Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2141328	(X3) Date Survey Completed 11/02/2021
Name of Provider or Supplier Dermatology Group Of Florida Pa	**Street Address, City, State** 1001 Nw 13th St Ste 100, Boca Raton, 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	Dermatology Group of Florida PA clinical laboratory is not in compliance with the 42 CFR Part 493, Requirements for Laboratories. A CLIA recertification survey was conducted 11/02/21.
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 store flammable liquid per the manufacturers' instructions since 12/31/19. Findings Included: During a tour of the lab on 11/12/21 at 3:00 PM it was observed chemicals (Eosin-Y, X3 xylene substitute, and 100% alcohol) being stored under the sink in a cabinet. Review of the manufacturers' instructions for Eosin-Y (lot# 125990 Exp. 07 /31/23) stated "Keep in fireproof place.", for X3 (lot#096229 Exp. 01/15/22) stated to "Keep container closed in a fireproof place.", and for 100% alcohol (lot# 110198 Exp. 10/31/22) it stated to "Store tightly closed in an approved Flammable Liquids storage area." Interview on 11/02/21 at 3:05 PM the Laboratory Manager confirmed that the cabinet under the sink was not a fireproof place.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.

	This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to perform competency evaluations on 3 (#A, #B, and #C) out of 3 Testing Personnel performing the Moderately complex Mycology, Parasitology, and Virology testing. Findings Included: Review of staff competency evaluations revealed no competency evaluations performed on Testing Personnel #A, #B, and #C who performed the Moderately complex Mycology, Parasitology, and Virology testing. Interview on 11 /02/21 at 4:30 PM the Laboratory Manager confirmed that there were no competencies for Testing Person #A, #B, and #C.
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 record review and interview the laboratory failed to verify the accuracy of Parasitology and Virology testing at least twice annually for 2 out of 2 years reviewed (2019-2021). Findings Included: Review of proficiency testing found no peer reviews for Parasitology or Virology. Policy and procedures (copyrighted 2019) stated that "Proficiency testing will be performed bi-annually." Interview on 11/02/21 at 4:11 PM the Laboratory Manager confirmed that there was no proficiency testing for the Parasitology and Virology testing since 2019.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(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 observations, record review, and interview the laboratory used expired Chlorazol Black since 09/12/21 and Wright-Giemsa stain since 07/16/21. Findings Included: During the tour of the laboratory on 11/02/21 at 3:00 PM HealthLink Chlorazol Black (lot# 9255 exp. 09/12/21) and Astral diagnostics Wright-Giemsa stain (lot# 0199 exp. 07/16/21) was observed on the counter next to the microscope. They were opened and no other Chlorazol Black or Wright -Giemsa stain were available. Review of Patient logs revealed that there were 8 Patients reported using the expired Chlorazol Black 2 on 09/15/21, 1 on 09/20/21, 1 on 09/21/21, 1 on 10/07/21, 1 on 10/14/21, 1 on 10/19/21, and 1 on 10/29/21. Review of Patient logs revealed that there was 1 patient reported using the expired Wright-Giemsa stain on 09/20/21. Interview on 11/02/21 at 3:10 PM the Laboratory Manager confirmed that the chemicals were expired.
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. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on record review and interview the laboratory failed to document the stain quality control of Hematoxylin and Eosin (H&E) stained slides for 3 days (03/10/20, 06/02/20, and 10/20/20) out of 8 days (02/18/20, 03/10/20, 06/02/20, 10/20/20, 02/16/21, 04/06/21, 07/20/21, and 09/21/21) reviewed. Findings Included: Review of H&E stain quality control records revealed no stain quality documented on 03/10/20, 06/02/20, and 10/20/20. Interview on 11/02/21 at 4:00 PM the Laboratory Manager stated that the stain quality is looked at but confirmed that it was not documented.