Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D0940726	01/09/2024
Name of Provider or Supplier	**Street Address, City, State**	
Shapiro And Borenstein Dermatology Llp D/B/A	11030 Rca Center Dr Ste 3015, Palm Beach Gardens, 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	A recertification survey was conducted on January 9, 2024. Shapiro and Borenstein Dermatology LLP dba Gardens Dermatology and Cosmetic Surgery Center clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the procedure manual and interview, the laboratory failed to include a procedure on the evaluation of quality control and patient

	Immunohistochemical (IHC) stained slides and Special stained slides from 10/05 /2021 to 01/09/2024. Findings: Review of the procedure manual revealed the the laboratory did not have a procedure on the evaluation of IHC stained slides and Special stained slides. Review of the laboratory's test menu showed the laboratory performed the interpretation of the following IHC and special stains: AE1/AE3 (Epithelial IHC stain), BCL-2 (B-cell lymphoma 2 IHC stain), BerEp4 (Epithelial Antigen IHC stain), CD3 (Cluster of Differentiation 3 T cell Lymphocytic IHC stain), CD20 (Cluster of Differentiation 20 B cell Lymphocytic IHC stain), CK20 (Cytokeratin 20 IHC stain), Melan-A (Melanocytic Marker IHC stain), MIB-1 (Ki-67) (Nuclear Non-histone Protein IHC stain), PRAME (melanocytic neoplasm IHC stain), S100 (Neural Tissue/Lesion and Melanoma IHC stain), SOX-10 (Melanoma IHC stain), Fontana Massom (melanin stain), Giemsa (histological stain), GMS (Gomori Methenamine-Silver stain for fungus), and Gram Stain (Bacteria stain). On 01/09 /2024 at 5:57 PM, Testing Personnel B stated the laboratory did not have a procedure on the evaluation of the stains.
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 observation of patient slides, review of patient biopsy reports and interview, the laboratory failed to have negative control slides for Immunohistochemical (IHC) stained slides, and failed to document the positive and negative reactivity of IHC stained slides for two of six (#5 and #6) patient's biopsy reports and slides reviewed. Findings: Observation of the patient slides on 01/09/2024 at 5:45 PM showed there were no negative control slides for the IHC stains for Patients #5 and #6 Review of the laboratory's test menu showed the laboratory performed the interpretation of the following IHC: AE1/AE3 (Epithelial IHC stain), BCL-2 (B-cell lymphoma 2 IHC stain), BerEp4 (Epithelial Antigen IHC stain), CD3 (Cluster of Differentiation 3 T cell Lymphocytic IHC stain), CD20 (Cluster of Differentiation 20 B cell Lymphocytic IHC stain), CK20 (Cytokeratin 20 IHC stain), Melan-A (Melanocytic Marker IHC stain), MIB-1 (Ki-67) (Nuclear Non-histone Protein IHC stain), PRAME (melanocytic neoplasm IHC stain), S100 (Neural Tissue/Lesion and Melanoma IHC stain), and SOX-10 (Melanoma IHC stain). Review of the patient biopsy reports and slides showed that Patient #5 had the following IHC stained slides evaluated: Melan-A (Melanocytic Marker IHC stain), PRAME (melanocytic neoplasm IHC stain), S100 (Neural Tissue/Lesion and Melanoma IHC stain), and SOX-10 (Melanoma IHC stain). Review of the patient biopsy reports and slides showed that Patient #6 had the following IHC stained slides evaluated: CD3 (Cluster of Differentiation 3 T cell Lymphocytic IHC stain), and CD20 (Cluster of Differentiation 20 B cell Lymphocytic IHC stain). On 01/09/2024 at 6:06 PM, the Testing Personnel B stated they did not receive a negative control slide and the reactivity for the IHC stains were not documented.
D5805	TEST REPORT

	CFR(s): 493.1291(c) The test report must indicate the following: (c)(1) For positive patient identification, either the patient's name and identification number, or a unique patient identifier and identification number. (c)(2) The name and address of the laboratory location where the test was performed. (c)(3) The test report date. (c)(4) The test performed. (c)(5) Specimen source, when appropriate. (c)(6) The test result and, if applicable, the units of measurement or interpretation, or both. (c)(7) Any information regarding the condition and disposition of specimens that do not meet the laboratory's criteria for acceptability. This STANDARD is not met as evidenced by: Based on review of patients' biopsy reports and interview, the laboratory failed to include name and address of the laboratory where the technical component for the immunohistochemical (IHC) stains were performed for two of six (#5 and #6)patients' biopsy reports reviewed. Findings: Review of the laboratory's test menu showed the laboratory performed the interpretation of the following IHC and special stains: AE1 /AE3 (Epithelial IHC stain), BCL-2 (B-cell lymphoma 2 IHC stain), BerEp4 (Epithelial Antigen IHC stain), CD3 (Cluster of Differentiation 3 T cell Lymphocytic IHC stain), CD20 (Cluster of Differentiation 20 B cell Lymphocytic IHC stain), CK20 (Cytokeratin 20 IHC stain), Melan-A (Melanocytic Marker IHC stain), MIB-1 (Ki-67) (Nuclear Non-histone Protein IHC stain), PRAME (melanocytic neoplasm IHC stain), S100 (Neural Tissue/Lesion and Melanoma IHC stain), SOX-10 (Melanoma IHC stain), Fontana Massom (melanin stain), Giemsa (histological stain), GMS (Gomori Methenamine-Silver stain for fungus), and Gram Stain (Bacteria stain). Review of the patient biopsy reports showed that Patient #5 had the following IHC stained slides evaluated: Melan-A (Melanocytic Marker IHC stain), PRAME (melanocytic neoplasm IHC stain), S100 (Neural Tissue/Lesion and Melanoma IHC stain), and SOX-10 (Melanoma IHC stain). Review of the patient biopsy reports showed that Patient #6 had the following IHC stained slides evaluated: CD3 (Cluster of Differentiation 3 T cell Lymphocytic IHC stain) and CD20 (Cluster of Differentiation 20 B cell Lymphocytic IHC stain). On 01/09/2024 at 5:59 PM, the Testing Personnel B stated the name and address where the IHC slides were stained was not listed on the biopsy reports.