

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2121729	(X3) Date Survey Completed 01/12/2023
Name of Provider or Supplier Cronin Dermatology & Skin Cancer Center	Street Address, City, State 5530 Wisconsin Ave Ste 1418, Chevy Chase, MD	
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
D5435	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)</p> <p>For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted.</p> <p>This STANDARD is not met as evidenced by: Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 05/29/2019 for not performing and documenting sterilization tests on the autoclave. The plan of correction stated that this would be corrected. Based on record review and interview with laboratory staff, the laboratory did not perform and document routine sterilization tests on the autoclave. Findings: 1. The laboratory uses a steam sterilizer to disinfect surgical equipment used during dermatological procedures. During an interview at 11:30 AM on the day of the survey, the histotech stated that a spore growth sterilizer check should be performed once a month on the autoclave. 2. A review of "Sterilizer Monitoring" logs for 2021 and 2022 showed that spore growth sterilizer checks were performed 5 of 12 months in 2021 and 3 of 12 months in 2022; and 3. A review of the "Sterilization Monitoring Service" report from the company which performs the spore growth sterilizer checks from 2021 to 2022 showed that on 07/28/2022 the test result was "Expired Product: We are unable to process expired product. Please contact your dealer to expedite a reorder of new tests" and on 08/22/2022 the test result was "Failed. Growth observed on one or more test strips and control strip." 4. Test results reported on 08/16/2022, 10/11/2022, 12/02/2022, and 12/14/2022 were reported as "Passed. No growth observed after incubation</p>

period." 5. Record review showed that there was no procedure available for how to perform autoclave sterilization checks to ensure patient safety. 6. During an interview on 01/12/2023 at 12:30 PM, laboratory staff confirmed that the laboratory did not perform and document routine sterilization tests on the autoclave.

D5473

CONTROL PROCEDURES

CFR(s): 493.1256(e)(2)(g)

(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (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:
Note: This is a repeat deficiency. The laboratory was cited during the re-certification survey on 05/29/2019 for not ensuring that daily stain quality control was consistently documented. The plan of correction stated that this would be corrected. Based on quality control (QC) and patient log record review and interview with laboratory staff, the laboratory did not ensure that daily stain QC was consistently documented, recording the quality of the staining characteristics of the Hematoxylin and Eosin (H&E) stain. Findings: 1. The laboratory performs H&E staining procedures to evaluate histopathology slides. Daily stain QC for H&E stains are recorded on the "Control Slide Log." 2. Laboratory patient logs and "Control Slide Logs" from 2021 and 2022 were reviewed. The laboratory patient log showed that 9 patients were tested on 07/27/2021, however there was no daily stain QC logged on that date; 3. Nine patients were tested on 04/05/2022, however there was no daily stain QC logged on that date; and 4. Six patients were tested on 08/29/2022, however there was no daily stain QC logged on that date. 5. During an interview on 01/12/2023 at 12:30 PM, the laboratory staff confirmed that daily slide QC was not consistently documented.