Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2001026	03/01/2018
Name of Provider or Supplier	**Street Address, City, State**	
Vitalogy Skincare Dba (Bastrop)	208 W Sh 71, Bastrop, 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
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 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. This STANDARD is not met as evidenced by: Based on a review of policies and procedures, personnel records, and interview of facility personnel it was revealed that the laboratory failed to have a procedure to assess the competency of the technical consultant and testing personnel . Findings were: 1. A review of policies and procedures found no written policy for assessing the competency of all supervisors, consultants and testing personnel. 2. .Interview of the clinic manager conducted on March 1, 2018 at 11:16 AM confirmed there was no procedure for assessing the competency of the technical consultant or testing personnel.
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) 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. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality assurance records from 2016 through 2018 and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for KOH preparations in 2017. Findings included: 1. A review of the laboratory's quality assurance records from 2016 through 2018 found no documentation of verification of the accuracy of results for KOH

	preparations in 2017. The last recorded verification of accuracy of results was documented on December 17, 2016. The laboratory was not enrolled in a CMS approved proficiency testing program for Clinical Microscopy. 2. An interview with the clinic manager conducted on March 1, 2018 at 10:58 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.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Review of policies and procedures and interview of facility personnel found that the laboratory director failed to approve, sign and date two of 3 procedures for Bacteriology found in the Competency assessment (new employees) notebook. Findings included: 1. Review of policies and procedures found in the notebook labeled Competency assessment (new employees) contained 3 procedures. Two of the three procedures were not approved signed and dated by the current laboratory director. The procedures titled Wet Prep/KOH and Scabies Prep Procedure had no documentation of approval by the current laboratory director. 2. Interview of the clinic manager conducted on March 1, 2018 at 11:27 AM confirmed the procedures had no documentation of approval by the current laboratory director.
D6031	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(13) 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)(13) Ensure that an approved procedure manual is available to all personnel responsible for any aspect of the testing process; This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, manufacturer's instructions and interview of facility personnel, the Laboratory Director failed to ensure an approved procedure was available for assessing the competency of all supervisors, consultants and testing personnel and for KOH and Scabies Prep testing . Refer to D 5209 and D5407.