Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0943459	10/01/2025
Name of Provider or Supplier	**Street Address, City, State**	
Abrams Dermatology Llc	3328 Bee Ridge Rd, Sarasota, 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 Abrams Dermatology LLC on 10/01/2025. The laboratory was surveyed under 42 CFR Part 493 CLIA requirements. Standard deficiencies cited are as follows:
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, supplies for Parasitology and Histopathology were used when they had exceeded their expiration dates. Finding included: 1. On 10/01/2025 at 10:00 a.m., tissue ink dyes used for Histopathology were observed with expiration dates of 8/31/2024, 09/30/2024, 03/31/2024, and 09/30 /2024. Mineral Oil used for Parasitology was observed with an expiration date of 3/08 /2025. The Chemical Log for Lab/Mohs Surgery documented Scotts Tap Water lot # 2234327 with an expiration date of 12/21/2023 with open date of 03/19/2024. 2. The Clinical Supervisor/Histology Tech confirmed on 10/01/2025 at 12:10 p.m. the listed expired supplies had been used for patient testing.
D6080	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(c) (c) The laboratory director must: (c)(1) Be onsite at least once every 6 months, with at least 4 months between the minimum two on-site visits. Laboratory directors may elect to be on-site more frequently and must continue to be accessible to the laboratory to provide telephone or electronic consultation as needed; and (c)(2) Provide documentation of these visits, including evidence of performing activities that

	are part of the laboratory director responsibilities. This STANDARD is not met as evidenced by: Based on record review and interview, it was determined the Laboratory Director failed to develop a policy or a procedure to document they were onsite or had documented onsite activities at least every once every six months for from 1/1/2025 to 10/1/2025. Findings included: 1. The laboratory policy and procedure manual last reviewed by the Laboratory Director on 3/8/98 failed to include a policy regarding performing and documenting the Laboratory Director onsite visits at least every six months. 2. The Clinical Supervisor on 10/01/2025 at 12:10 p.m. confirmed the lack of policy and documentation of the Laboratory Director onsite visits at least every six months.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) (e)(5) Ensure that the quality control and quality assessment 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 the quality assessment (QA) program was maintained for two of two years (2023-2025). Findings included: 1. The laboratory policy and procedure manual last reviewed by the Laboratory Director on 3/8/98 included a Policy Assurance Policy which stated the QA program would include patient test management, quality control, comparison of test results, relationship of patient information to test results, personnel assessment, communication, complaint investigations, quality assurance review with staff, and quality assurance records. 2. The laboratory policy and procedure manual last reviewed by the Laboratory Director on 3/8/98 included a job description of the Laboratory Director which stated, item 5, the Laboratory Director would "Ensure that the quality control and quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur". 3. No documentation of the Laboratory Director following the written QA policy was provided for review for 2023-2025. The Clinical Supervisor confirmed on 10/01/2025 at 12:10 p.m. there was no documentation of QA for 2023-2025.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) (e)(12) Ensure that prior to testing patients specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results; This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to ensure that prior to testing patients ' specimens, Testing Personnel (TP) received the appropriate training and had demonstrated that they could perform all testing operations reliably to provide and report accurate results for one (TP-A) of two Testing Personnel.

	Findings include: 1. The CMS-209 Laboratory Personnel Report signed and dated by the Laboratory Director on 10/01/2025 listed two Testing Personnel (TP-A and TP-B). TP-B was the Laboratory Director. The Clinical Supervisor stated on 10/01/2025 at 10: 40 a.m. that TP-A started testing patients on 4/7/2025. 2. The Quality Control Log for H & E Stain for Lab/Mohs Surgery documented TP-A performed testing on 4/7/2025. 3. The laboratory policy and procedure manual last reviewed by the Laboratory Director on 3/8/98 included a job description of Laboratory Director which stated, item 11, the Laboratory Director would "Ensure that prior to testing patients ' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results." 4. No documentation of appropriate training and demonstration that TP-A could perform all testing operations reliably in the laboratory was presented at the time of the survey. 5. The Laboratory Director confirmed on 10 /01/2025 at 10:45 AM that there were no training or competency documentation for TP-A prior to testing patients' specimens.