Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	06D1057160	07/28/2023
Name of Provider or Supplier	**Street Address, City, State**	
Flatirons Dermatology, Pllc	13605 Xavier Ln, Ste B, Broomfield, CO	

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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on records review and interview with the lead Mohs technician (not included on CMS-209 form), the laboratory failed in 2022 to twice annually verify the accuracy of the histopathology slide interpretation. The laboratory performs approximately 500 Mohs histopathology procedures per year. Findings include: 1. Records review revealed no documentation of accuracy verification for histopathology slide interpretation for the year 2022. 2. An interview with the lead Mohs technician at approximately 10:51 AM on July 28, 2023, confirmed that there was no documentation of accuracy verification performed for the year 2022.
D5449	CONTROL PROCEDURES CFR(s): 493.1256(d)(3)(ii)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must-- At least once a day patient specimens are assayed or examined perform the following for-- Each qualitative procedure, include a negative and positive control material; (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on a review of quality control (QC) records, and an interview with the lead Mohs technician (not included on CMS-209 form), the laboratory failed to document stain acceptability QC at least once daily for their Mohs Hematoxylin and Eosin

	(H&E) slide preparations. The laboratory performs approximately 500 Mohs histopathology procedures per year. Findings include: 1. A review of QC records revealed stain acceptability QC was not documented on the following days: a) 12/07 /2021, 4 patients b) 12/13/2021, 2 patients c) 10/17/2022, 5 patients d) 12/12/2022, 4 patients e) 12/13/2022, 4 patients f) 03/13/2023, 5 patients g) 06/26/2023, 4 patients h) 07/17/2023, 5 patients i) 07/24/2023, 4 patients 2. An interview with the lead Mohs technician at approximately 11:30 AM on 07/28/2023, confirmed that the laboratory failed to document H&E stain quality for each day of testing.
D5787	TEST RECORDS CFR(s): 493.1283(a) The laboratory must maintain an information or record system that includes the following: (a)(1) The positive identification of the specimen. (a)(2) The date and time of specimen receipt into the laboratory. (a)(3) The condition and disposition of specimens that do not meet the laboratory's criteria for specimen acceptability. (a)(4) The records and dates of all specimen testing, including the identity of the personnel who performed the test(s). This STANDARD is not met as evidenced by: Based on record review and interview with the lead Mohs technician (not included on the CMS-209 form) the laboratory failed to document the lot numbers and expiration dates of reagents and stains used for histopathology slide preparation since January 2022. The laboratory performs approximately 500 Mohs histopathology procedures per year. Findings include: 1. A record review of the stain reagent logs revealed that the use of the logs had been discontinued in January 2022. 2 An interview with the lead Mohs technician on 07/28/2023 at approximately 11:15 AM confirmed that the laboratory failed to document the lot numbers and expiration dates of reagents and stains used in the Hematoxylin and Eosin (H&E) staining process.