Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2103015	**(X3) Date Survey Completed** 05/20/2022
Name of Provider or Supplier Us Dermatology Partners	**Street Address, City, State** 1515 Medical Parkway Building 1, Suite 100, Cedar Park, TX	

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	The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended.
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 review of Mohs accuracy peer reviews and interview, the laboratory failed to access accuracy of its Mohs testing of clear margins on the final stage and accurate maps for 2 of 2 years reviewed. Findings follow. A. Review of the Twice Annual Quality Assurance performed on 12/08/2021, 05/18/2021, 12/04/2020, and 06/16 /2020 showed the peer reviews were performed for "Final diagnosis". B. Interview with the histotech on May 20, 2022 at 1100 confirmed the diagnosis comes off the biopsy and agreed Mohs checks for clear margins on the final stage and should have accurate maps.
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 review of the manufacturer's instructions, quality control records, patient charts, and interview, the laboratory failed to document the reactions of the immunohistochemical (IHC) stain control slides for two of two years reviewed. Findings follow. A. Review of the Novodiax ihcDirect SOX10 Ab-Enh Instructions for Use, IFU-00036-EN-A July 2020, under Quality Control Procedures stated, "Positive and negative controls should be run simultaneously with patient specimens. Positive Tissue Control: The recommended positive control tissues for this antibody are properly processed melanoma and skin. The staining is nuclear for melanoma cells and melanocytes in skin. One positive tissue control for each set of test conditions should be included in each staining run. Previous tissue specimens that have been frozen and freshly cut or in some cases, an individual's own tissue may be used as controls... Negative Tissue Control: The same tissue used for the positive control may be used as the negative tissue control." B. Review of the laboratory's quality control records from 2022- 2020 showed no documentation of the ICH stains. C. Review of 11 patient test reports, slides, and maps showed 4 included the ihc stain SOX10. Review of the patient charts for the 2022 cases: 0277, 0273, 0254, 0186 did not mention the performance of the controls. D. Interview with the histotech on May 20, 2022 at 1340 confirmed the quality control for SOX10 was not noted in the patient's chart.
D5891	POSTANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1299(a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess and, when indicated, correct problems identified in the postanalytic systems specified in 493.1291. This STANDARD is not met as evidenced by: Based on review of the testing logs, patient charts, and interview, the laboratory failed to ensure testing for KOH and Scabies was recorded on the appropriate testing logs for two of two months reviewed for four of four patients. Findings follow. A. Review of the Scabies Logs showed results for 4 patients (3 negative, 1 positive) from 09/01 /2021 - 10/12/2021. B. Review of the corresponding patient charts showed all were reported as a KOH: three negatives for hyphae, and one positive for spores. No mention of Scabies test performed. MRN 1076754, 09/01/2021, postitive: spores; MRN 5380045, 09/28/2021, negative: no hyphae; MRN 5203648, 10/08/2021, negative: no hyphae; MRN 2674649, 10/12/2021, negative: no hyphae. C. Interview with the Lead Medical Assistant on May 20, 2022 at 1415 acknowledged the medical assistants logged the testing for the physician, and the Scabies Log must have been used to document the KOH testing.