Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1084862	04/08/2026
Name of Provider or Supplier	**Street Address, City, State**	
Bracciano Dermatology Plc	8430 Cooper Creek Blvd Ste 102, University Park, 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 BRACCIANO DERMATOLOGY PLC from March 12, 2026 to April 8, 2026. The laboratory is not in compliance with 42 CFR Part 493, Requirement for Laboratories. The following Condition was cited: D5400 493.1240 Condition: Analytic Systems
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 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. This CONDITION is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to monitor and remove expired chemicals and failed to correctly identified problems from July 2025 to March 12, 2026. See D5417
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) (b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (b)(1) Water quality. (b)(2) Temperature. (b)(3) Humidity. (b)(4) Protection of equipment and instruments from fluctuations and

	interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on the review of the procedure manual, record review, and interview, the laboratory failed to document the room temperature and humidity for two days (08/22 and 08/29) out of three days (08/08, 08/22 and 08/29) of micrographical oriented histographic surgery (Mohs) surgical procedures performed in August 2025. Finding included: 1- Review of the Laboratory Daily Maintenance policy stated in step in "7. Temperature Charts and Logs are checked daily or whenever in use." 2- Review of the 2025 Room Temperature/Humidity Log revealed that there was no documentation for temperature on 08/22/2025 and 08/29/2025. This log also stated at the bottom of the form the following steps: "1. The room temperature will be checked at the beginning of each workday ... 2. The humidity will be documented at the beginning of each workday." 3- Review of the (Mohs) Patient log revealed that on 08/22/2025 the laboratory tested 15 patients, and on 08/29/2025 the laboratory tested 10 patients. A total of 25 patients were tested with no room temperature/humidity documentation by the laboratory technician. 4- During an interview on 03/12/2025 at 12:45 PM, the Practice Administrator confirmed that room temperature and humidity was not recorded.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) (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 with the office manager, the laboratory failed to ensure the Scott Tap Water Substitute (lot number 2421544), was not expired prior to performing 279 patient tested from 08/17/2025 to 03/12/2026, and failed to ensure the Blue Tissue Marking Dye (lot number 23170) was not expired prior to performing 324 patient test from 07/01/2025 to 03/12/2026 for Histopathology (Hematoxylin and Eosin stain) high complexity testing. This is a repeat citation from the 05/13/2024 recertification survey. Findings included: 1. Review of the plan of correction signed and dated by the Laboratory Director on 05/28 /2024 from the 05/13/2024 recertification survey revealed that "chemicals will be checked monthly to ensure they are not expired by the lab technicians". 2. During a laboratory tour on 3/12/2026 at approximately 10:14 AM, the surveyor observed that the laboratory had a 1/10th gallon remaining of Scott Tap Water (Mercedes Scientific) lot number 2421544 exp. date 08/16/2025 marked open on 06/20/2025. The Mohs technician replaced the expired reagent with a new lot at the time of the survey on 03 /12/2026. The surveyor also observed Blue Tissue Marking Dye (Mercedes Scientific) lot number 23170 with expiration date 06/30/2025 in use with no open date marking. 3. Review of the patient's micrographic oriented photographic surgery (Moths) log confirmed that the laboratory tested a total of 324 patients with expired reagents on the following dates: 07/18/2025 - the laboratory tested 15 patients 07/25/2025 - the laboratory tested 15 patients 08/08/2025 - the laboratory tested 15 patients 08/22/2025 - the laboratory tested 15 patients 08/29/2025 - the laboratory tested 10 patients 09/05 /2025 - the laboratory tested 10 patients 09/19/2025 - the laboratory tested 10 patients

	09/26/2025 - the laboratory tested 15 patients 10/17/2025 - the laboratory tested 12 patients 10/24/2025 - the laboratory tested 14 patients 10/31/2025 - the laboratory tested 14 patients 11/07/2025 - the laboratory tested 12 patients 11/14/2025 - the laboratory tested 15 patients 11/21/2025 - the laboratory tested 14 patients 12/05/2025 - the laboratory tested 14 patients 12/12/2025 - the laboratory tested 12 patients 12/19 /2025 - the laboratory tested 14 patients 01/16/2026 - the laboratory tested 13 patients 01/23/2026 - the laboratory tested 16 patients 01/30/2026 - the laboratory tested 15 patients 02/13/2026 - the laboratory tested 14 patients 02/20/2026 - the laboratory tested 14 patients 02/27/2026 - the laboratory tested 11 patients 03/06/2026 - the laboratory tested 15 patients 4. Interview on 03/12/2026 at 11:00 AM the Practice Administrator confirmed that the reagent Scott Tap Water and Blue Tissue Marking Dye were expired. Both expired reagents were removed from the laboratory and new lots were opened during the survey.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. This STANDARD is not met as evidenced by: Based on review of records and staff interview, the Laboratory failed to document the acceptability of the Hematoxylin and Eosin (H&E) Quality Control (QC) slide stain for two days (8/22 and 8/29) out of three days (08/08, 08/22 and 08/29) of micrographical oriented histographic surgery (Mohs) testing in August of 2025. Findings included: 1. Review of random month August 2025 for the daily Quality Control Staining Log record showed that the documentation was not recorded and not signed by the Laboratory Director for testing days 08/22/2025 and 08/29/2025. 2. Review of the (Mohs) Patient log revealed that on 08/22/2025 the laboratory tested 15 patients, and on 08/29/2025 the laboratory tested 10 patients. A total of 25 patients were tested with no QC documentation by the physician. 3. Review of the Quality Control Policies and Documentation procedure, stated under Reagents, "3. The stains are checked each day for intended reactivity. A control slide is prepared and approved by the physician prior to any testing. The approval is recorded on a QC log." 4. During an interview on 03/12/2025 at 12:45 PM, the Practice Administrator confirmed that H&E QC was not recorded.
D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) (b)(9) Evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on record review and staff interview, the Technical Supervisor (TS) or a designee failed to perform initial competency evaluations for one Testing Personnel (TP1) out of two (TP1, TP2) in the Histology laboratory during the first year (2025).

	Findings included: 1. Review of FORM CMS 209 signed by the Laboratory Director (LD) on 03/12/2026, revealed the following: LD was also Clinical Consultant (CC), Technical Supervisor (TS2), and the General Supervisor (GS). The laboratory also had a TS1, a TP1 and TP2 for the Histology laboratory. 2. Review of random Patient report on 08/29/2025 revealed TP1 (Mohs Surgeon) performed testing at this laboratory. 3. Review of personnel records revealed that there was no initial competency evaluation for TP1 for Patient testing observed by the TS/LD or designee. 4. During an interview on 04/08/2025 at 12:00 PM, the LD, the TS1, and Practice Administrator all confirmed that the initial competency assessment was not performed prior to TP1 who started testing on 08/29/2025 for the Histopathology subspecialty.