

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2141186	(X3) Date Survey Completed 01/03/2024
Name of Provider or Supplier Sanctuary Medical Aesthetic Center Of Boca Raton	Street Address, City, State 4800 N Fed Hwy C100, Boca Raton, 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 January 3, 2024. Sanctuary Medical Aesthetic Center of Boca Raton 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 review of quality control (QC) and Mohs logs, and interview, the laboratory failed to maintain documentation of the H&E stain acceptability, stain maintenance, changing and rotation of reagents, cryostat temperature and maintenance, room temperature and humidity, and microscope maintenance for 5 (04/29/2022, 05/20/2022, 02/24/2023, 03/10/2023, 03/14/2023) of 22 days (11/12/2021, 01/14/2022, 02/18/2022, 03/25/2022, 04/29/2022, 05/20/2022, 06/24/2022, 07/29/2022, 09/23/2022, 10/28/2022, 02/17/2023, 02/24/2023, 03/10/2023, 03/14/2023, 05/05/2023, 06/02/2023, 07/07/2023, 08/04/2023, 09/08/2023, 10/06/2023, 11/03/2023, 12/11/2023) Mohs surgical procedures were performed. Findings: The laboratory recorded the H&E stain acceptability, stain maintenance, changing and rotation of reagents, cryostat temperature and maintenance, room temperature and humidity, and microscope maintenance on their Daily QC Worksheet. Review of the Mohs Log listing the Mohs surgical procedures performed showed on 04/29/2022 there were six procedures, on 05/20/2022 there were nine procedures, on 02/24/2023 there were seven procedures, on 03/10/2023 there were two procedures, and on 03/14/2023 there were three procedures. Review of the Daily QC Worksheet showed worksheets for 04</p>

/29/2022, 05/20/2022, 02/24/2023, 03/10/2023, and 03/14/2023 were missing. On 01/03/2024 at 2:12 PM, the Mohs Tech stated he did not know where the missing worksheets were located.

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 review of the laboratory's test reports and interview, the laboratory failed to have the full address of the laboratory for three of three patients, (#1, #2, #3) on the laboratory's patient reports (surgical notes). Findings: Review of the surgical notes for patient's #1, #2, and #3, showed the address of the laboratory was not listed on the notes. On 01/03/2024 at 3:42 PM, the Medical Assistant stated they give the surgical notes to patients, if requested. The Medical Assistant acknowledged the address of the laboratory was not listed on the notes.