

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D2116798	<b>(X3) Date Survey Completed</b>  08/17/2018
<b>Name of Provider or Supplier</b>  Dermisurgery Associates-The Woodlands	<b>Street Address, City, State</b>  17183 I-45 Suite 510, Conroe, TX	
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>D0000</b>	The laboratory was found out of compliance with the CLIA regulations. The conditions not met were: D5400 - 42 C.F.R. 493.1250 Condition: Analytic systems; D6076 - 42 C.F.R. 493.1441 Condition: Laboratories performing high complexity testing; laboratory director; The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
<b>D5217</b>	<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:</p> <p>A. Based on review of the laboratory records and confirmed in an interview, the laboratory failed to document at least twice annually the accuracy of 1 of 4 tests. (grossing) Findings were: 1. A review of laboratory testing records from 2016 and 2017 revealed no documentation of the laboratory verifying the accuracy for the test grossing for 2016 and 2017. 2. An interview with the Director of Operations on 8/17/18 at 0940 hours in the laboratory confirmed the above findings. She acknowledged that the laboratory did not perform the twice annual accuracy assessment for 2016 or 2017 for grossing. B. Based on review of the laboratory records and confirmed in an interview, the laboratory failed to include a policy to assess the twice annual accuracy assessments of 4 of 4 tests. (grossing, H/E, Toluidine blue, Mart-1) Findings were: 1. Review of the laboratory policy revised 8/17 revealed no documentation of the acceptance criteria of the physician peer review for the proficiency testing performed for 4 of 4 tests (grossing, H/E, Toluidine blue, Mart-1). 2. A review of the 2016 and 2017 laboratory records revealed the laboratory performed proficiency testing for 3 of 4 tests (H/E, Toluidine blue, and Mart-1) on the following dates with no documentation of the assessment of the proficiency testing performed. 9/1/16 10/27/16 5/3/17 9/1/17</p>

3. An interview with the Director of Operations on 8/17/18 at 0940 hours confirmed the above findings. key: H/E - Hematoxylin and eosin stain Mart-1: Melan-A (Melanoma Marker) (Cocktail) Ab-3

**D5291**

**GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT**  
CFR(s): 493.1239(a)

The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and, when indicated, correct problems identified in the general laboratory systems requirements specified at 493.1231 through 493.1236.

This STANDARD is not met as evidenced by:  
Based on review of laboratory policies and records, the laboratory quality assessment failed to identify that the laboratory did not perform and/or assess the twice annual accuracy assessment for all tests performed in the laboratory (refer to D5217A, B).

**D5400**

**ANALYTIC SYSTEMS**  
CFR(s): 493.1250

Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed.

This CONDITION is not met as evidenced by:  
Based on review of the manufacturer package inserts, patient test logs, a review of the FDA (Federal Drug Administration) website, laboratory's procedure manual and confirmed in interview, the laboratory failed to have a procedure and perform the establishment studies for the MART-1 immunostaining put into use in 2016 (refer to D5423 A, B).

**D5413**

**TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT**  
CFR(s): 493.1252(b)

The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.

This STANDARD is not met as evidenced by:  
Based on observation, a review of manufacturer's product packaging, and confirmed in interview, the laboratory failed to document the room temperature of the laboratory's storage area. Findings were: 1. During a tour of the laboratory on 8/17/18 at 1020 hours revealed no chart or thermometer for recording room temperature

available for review at the time of the survey for the laboratory's storage area. 2. A random review of the laboratory supplies in the storage area in the flammable cabinet revealed 1 container of Pro-par Clearant (lot 6290, exp 2020/02) and 1 container of 100% Reagent Alcohol (6900-1, lot 061672, exp 11/19). Review of the manufacturer product packaging of both containers revealed the storage required was "store at room temperature." 3. An interview of the testing person #2 on 8/17/18 at 1030 hours in the laboratory confirmed she was not documenting the room temperature of the laboratory's storage area.

**D5423**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
CFR(s): 493.1253(b)(2)

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.

This STANDARD is not met as evidenced by:

A. Based on review of the manufacturer package inserts, patient test logs, a review of the FDA (Federal Drug Administration) website, laboratory's procedure manual and confirmed in interview the facility failed to have a procedure for conducting establishment studies for the MART-1 immunostaining put into use in 2016. 1. A review of the Thermoscientific MART-1 package insert (REV 102414M) revealed the test was "For Research Use Only". 2. A review of patient test logs from 2016-2018 revealed the facility performed 4 MART-1 immunostaining tests. 4/1/16 17DST20 7/27/17 17DST188 7/31/17 17DST197 8/21/17 17DST214 3. A review of the FDA (Federal Drug Administration) website revealed the Thermoscientific MART-1 was not an FDA-approved test. Since the test system was not approved by the FDA, the test system performance specifications for analytical sensitivity, analytical specificity, accuracy, precision must be established and verified by the laboratory. 4. A review of laboratory procedures revealed no procedure for conducting method validation studies to establish performance specifications and to validate method performance for the following method characteristics for new test systems, as applicable: accuracy precision (within run, between run, between day) reportable range analytical sensitivity and specificity reference intervals reagent lot variation 5. An interview with the Director of Operations on 08/17/2018 at 0950 hours in the laboratory confirmed the above findings. B. Based on review of the laboratory's patient test logs, a review of the FDA (Federal Drug Administration) website, laboratory records and staff interview, the laboratory failed to document complete establishment studies prior to patient testing for MART-1 immunostaining put into use in 2016. Findings were: 1. A review of the laboratory's patient test logs revealed the laboratory started using the MART-1 immunostaining on 4/1/16. 2. A review of the laboratory's patient test logs from 2016-2018 revealed the laboratory performed MART-1 immunostaining on 4 patients. 4/1/16 17DST20 7/27/17 17DST188 7/31/17 17DST197 8/21/17 17DST214 3. A review of the FDA website revealed the Thermoscientific MART-1 was not an FDA-approved test. Since the test system was not approved by the FDA, the test

	<p>system performance specifications for analytical sensitivity, analytical specificity, accuracy, precision must be established and verified by the laboratory. 3. Review of the laboratory records revealed no documentation of the laboratory establishing the performance specifications for analytical sensitivity, analytical specificity, accuracy, precision studies prior to patient testing for MART-1 immunostaining. 4. An interview with the Director of Operations on 08/17/2018 at 0950 hours in the laboratory confirmed the above findings. Key: Mart-1: Melan-A (Melanoma Marker) (Cocktail) Ab-3</p>
<p><b>D6076</b></p>	<p><b>LABORATORY DIRECTOR</b> CFR(s): 493.1441</p> <p>The laboratory must have a director who meets the qualification requirements of 493.1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart.</p> <p>This CONDITION is not met as evidenced by: Based on a review of laboratory records and interview of facility personnel it was revealed that the laboratory director failed to provide overall management and direction of the laboratory services. (refer to D6086)</p>
<p><b>D6086</b></p>	<p><b>LABORATORY DIRECTOR RESPONSIBILITIES</b> CFR(s): 493.1445(e)(3)(ii)</p> <p>The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the laboratory's test system records and interview of facility personnel it was revealed that the laboratory director failed to ensure the laboratory documented complete establishment studies of all test systems before reporting patient test results. (Refer to D5423 A, B)</p>