Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2189526	(X3) Date Survey Completed 01/03/2023
Name of Provider or Supplier Orlando Dermatology Clinic Llc	**Street Address, City, State** 1040 Lake Sumter Landing, The Villages, 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, 2023. Orlando Dermatology Clinic LLC clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to provide documentation showing the Eosin used in their Hematoxylin and Eosin Staining (H&E) was not expired prior to patient testing from 12/01/2022 to 01/02/2023. Findings: Observations made during a tour of the laboratory on 01/03/2023 at 9:30 AM, revealed an opened bottle of Eosin-Y Alcohol 0.25 % lot #111040 with an expiration date of 11/30/2022. Review of the "Media and Stain Receipt Log" showed the Eosin lot #111040 was opened on 12/20/2021 and no other lot number of Eosin was recorded on the reagent log. Review of the patient accession log showed Mohs surgical procedures were performed on patients on the following dates: 12/02/2022 - 6 patients 12/05/2022 - 4 patients 12/07/2022 - 4 patients 12/08/2022 - 9 patients 12/09 /2022 - 3 patients 12/12/2022 - 3 patients 12/14/2022 - 2 patients 12/16/2022 - 3 patients 12/19/2022 - 4 patients 12/21/2022 - 4 patients 12/22/2022 - 9 patients 12/28 /2022 - 4 patients 12/30/2022 - 1 patients 01/02/2023 - 3 patients On 01/03/2023 at 9: 40 AM, the Mohs Technician stated he failed to record the new lot number of Eosin on the reagent log. He explained he used all of the new lot number of Eosin in the bottle and was not sure when the bottle was opened.
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 six months(August 2021, November 2021, January 2022, April 2022, November 2022, and December 2022) reviewed out of seventeen months (July 2021 to December 2022). The laboratory also failed to record the maintenance on the automated stainer for seventeen of seventeen months (July 2021 to December 2022). Findings: Review of the Daily Routine Maintenance, Cryostat temperature log, Room Temperature and Humidity Log, and the Microscope maintenance log, showed maintenance was not recorded for all days in which Mohs surgical procedures were performed. Review of the patient accession log listed the dates and the patients who had Mohs surgical procedure. Review of the Daily Routine Maintenance log showed the routine maintenance was not recorded on the following dates patient testing was performed: 08/04/2021 - 2 patients 08/11/2021 - 1 patients 08/18/2021 - 2 patients 08/25/2021 - 2 patients 11/03/2021 - 2 patients 11/10/2021 - 3 patients 11/17/2021 - 3 patients 11/24/2021 - 3 patients 01/05/2022 - 4 patients 01/12/2022 - 3 patients 01/19/2022 - 3 patients 01/26/2022 - 3 patients 04/06/2022 - 3 patients 04/07/2022 - 7 patients 04/13/2022 - 2 patients 04/20/2022 - 3 patients 04/21/2022 - 7 patients 04/27/2022 - 2 patients 11/10/2022 - 6 patients Review of the Cryostat temperature log showed the temperature of the cryostat was not recorded on the following dates patient testing was performed: 04/07/2022 - 7 patients 04/21/2022 - 7 patients Review of the Room Temperature and Humidity Log showed the temperature and humidity of the laboratory was not recorded on the following dates patient testing was performed: 04/07/2022 - 7 patients 04/21/2022 - 7 patients 12/28/2022 - 4 patients Review of the Microscope maintenance log showed maintenance of the microscope was not recorded on the following dates patient testing was performed: 08/06/2021 - 1 patients 08/13/2021 - 1 patients 08/18/2021 - 2 patients 08/20/2021 - 1 patients 08/25/2021 - 2 patients 11/22/2021 - 3 patients 04/07/2022 - 7 patients 04/21/2022 - 7 patients 12/28/2022 - 4 patients Review of the laboratory's quality control records revealed the laboratory did not have records of the stain maintenance for the automated stainer from July 2021 to December 2022. According to the Clinical Laboratory Improvement Amendment (CLIA) Application for Certification, signed and dated by the Laboratory Director on 01/03/2023, the laboratory had an annual test volume of 500 tests. On 01/03/2023 at 10:50 AM, the Mohs Technician acknowledged there was missing information on the logs. On 01/03/2023 at 11:42 AM, the Mohs Technician said there was no stain maintenance log recording the changing of the reagents for the stainer.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify

	failures in quality as they occur. This STANDARD is not met as evidenced by: Based on record review, and interview, the Laboratory Director failed to ensure quality controls were maintained from January 2021 to December 2022. Findings: Review of the Quality Assurance policy noted, "All maintenance and repairs of equipment will be recorded and maintained by the laboratory personnel and will be reviewed by the Laboratory Director on a periodic basis." Review of the laboratory's quality control records showed there were no records documenting the periodic review of the Daily Routine Maintenance, Cryostat temperature log, Room Temperature and Humidity Log, and Microscope maintenance, On 01/03/2023 at 12: 15 PM, the Mohs Technician acknowledged the Laboratory Director had not documented the review of the maintenance logs by signing or initialing the forms.