

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  46D2146160	<b>(X3) Date Survey Completed</b>  09/26/2018
<b>Name of Provider or Supplier</b>  Vivida Dermatology	<b>Street Address, City, State</b>  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.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5423</b>	<p><b>ESTABLISHMENT AND VERIFICATION OF PERFORMANCE</b> CFR(s): 493.1253(b)(2)</p> <p>Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.</p> <p>This STANDARD is not met as evidenced by: Based on procedure manual review, lack of documentation, and interview with staff, the laboratory failed to establish the test performance characteristics for accuracy, precision, and analytical sensitivity and specificity for 3 of 3 immunohistochemical stains included in their test menu. Finding include: 1. The procedure manual contained procedures for performing Mart 1, CK 7 and CK 5/6 tests on Mohs surgery frozen tissue samples. 2. The laboratory lacked documentation of onsite validation studies for test accuracy, precision, sensitivity, and specificity performed with their reagents and personnel to determine test performance specifications. 3. In an interview on 09/26 /2018 at approximately 11:00 a.m. the director stated he was not aware that the laboratory needed to do their own validation studies to assure test reliability.</p>
<b>D5473</b>	<p><b>CONTROL PROCEDURES</b> CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e)</p>

(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 laboratory testing records review, lack of documentation and interview with staff, the laboratory failed to document Hematoxylin and Eosin (H&E) stain quality adequacy each day of testing for 7 of 7 days of testing reviewed. Findings include: 1. Laboratory testing records document Histopathology testing including H&E staining on 07/18/2018, 05/23/2018, 06/25/2018, 07/23/2018, 08/20/2018, 09/12/2018, and 05/09/2018. 2. The laboratory lacked documentation H&E stain quality had been evaluated for intended reactivity each day of testing. 3. Staff confirmed on 09/26/2018 at approximately 11:00 a.m. they had not been documenting H&E stain quality daily.

**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 patient record review and interview with staff, the laboratory failed to document Mart 1 immunohistochemical (IHC) stains had been checked for positive and negative reactivity each time of use for 3 of 3 Mohs surgery test records reviewed that included the evaluation of Mart 1 staining in the test results. Findings include: 1. Patient records included documentation of Mart 1 stain performance for patient 18-0014 on 05/23/2018, patient 18-0089 on 08/20/2018, and patient 18-0056 on 07/18/2018. 2. Patient test records included a blank space for evaluation of stain adequacy for IHC stains. 3. All 3 records failed to include documentation the stain had been evaluated for positive and negative reactivity. 4. The director confirmed on 09/26/2018 at approximately 11:00 a.m. Mart 1 stain adequacy had not been documented on the report or elsewhere in the laboratory.