1. A review of the laboratory's quality assurance records from 2017 through 2018 found no documentation of verification of the accuracy of results for KOH preparations. The laboratory provided one testing event for the 2017 MLE-M3 Medical Laboratory Evaluation (MLE) proficiency testing records for CLIA 45D1069391 as their own. The laboratory also provided the enrollment form for 2018 for the same laboratory. 2. Review of patient test records found that the laboratory tested 16 patient specimens for KOH between February 3, 2017 and May 16, 2018 without verifying the accuracy of the results for KOH or participating in a Proficiency testing program. 3. An interview with the clinic manager conducted on September, 2018 at 10:28 AM confirmed the laboratory was neither enrolled in a proficiency testing program nor did the laboratory have a method in place to verify the accuracy of the test results for KOH at least twice a year.</p>
D6079	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b)</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, record and report test results promptly, accurately and proficiently,</p>

and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed.

This STANDARD is not met as evidenced by:

Review of policies and procedures, patient test records, verification of accuracy of results and interview of facility personnel found that the laboratory director failed to ensure that the results for KOH had been verified at least twice annually in 2017 and 2018. (see D 5217)