

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D0918081	(X3) Date Survey Completed 02/01/2022
Name of Provider or Supplier Medical And Surgical Dermatology Cntr	Street Address, City, State 108 West Pleasant Street, Mount Pleasant, TX	
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
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: I. Based on a review of the Instruction Manual for the Leica CM1510 Cryostat, a review of the laboratory's records, and staff interview, it was revealed that the laboratory failed to have documentation of monitoring the laboratory's temperature and humidity for the operation of the Leica CM1510 Cryostat for 24 of 24 months from December 2019 to December 2021. Findings include: 1. A review of the</p>

Instruction Manual for the Leica CM1510 Cryostat (V2.1- 12/2001) revealed the following: "Operating temperature range: 18 - 40C and air humidity less than or equal to 60%." 2. A review of the laboratory's records revealed the laboratory failed to have documentation of monitoring the laboratory's temperature and humidity for the operation of the Leica CM1510 Cryostat from December 2019 to December 2021. 3. An interview with the laboratory director on 2/1/22 at 1:25 p.m. in the laboratory, after review of the records, confirmed the above findings. Key: C = degrees Celsius II. Based on a review of the laboratory's policies, the Temperature Logs from January 2021 to December 2021, a random review of patient test records, and staff interview, it was revealed that the laboratory failed to document the chamber temperature of the Leica CM1510 Cryostat for 100 of 100 days from January 2021 to December 2021. Findings include: 1. A review of the laboratory's policies revealed the Leica CM 1510 Cryostat was to be operated with a chamber temperature between -15 to -25C. 2. A review of the Temperature Logs from January 2021 to December 2021 revealed the following 100 days when the chamber temperature of the Cryostat was not documented: 4/6/21 6/2/21 8/2/21 10/5/21 4/13/21 6/3/21 8/3/21 10/12/21 4/14/21 6/7/21 8/4/21 10/13/21 4/15/21 6/8/21 8/9/21 10/14/21 4/19/21 6/9/21 8/10/21 10/25/21 4/20/21 6/10/21 8/11/21 10/27/21 4/22/21 6/14/21 8/12/21 10/29/21 4/26/21 6/15/21 8/16/21 11/2/21 4/27/21 6/16/21 8/17/21 11/3/21 4/28/21 6/17/21 8/18/21 11/4/21 4/29/21 6/21/21 8/19/21 11/8/21 5/3/21 6/22/21 8/23/21 11/9/21 5/4/21 6/23/21 8/24/21 11/10/21 5/5/21 6/28/21 8/25/21 11/11/21 5/6/21 6/29/21 8/26/21 11/18/21 5/10/21 6/30/21 8/30/21 11/22/21 5/12/21 7/5/21 8/31/21 11/23/21 5/13/21 7/6/21 9/1/21 11/24/21 5/17/21 7/7/21 9/2/21 11/30/21 5/18/21 7/8/21 9/7/21 12/1/21 5/19/21 7/13/21 9/8/21 12/2/21 5/20/21 7/14/21 9/9/21 12/7/21 5/24/21 7/15/21 9/10/21 12/9/21 5/25/21 7/28/21 9/15/21 12/20/21 5/27/21 7/29/21 10/4/21 12/28/21 3. A random review of the laboratory's patient test records revealed the following patient's specimens were processed on the above listed dates: PATIENT ID: AG-005 Processed: 4/14/21 PATIENT ID: AG- 013 Processed: 5/25/21 PATIENT ID: AG- 011 Processed: 6/21/21 PATIENT ID: AG-009 Processed: 7/29/21 PATIENT ID: AG-015 Processed: 8/16/21 PATIENT ID: AG-007 Processed: 9/15/21 PATIENT ID: AG-010 Processed: 10/29/21 PATIENT ID: AG-017 Processed: 11/30/21 PATIENT ID: AG-003 Processed: 12/7/21 4. An interview with the laboratory director on 2/1/22 at 1:25 p.m. in the laboratory, after review of the records, confirmed the above findings.

D5429

MAINTENANCE AND FUNCTION CHECKS
CFR(s): 493.1254(a)(1)

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 a review of the Instruction Manual for the Leica CM1510 Cryostat, a review of the laboratory's maintenance records, and staff interview, it was revealed that the laboratory failed to have documentation of performing the required maintenance on the cryostat for 24 of 24 months from December 2019 to December 2021. Findings include: 1. A review of the Instruction Manual for the Leica CM1510 Cryostat (V2.1-12/2001) revealed the following: "- Clean the instrument every day. - Have the instrument inspected by a qualified service engineer authorized by Leica at least once a year." 2. A review of the laboratory's maintenance records revealed the laboratory failed to have documentation of performing the required maintenance on the Leica CM1510 Cryostat for 24 months from December 2019 to December 2021. 3. An

interview with the laboratory director on 2/1/22 at 1:15 p.m. in the laboratory, after review of the records, confirmed the above findings.

D5805

TEST REPORT
CFR(s): 493.1291(c)

The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability.

This STANDARD is not met as evidenced by:
Based on a random review of patient's test reports from December 2019 to November 2021, and staff interview, it was revealed that the laboratory failed to include the testing facility's address on five of five patient's test reports reviewed from 2019, 2020, and 2021. Findings include: 1. A random review of patient's test reports from December 2019 to November 2021 revealed the laboratory failed to include the testing facility's address on the following 5 patient's test reports: Patient ID: 05201938 Tested on 12/18/2019 Patient ID: 03041942 Tested on 5/6/2020 Patient ID: 08091950 Tested on 10/26/2020 Patient ID: 11251942 Tested on 6/30/2021 Patient ID: 09141945 Tested on 11/30/2021 2. An interview with the laboratory director on 2/1/22 at 1:30 p.m. in the laboratory, after review of the records, confirmed the above findings.