

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0276369	(X3) Date Survey Completed 04/12/2022
Name of Provider or Supplier Brevard Skin & Cancer Center	Street Address, City, State 1286 S Florida Ave, Rockledge, FL	
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 conducted on April 12, 2022. Brevard Skin and Cancer Center clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D3031	<p>RETENTION REQUIREMENTS CFR(s): 493.1105(a)(3)</p> <p>Analytic systems records. Retain quality control and patient test records (including instrument printouts, if applicable) and records documenting all analytic systems activities specified in 493.1252 through 493.1289 for at least 2 years.</p> <p>This STANDARD is not met as evidenced by: Based on record review, and interview, the laboratory failed to retain quality control documents for nine (July, August, September, October, and November 2020, and February, March, April and May 2021) of 25 (April 2020 to April 2022) months reviewed. Findings: Review of the laboratory's quality control documents revealed the laboratory's "Reagent Control Sheet" for 07/1/2020 to 11/30/2020 and 02/01/2021 to 05/31/2021 were not available. On 04/12/2022 at 1:24 PM, the Laboratory Assistant stated she did not know where the logs were located.</p>
D5400	<p>ANALYTIC SYSTEMS CFR(s): 493.1250</p> <p>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.</p>

This CONDITION is not met as evidenced by:
Based on observation, record review, and interview, the laboratory's quality assessment program failed to monitor and evaluate the overall quality of the analytic system and identify problems. Findings: Cross Reference D5433. Based on record review and interview, the laboratory failed to document all maintenance activities for 4 (September 2020, March 2021, July 2021, January 2022) of 5 months (September 2020, January 2021, March 2021, July 2021, January 2022) reviewed. This is a repeat deficiency from the recertification survey on 06/17/2020.

D5433

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

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 establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:
Based on record review, and interview, the laboratory failed to document all maintenance activities for 4 (September 2020, March 2021, July 2021, January 2022) of 5 months (September 2020, January 2021, March 2021, July 2021, January 2022) reviewed. This is a repeat deficiency from the recertification survey on 06/17/2020. Findings: Review of the "Hematoxylin and Eosin Quality Control," the "Quality Control Maintenance Checklist," and "Monthly Log" showed that not all days in which testing was performed were documented. Review of the Frozen Section Worksheet" listed the dates and the patients who had Mohs surgical procedure. Documentation on the "Hematoxylin and Eosin Daily Maintenance" log was missing for the following dates when patient testing was performed: 09/01/2020 - 6 patients 03/09/2021 - 9 patients 03/18/2021 - 6 patients 01/06/2021 - 10 patients Documentation on the "Quality Control Maintenance Checklist" log was missing for the following dates when patient testing was performed: 09/01/2020 - 6 patients 03/11/2021 - 10 patients 03/18/2021 - 6 patients 01/04/2021 - 9 patients 01/06/2021 - 10 patients 01/07/2021 - 5 patients 01/11/2021 - 9 patients 01/13/2021 - 9 patients 01/16/2021 - 7 patients 01/18/2021 - 9 patients Documentation on the "Monthly Log" used to record temperature and humidity of the Mohs laboratory was missing for the following dates when patient testing was performed: 09/01/2020 - 6 patients 03/02/2021 - 10 patients 03/18/2021 - 6 patients 03/23/2021 - 10 patients 03/25/2021 - 9 patients 07/27/2021 - 12 patients 07/30/2021 - 6 patients On 04/12/2022 at 12:00 PM, the Office Manager acknowledged some of the documentation was not completed.