Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1017116	07/17/2025
Name of Provider or Supplier	**Street Address, City, State**	
Flores Dermatology Llc	6705 Sw 57th Ave Ste 400, Coral Gables, 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	An announced CLIA recertification survey was conducted at FLORES DERMATOLOGY on July 17, 2025. The laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g) (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. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to have documentation of the acceptability of the Quality Control (QC) slide for Hematoxylin & Eosin (H&E) stain for one out of five testing dates in March 2025. Findings included: 1-The laboratory used the "MOHS DAILY QC WORKSHEET" to record the acceptability of the daily H&E stain. Review of the QC log for March 2025 revealed that on March 10, 2025, there was no record of QC approval. 2-Review of patient Log for the day of reference revealed that 8 patients were tested on that day. 3-During an interview on 07/17/2025 at 12:00 PM the Office Consultant confirmed that the Mohs surgeon failed to document the acceptability of the Daily QC slide for H& E Stain for March 10, 2025.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283.

	This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory Quality Assessment (QA) failed to identify and correct the deficiency of missing record in Hematoxylin and Eosin (H&E) stain maintenance log in one out of four testing dates in August 2023. Based on record review and staff interview, the laboratory Quality Assessment (QA) failed to identify and correct the deficiency of missing record in the Mohs Daily Quality Control (QC) log and Hematoxylin and Eosin (H&E) stain maintenance log in one out of five testing dates in March 2025. Findings included: 1-Review of the "QUALITY ASSURANCE PROGRAM" Policy in the Procedure Manual signed by the Laboratory Director on 01/06/2025, revealed that in section "VI Specimen Collection and Slide preparation" listed the parameters to consider in the slide preparation, temperature for Cryostat, staining solutions for Frozen sections must be filtered or changed at least weekly depending in usage, instrument maintenance. 2-The Laboratory implemented a Quarterly Checklist to monitor the QA activity. This QA checklist included different sections in "Analytical "listed the following parameters: "1. Overall assessment of laboratory testing. 2. Overall assessment of diagnostic procedure. 3. Overall assessment of processing. 4. Overall adequacy of stain line. 5. Monitoring Chemicals quality." 3-The laboratory used "MOHS DAILY QC WORKSHEET" log (Log #1) to record Daily H&E QC stain, Microscope verification, Cryostat Maintenance, Room Temperature and Humidity and log "HEMATOXYLIN AND EOSIN STAINING MAINTENANCE LOG MOHS" (Log #2) to document the actions performed by the technical to the maintenance of the reagents used for the H&E stain. 4-Review of the Log 1 for August 2023 revealed that the laboratory performed five testing days (08/07/2023, 08/17/2023, 08/21/2023 and 08/28/2023). Review of Log #2 revealed that the laboratory missed recording the H&E stain maintenance for 08/28/2023. Review of the Quarterly QA checklist for August 2023 revealed no reference to the missing record in point "4. Overall adequacy of stain line" and the Laboratory Director graded with an "Outstanding" qualification. The laboratory tested six patients on 08/28/2025. 5-Review of Patient log, Log1 and Log 2 for March 2025, revealed that the laboratory performed five testing days: 03/03/2025, 03/10/2025, 03/17/2025, 03/24/2025 and 03/31/2025. Reviews of Log #1 and Log #2 revealed that the laboratory failed to record all the data for 03/10/2025, the laboratory tested 8 patients that day. The Quarterly QA checklist report for April 2025 was signed by the Laboratory Director but failed to have an evaluation of the activity and did not mention any corrective action for the missing records for 03/10/2025.
D5893	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(b)(c) (b) The postanalytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of postanalytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all postanalytic systems quality assessment activities. This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory Quality Assessment (QA) failed to identify and correct the deficiency of missing the accession number in the final report for two out of seven final reports reviewed from August 2023 to June

	2025. Findings included: 1-Review of the "QUALITY ASSURANCE PROGRAM" Policy in the Procedure Manual signed by the Laboratory Director on 01/06/2025, revealed that stated the following: Section "X Quality Control Standard" D The laboratory report must: 1. contain: a) Patient name. b) Accession number. c) Date of specimen ...." 2- Review of seven patient reports with the following dates: P#1 (08/21 /2023), P#2 (12/04/2023), P#3 (02/05/2025), P#4 (05/20/2024), P#5 (08/19/2024), P#6 (03/24/2025) and P#7 (06/09/2025); revealed that P#2 and P#6 final reports missed to include the accession number for sample for the cases of reference. 3-QA checklist review for the period of reference revealed that no checklist included corrective actions to correct this deficiency. 4-During an interview on 07/17/2025 at 12:40 PM, with the laboratory Consultant, she confirmed that the QA failed to correct the missing information in the reports of reference.