

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 19D0918803	<b>(X3) Date Survey Completed</b> 08/06/2018
<b>Name of Provider or Supplier</b> Louisiana Dermatology Associates	<b>Street Address, City, State</b> 10154 Jefferson Highway, Baton Rouge, LA	
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>	A CERTIFICATION SURVEY was performed at Louisiana Dermatology Associates - CLIA # 19D0918803 on August 6, 2018. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policy and procedure manual and interview with personnel, the laboratory failed to ensure the laboratory policy and procedure manual contained complete policies and procedures. Findings: 1. Review of the laboratory policy and procedure manual revealed the laboratory failed to have policies and procedures for: Twice a year verification for Grossing of Histopathology Specimens: a) What system are you going to use to meet the twice a year verification for Grossing accuracy. b) How to handle Histopathology samples for 2/year verification; who will test, when to test, how do you assure no inter and intra laboratory communication takes place c) How to record results and who will score. d) What acceptability criteria will be used to score the verification. e) What records to maintain. f) What steps to take if corrective action is needed. Complaint policies and procedures. Communication policies and procedures. 2. Interview with personnel 2 on August 6, 2018 confirmed the policy and procedure manual was incomplete</p>
<b>D5429</b>	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p>

For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.

This STANDARD is not met as evidenced by:

Based on record review and interview with personnel, the laboratory failed to perform daily maintenance for the Grossing Station for six (6) of eight (8) patient test days reviewed. Findings: 1. Review of the Gross Area Cleaning Log revealed the laboratory is required to do the following each day of patient testing: a) Wipe down all surfaces of station for possible contaminants. b) Bleach area using 10% bleach. c) Replace with new formalin in holding area. d) Replace with new sharps container. Further review of the Gross Area Cleaning Log Maintenance Log from July 31, 2017 through July 16, 2018 revealed the laboratory failed to document the performance of the daily cleaning of the Grossing Station for the following six (6) days. July 31, 2017. November 9, 2017. March 5, 2018. April 2, 2018. June 7, 2018. July 16, 2018. 2. Interview with Personnel 2 on August 6, 2018 confirmed the laboratory failed to document the daily maintenance for the Grossing Station for the six (6) days cited above.

**D6023**

**LABORATORY DIRECTOR RESPONSIBILITIES**

CFR(s): 493.1407(e)(6)

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)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

This STANDARD is not met as evidenced by:

Based on review of manufacturer's instructions, instrument maintenance records and interview with laboratory personnel, the Laboratory Director failed to ensure that the laboratory performed the required maintenance to ensure acceptable levels of analytical performance. Findings: 1. The laboratory failed to perform daily maintenance for the Grossing Station for six (6) of eight (8) patient test days reviewed. Refer to D5429. 2. Interview with Personnel 2 on August 6, 2018 confirmed the laboratory failed to document the daily maintenance for the Grossing Station.

**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 record review and interview with laboratory personnel, the Laboratory Director failed to ensure that an approved procedure manual was available to all personnel responsible for any aspect of the testing process. Findings: 1. Review of the policy and procedure manual revealed the laboratory did not have detailed policies and procedures for the following: Twice a year verification for Grossing of Histopathology Specimens: a) What system are you going to use to meet the twice a year verification for Grossing accuracy. b) How to handle Histopathology samples for 2/year verification; who will test, when to test, how do you assure no inter and intra laboratory communication takes place c) How to record results and who will score. d) What acceptability criteria will be used to score the verification. e) What records to maintain. f) What steps to take if corrective action is needed. Complaint policies and procedures. Communication policies and procedures. 2. Interview with personnel 2 on August 6, 2018 confirmed the policy and procedure manual was incomplete