Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0930456	10/23/2019
Name of Provider or Supplier	**Street Address, City, State**	
Epiphany Dermatology	1916 Paseo San Luis, Sierra Vista, AZ	

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
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- (d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of quality control (QC) documentation and interview with the facility personnel, the laboratory failed to perform and document control procedures using the number and frequency as required. Findings include: 1. The laboratory performs DTM testing using the Acu-DTM media under the sub-specialty of Mycology, with an approximate annual test volume of 7. 2. It is the policy of the laboratory to perform Quality Control testing on each new lot or shipment of DTM media. The QC process includes testing 4 vials with specific organisms that either support or inhibit growth as expected. 3. No documentation of Quality Control testing was provided for review during the survey conducted on October 23, 2019 to indicate the laboratory checked the lot of media currently used by the laboratory for patient testing, for its ability to support growth and inhibit specific organisms and produce a biochemical response. The lot of DTM media in use at the time of the survey was lot# D-1295-1018, exp. 10 /08/2020. The laboratory noted that it was received on 12/10/2018. 4. The facility personnel confirmed that the laboratory did not perform and document controls as required for the DTM lot in use at the time of the survey. 5. There were approximately 8 patients tested since the date in which the new lot was received by the laboratory.

D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on lack of Quality Control (QC) documentation and interview with the facility personnel, the laboratory failed to document the acceptability of staining materials used for testing performed in the sub-specialty of histopathology. Findings include: 1. The laboratory performs Mohs testing in the sub-specialty of Histopathology, with an approximate annual test volume of 393. 2. No documentation of the Hematoxylin & Eosin (H & E) stain acceptability was presented for review for testing that occured on 07/31/2018. Approximately 5 patients were tested that day. 3. The facility personnel confirmed that the laboratory evaluated the H & E stain acceptability each day prior to testing patients but failed to document the stain acceptability on the date indicated above.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on lack of Quality Control records for review, the laboratory director failed to ensure that quality control programs are maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. See D5445 and D5473 for findings.