Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0865260	07/31/2025
Name of Provider or Supplier	**Street Address, City, State**	
Dermatology Group Of Florida, Pa	9090 Park Royal Dr, Fort Myers, 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 unannounced CLIA recertification survey was conducted at Dermatology Group of Florida, PA on 07/31/2025. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, the laboratory failed to safely store one of one reused reagent plastic jug with chemical waste to ensure protection from chemical hazards, failed to maintain chemicals in a manner to ensure protection from hazard by storing bleach (sodium hypochlorite) alongside waste reagents, and failed to utilize a fume hood to protect personnel from chemical hazards. Findings included: 1. A tour of the lab was conducted on 7/31/2025 beginning at 9:50 a.m. Observations included: 1a. One reused reagent plastic jug with chemical reagent waste was observed stored under the laboratory sink and not in the safety cabinet to ensure protection from chemical hazards. 1b. A gallon bottle of germicidal bleach and a quart spray bottle of germicidal bleach cleaner were stored with the chemical waste. 1c. Reagents observed in use and in the flammable storage cabinet included 100% Reagent Alcohol, XS-3 Xylene Substitute, 95% Reagent Alcohol, Eosin-Y Alcoholic 0.25%, and Gill 3 Hematoxylin. 1d. An autostainer on a raised counter near the cryostat. 1e. A fume hood over the flammable storage cabinet rather than over the autostainer, which contained reagents. 2. Safety Data Sheets (SDS) for the reagents were reviewed. 2a. The SDS for germicidal bleach, with a revision date of 07/24/2018 stated the pH was approximately 12 (a strong base). "Store locked up. Product

	contains a strong oxidizer" and "reacts with acids to produce hazardous irritating gases, such as chlorine and other chlorinated compounds." 2b. The SDS for 100% Reagent alcohol, with a revision date of 11/06/2015 stated "highly flammable liquid and vapor...do not breathe mist, spray, vapors, gas." It also stated the reagent is incompatible with strong bases. 2c. The SDS for XS-3 Xylene Substitute, with a revision date of 10/05/2016 stated "flammable liquid and vapor.../avoid breathing vapors, mist, or spray...incompatible materials: ...strong bases, strong oxidizers." 2d. The SDS for Eosin-Y, Alcoholic 0.25%, with a revision date of 06/17/2015 stated "flammable liquid and vapor...reacts with (strong) oxidizers." 2e. The SDS for Gill 3 Hematoxylin, with a revision date of 05/30/2014 stated "incompatible materials: strong acids, strong bases, strong oxidizers." 2. The Histology Technician confirmed on 7/31/25 at 9:55 a.m., the reused reagent plastic jug with chemical waste should not be stored under the laboratory sink and should be put in the safety cabinet to ensure protection from chemical hazards. 3. The Laboratory Manager was interviewed on 7 /31/2025 at 9:55 a.m. They confirmed the fume hood was not being used, the fume hood was not placed over the work area where reagents were used, and the bleach was being stored alongside incompatible reagents (waste reagents listed in 2).
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) (c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (c)(1) Identity and when significant, titer, strength or concentration. (c)(2) Storage requirements. (c)(3) Preparation and expiration dates. (c)(4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, record review, and interview, three of three tissue inks used for Histology patient testing failed to be labeled with identity, preparation and expiration dates. Findings Included: 1. On 7/31/25 at 9:55 a.m., three of three formalin containers filled with tissue inks used for Histology patient testing failed to be labeled with identity, preparation and expiration dates. 2. The Histology Technician on 7/31 /25 at 9:55 a.m., stated the three of three formalin containers filled with tissue inks used for Histology patient testing, failed to be labeled with identity, preparation and expiration dates and that the tissue ink was placed in the formalin containers because the tissue inks available were expired. 3. The Reagent Logs for 2023, 2024, and 2025 included two lines to document lot number, expiration date, date received, and initials for Tissue Ink. The logs failed to have documentation of lot number, expiration date, date received, and initials for Tissue Ink for 2023, 2024, and 2025. The Laboratory Manager confirmed on 7/31/25 at 11:00 a.m., the laboratory failed to document and monitor the lot number, expiration date, date received, and initials for Tissue Ink on the Reagent Logs for 2023, 2024, and 2025.
D6079	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(a)(b) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, record and report test results promptly, accurately and proficiently, and for assuring compliance with the applicable regulations. (a) The laboratory director, if qualified, may perform the duties of the technical supervisor, clinical

	consultant, general supervisor, and testing personnel, or delegate these responsibilities to personnel meeting the qualifications under 493.1447, 493.1453, 493.1459, and 493.1487 respectively. (b) If the laboratory director reapportions performance of his or her responsibilities, he or she remains responsible for ensuring that all duties are properly performed. This STANDARD is not met as evidenced by: Based on record review and interview, the Laboratory Director failed to provide operational and administrative oversight by failing to review pre-analytic, analytic, and post-analytic quality assessment from 10/2023 through 07/2025. Findings included: 1. The CMS 209 Laboratory Personnel Report, signed and dated by the Laboratory Director on 06/20/2025 was reviewed. The Laboratory Director held all positions (clinical consultant, technical supervisor, general supervisor, testing person). 2. Quality Assessment forms titled; Pre-Analytic Assessment, Analytic Assessment, and Record Retrieval (post-analytic) were reviewed from 10/25/2023 through 07/08 /2025. The forms were filled out but not signed or dated by the Laboratory Director to reflect they were reviewed. 3. The Laboratory Manager was interviewed on 07/31 /2025 at 10:20 a.m. The Laboratory Manager stated a Laboratory Consultant completed the above forms. 4. The Laboratory Director was interviewed on 07/31 /2025 at 10:30 a.m. The Laboratory Director confirmed the above data.