

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 19D2028358	(X3) Date Survey Completed 12/28/2022
Name of Provider or Supplier Green Clinic Mohs Laboratory	Street Address, City, State 1200 S Farmerville Hwy, Ruston, LA	
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	A Recertification survey was performed at Green Clinic MOHS, CLIA #19D2028358 on December 28, 2022. The laboratory was found in compliance with 42 CFR 493 Requirements for Laboratories; however, standard level deficiencies were cited.
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <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.</p> <p>This STANDARD is not met as evidenced by: I. Based on review of the laboratory's policy and procedure manual, maintenance records, patient logs and interview with personnel, the laboratory failed to document cryostat temperature on the maintenance log for one (1) of one hundred one (101) days reviewed. Findings: 1. Review of the laboratory's policy for "Cryostat Maintenance" revealed the laboratory is required to document the console temperature daily of patient testing. 2. Review of the laboratory's cryostat maintenance log for 2022 revealed the laboratory did not have documentation for the console temperature on November 4, 2022. 3. Review of patient logs from January 5, 2022 through December 28, 2022 revealed the laboratory performed patient testing on November 4, 2022 for the following three (3) of three (3) patients reviewed: a) M22-0442 performed on November 4, 2022 at 9:45 am b) M22-0443 performed on November 4, 2022 at 1:15 pm c) M22-0444 performed on November 4, 2022 at 2:24 pm 4. In interview on December 28, 2022 at 10:35 am, the Laboratory Director confirmed the laboratory did not document the cryostat temperature for the identified date. II. Based on review of the laboratory's policy and procedure manual, maintenance records, patient logs and interview with personnel, the laboratory failed to document daily routine maintenance for one (1) of one hundred one (101) days reviewed. Findings: 1. Review of the "Laboratory Daily Maintenance" policy revealed the following: a) All</p>

laboratory equipment is to be cleaned daily when laboratory is in use. Manufacturer's recommendations are to be followed concerning daily maintenance of each piece of equipment. b) All countertops, cutting boards, and tops of cryostats are to be disinfected with 0.05% bleach solution or similar disinfectant daily. c) The cryostat will be wiped out with dry gauze, and then everything will be wiped down with gauze of isopropyl alcohol. After wiping with alcohol, the machine will be dried with a gauze and as soon as the machine goes into a defrost cycle will be ready for use. d) The defrost cycle will be set for nightly defrosting. e) Slides, Petri dishes, and maps are made the day prior to surgery. f) Staining set-up will be changed as the protocol is stated under stain maintenance. g) Temperature charts and logs are checked daily or whenever in use. h) Follow procedure for microscope care and document. i) Follow correct procedure for eye wash station as documented. j) Document that daily maintenance has been completed by initialing daily maintenance log. k) Changes and updates as needed. 2. Review of the laboratory's daily maintenance log for 2022 revealed the laboratory did have documentation for daily routine maintenance on October 13, 2022. 3. Review of patient logs from January 5, 2022 through December 28, 2022 revealed the laboratory performed testing on October 13, 2022 with no documentation of daily routine maintenance for the following five (5) of five (5) patients reviewed: a) M22-0425 performed on October 13, 2022 at 9:23 am b) M22-0426 performed on October 13, 2022 at 10:54 am c) M22-0427 performed on October 13, 2022 at 10:54 am d) M22-0428 performed on October 13, 2022 at 1:20pm e) M22-0429 performed on October 13, 2022 at 1:20 pm 4. In interview on December 28, 2022 at 10:35 am, the Laboratory Director confirmed the laboratory did not document the daily routine maintenance for the identified date.

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 laboratory policies, maintenance records, and interview with personnel, the Laboratory Director failed to ensure that the laboratory performed required maintenance. Findings: 1. The laboratory failed to document cryostat temperature on the maintenance log for one (1) of one hundred one (101) days reviewed. Refer to D5429 I. 2. The laboratory failed to document daily routine maintenance for one (1) of one hundred one (101) days reviewed. Refer to D5429 II.