Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2159884	04/30/2021
Name of Provider or Supplier	**Street Address, City, State**	
Dermasurgery Specialist, Pllc	2020 West State Highway 114 Suite 340, Grapevine, 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	Laboratory representatives were present at the entrance conference conducted 04/30 /2021. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the laboratory representatives on 04/30 /2021. The laboratory was found to be in substantial compliance for the specialties /subspecialties for which it was surveyed. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. CMS form 2567 will be emailed from the Texas State Health and Human Services Commission, Health Facility Compliance Arlington Group.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the laboratory's environmental monitoring records and staff interview, the laboratory failed to ensure room temperature ranges were within the laboratory's specifications prior to performing patient testing for 35 of 73 days in 2019 (09/2019-12/2019), 42 of 124 days in 2020 (01/2020-12/2020), and 17 of 66 days in 2021 (01-04/2021). Findings: 1. A review of the laboratory's environmental monitoring records from 01/2019 through 04/2021 revealed the laboratory had an established an acceptable room temperature range for the laboratory of 65-75F. 2. Further review of the laboratory's environmental monitoring records revealed the

	following days when the temperature was out of the acceptable range of 64 to 75F: Date: 10/11/2019; Temperature: 62 F Date: 10/29/2019; Temperature: 62 F Date: 10 /30/2019; Temperature: 61 F Date: 11/11/2019; Temperature: 61 F Date: 11/12/2019; Temperature: 64 F Date: 11/13/2019; Temperature: 63 F Date: 11/14/2019; Temperature: 64 F Date: 11/15/2019; Temperature: 63 F Date: 11/18/2019; Temperature: 62 F Date: 11/19/2019; Temperature: 63 F Date: 11/20/2019; Temperature: 62 F Date: 11/21/2019; Temperature: 62 F Date: 11/26/2019; Temperature: 63 F Date: 11/27/2019; Temperature: 64 F Date: 12/02/2019; Temperature: 62 F Date: 12/03/2019; Temperature: 63 F Date: 12/04/2019; Temperature: 62 F Date: 12/05/2019; Temperature: 62 F Date: 12/06/2019; Temperature: 63 F Date: 12/09/2019; Temperature: 63 F Date: 12/10/2019; Temperature: 62 F Date: 12/11/2019; Temperature: 63 F Date: 12/12/2019; Temperature: 63 F Date: 12/16/2019; Temperature: 62 F Date: 12/17/2019; Temperature: 63 F Date: 12/18/2019; Temperature: 62 F Date: 12/19/2019; Temperature: 63 F Date: 12/20/2019; Temperature: 64 F Date: 12/23/2019; Temperature: 62 F Date: 12/24/2019; Temperature: 63 F Date: 12/25/2019; Temperature: 62 F Date: 12/26/2019; Temperature: 62 F Date: 12/27/2019; Temperature: 62 F Date: 12/30/2019; Temperature: 62 F Date: 12/31/2019; Temperature: 62 F Date: 01/06/2020; Temperature: 63 F Date: 01/07/2020; Temperature: 63 F Date: 01/08/2020; Temperature: 63 F Date: 01/13/2020; Temperature: 64 F Date: 01/15/2020; Temperature: 64 F Date: 01/20/2020; Temperature: 62 F Date: 01/21/2020; Temperature: 62 F Date: 01/27/2020; Temperature: 61 F Date: 01/28/2020; Temperature: 63 F Date: 01/29/2020; Temperature: 61 F Date: 01/30/2020; Temperature: 61 F Date: 02/02/2020; Temperature: 60 F Date: 02/04/2020; Temperature: 64 F Date: 02/05/2020; Temperature: 62 F Date: 02/06/2020; Temperature: 64 F Date: 02/11/2020; Temperature: 63 F Date: 02/12/2020; Temperature: 62 F Date: 02/13/2020; Temperature: 61 F Date: 02/18/2020; Temperature: 64 F Date: 02/19/2020; Temperature: 63 F Date: 02/25/2020; Temperature: 63 F Date: 02/26/2020; Temperature: 62 F Date: 02/27/2020; Temperature: 61 F Date: 03/04/2020; Temperature: 64 F Date: 03/09/2020; Temperature: 64 F Date: 10/26/2020; Temperature: 64 F Date: 10/27/2020; Temperature: 60 F Date: 10/28/2020; Temperature: 59 F Date: 10/29/2020; Temperature: 61 F Date: 11/02/2020; Temperature: 64 F Date: 11/04/2020; Temperature: 56 F Date: 11/24/2020; Temperature: 62 F Date: 12/03/2020; Temperature: 61 F Date: 12/10/2020; Temperature: 62 F Date: 12/14/2020; Temperature: 61 F Date: 12/15/2020; Temperature: 64 F Date: 12/16/2020; Temperature: 61 F Date: 12/17/2020; Temperature: 61 F Date: 12/21/2020; Temperature: 64 F Date: 12/22/2020; Temperature: 64 F Date: 12/29/2020; Temperature: 62 F Date: 12/31/2020; Temperature: 62 F Date: 01/04/2021; Temperature: 64 F Date: 01/05/2021; Temperature: 63 F Date: 01/06/2021; Temperature: 64 F Date: 01/11/2021; Temperature: 64 F Date: 01/12/2021; Temperature: 62 F Date: 01/18/2021; Temperature: 62 F Date: 01/21/2021; Temperature: 63 F Date: 01/26/2021; Temperature: 61 F Date: 01/27/2021; Temperature: 61 F Date: 01/28/2021; Temperature: 61 F Date: 02/01/2021; Temperature: 61 F Date: 02/09/2021; Temperature: 63 F Date: 02/10/2021; Temperature: 62 F Date: 02/11/2021; Temperature: 61 F Date: 02/22/2021; Temperature: 61 F Date: 02/26/2021; Temperature: 61 F Date: 04/05/2021; Temperature: 64 F 3. During an interview on 04 /30/2021 at 10:35 pm, the laboratory director confirmed the findings.
D5473	CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)

	(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) logs, Mohs case logs, and confirmed in interview, the laboratory failed to define for each day of use, test staining materials for intended reactivity to ensure the predictable staining characteristics for the Hematoxylin and Eosin (H&E) QC for 86 of 87 days in 2020 (02 /2020, 04/2020-08/2020). Findings: 1. A review of the "Daily Stain Quality" log in 2020 revealed the following: The log had a column for "Quality" and each day QC was documented with a checkmark in the column and the initials the laboratory director in another column. The log did not specify the meaning of the checkmark. The bottom of the log stated, "The first case submitted each day will have an additional slide cut and stained as the H&E control slide. This slide will be kept on file. The quality control slide will show blue nuclei and pink cytoplasm. If stain quality is not adequate, corrections must be documented and an additional control slide must be submitted." The following dates were observed to be documented with a checkmark: 02/2020: 5, 6, 10, 11, 12, 13, 17, 18, 19, 25, 26, 27, 28 04/2020: 13, 22, 23, 27, 28, 29, 30 05/2020: 4, 5, 6, 7, 11, 12, 13, 14, 18, 19, 20, 21, 26, 27, 28 06 /2020: 1, 2, 3, 4, 8, 9, 10, 11, 15, 16, 17, 18, 22, 23, 24, 25, 29, 30 07/2020: 1, 2, 6, 7, 8, 9, 13, 14, 15, 16, 20, 21, 22, 23, 27, 28, 29, 30 08/2020: 3, 4, 5, 6, 10, 11, 12, 14, 17, 18, 19, 20, 24, 25, 26, 31 The laboratory failed to document the staining characteristics for the H&E stain. 2. Review of the laboratory's "2020 Mohs Case Log" revealed 676 patients that were tested and reported when the laboratory failed to document intended reactivity for the H&E stain for the above-mentioned dates. The following are a random sampling of patients from those dates: 02/05/2020 Patient IDs: M20-0110, M20-0111, M20-0112, M20-0113, M20-0114, M20-0115 02/10/2020 Patient IDs: M20-0122, M20-0123, M20-0124, M20-0125, M20-0126, M20-0127, M20-0128 04/13/2020 Patient IDs: M20-0331, M20-0332, M20-0333 04/22/2020 Patient IDs: M20-0334, M20-0335, M20-0336, M20-0337, M20-0338, M20-0339 05 /14/2020 Patient IDs: M20-0434, M20-0435, M20-0436, M20-0437, M20-0438, M20-0439, M20-0440, M20-0441 05/19/2021 Patient IDs: M20-0449, M20-0450, M20-0451, M20-0452, M20-0543, M20-0455, M20-0446 06/3/2020 Patient IDs: M20-0515, M20-0516, M20-0517, M20-0518, M20-0519, M20-0520 06/04/2020 Patient IDs: M20-0521, M20-0522, M20-0523, M20-0524, M20-0525, M20-0526, M20-0527 07/01/2020 Patient IDs: M20-0637, M20-0638, M20-0639, M20-0640, M20-0641, M20-0642, M20-0643, M20-0644 07/21/2020 Patient IDs: M20-0727, M20-0728, M20-0729, M20-0730, M20-0731, M20-0731, M20-0732, M20-0733, M20-0734, M20-0735 08/10/2020 Patient IDs: M20-0821, M20-0822, M20-0823, M20-0824, M20-0825, M20-0826, M20-0827, M20-0828, M20-0829, M20-0830 08/20/2020 Patient IDs: M20-0888, M20-0889, M20-0890, M20-0891, M20-0892, M20-0893, M20-0894, M20-0895, M20-0896, M20-0897 The laboratory failed to document the staining characteristics for the H&E stain for each day of use. 3. During an interview on 04/30/2021 at 10:35 am, the Laboratory Director confirmed the above findings.