Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2146160	02/04/2020
Name of Provider or Supplier	**Street Address, City, State**	
Vivida Dermatology	1490 E Foremaster Dr #150, Saint George, UT	

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
D3031	RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3) Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years. This STANDARD is not met as evidenced by: Based on patient test records review and interview with staff, the laboratory failed to retain Mohs frozen section maps for at least 10 years that included the color designation of the specimen ink used to determine orientation of the specimenfor 1 of 4 Mohs maps reviewed (case # 19-0098). Findings include. 1. Patient test records for Mohs maps reviewed were scanned into the patient's chart in the electronic medical record. 2. Patient's electronic medical record of the Mohs frozen section specimen map for case 19/0098 for a 3 stage procedure was scanned into the record using black and white ink. The scanned map did not include the ink colors used to designate the specimen orientation in stages I, II, and III. and location of the residual tumor cells in stages I and II. 3. In an interview with staff on 02/04/2020 at approximately 2:30 P.M. staff stated the scans were made without a method to identify the specimen orientation for specimen 19-0036.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

	This STANDARD is not met as evidenced by: Based on lack of quality control tissue, manufacturer's instructions review, and interview with staff, the laboratory failed to check Mart 1 immunohistochemical (IHC) stains for positive and negative antibody reactivity each time of use for 2 of 2 IHC stained specimen records reviewed for Mohs case #18-287. Findings include: 1. The laboratory did not have tissue specimens with known positive and negative reactivity for the Mart 1 antibody on 02/04/2020. 2. The Mart 1 IHC stain kit stated the positive control cells for the Kit included CaCl (Calcium Chloride) melanoma cells. 3. In an interview conducted on 02/04/2020 at approximately 2:30 P.M. staff stated their process was to view the positively stained cells in the patients tissue as documentation of the positive control and the negative control was to view the cells that did not stain differentially in the patient's tissue. It could not be determined how the laboratory verified the antibody reaction was specific for melanocytes versus non specific staining.