Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2096456	11/18/2019
Name of Provider or Supplier	**Street Address, City, State**	
Us Dermatology Partners	2801 S Hulen Street, Suite 400, Fort Worth, 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 Histotechnician, Regional Clinical Manager, and Office Manager were at the entrance conference conducted 11/18/2019. The survey process was discussed. An opportunity for questions and comments was given. Exit conference was held with the Laboratory Director, Histotechnicians, Regional Clinical Manager, and Office Manager on 11/18/2019. 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 manufacturer's instructions, cryostat maintenance logs, and staff interview, the laboratory failed to properly monitor and document cryostat temperatures used to process patient histology specimens for 151 of 167 days in 2018 and 155 of 157 days in 2019. Findings: 1. Review of the cryostat operator's manual revealed "Chamber Temperature Max -35C". 2. Review of the laboratory's Cryostat Maintenance log revealed a defined cryostat temperature range of "-25 to -35". Note the range was not defined in Celcius or Fahrenheit. Review of the logs from 01/2018 through 12/2018 and 01/2019 through 11/2019 revealed the documented temperatures

	were not within the defined range. The following are a sampling of those dates and temperature: 04/02/2018 "34" 04/03/2018 "33" 04/04/2018 "32" 04/10/2018 "33" 12 /11/2018 "34" 12/12/2018 "34" 12/17/2018 "35" 12/18/2018 "34" 12/19/2018 "34" 10 /28/2019 "34" 10/29/2019 "34" 10/30/2019 "34" 11/04/2019 "33" 11/05/2019 "34" 11 /06/2019 "35" 11/08/2019 "34" 11/11/2019 "33" 11/12/2019 "34" 11/13/2019 "35" The laboratory failed to properly monitor and document cryostat temperatures. 3. During an interview on 11/18/2019 at 10:12 am the histotechnician stated that the documented temperatures should be "negative" and the histotechnicians do not write the negative sign in front of the number for the temperature because they know it is negative. This confirmed the above 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: I. Based on review of the laboratory's procedure manual, Quality Control (QC) 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 12 of 12 days in 2018 (random review 12/2018) and 25 of 25 days in 2019 (random review 08/2019, 10 /2019). Findings: 1. Review of laboratory policy Hematoxylin and Eosin Stain revealed: "Quality Control: Frozen sections have an internal control. There is a QC sheet that will be filled out daily (see last sheet in procedure. [sic] ... RESUTLS Nuclei Blue Erythrocytes and eosinophillic granules Bright pink to red Cytoplasm and other tissue elements Various shades of pink" 2. A random review of the "Slide Quality & Maintenance" log in 2018 and 2019 revealed the following: The log had a column for "Stain 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 "H&E stain and section quality should be completed daily by the physician." The following dates were observed to be documented with a checkmark: December 2018: 3, 4, 5, 7, 10, 11, 12, 18, 19, 20, 26, 27 August 2019: 5, 6, 7, 12, 13, 14, 16, 19, 20, 21, 26, 27 October 2019: 1, 2, 7, 8, 14, 15, 16, 21, 22, 23, 25, 28, 29, 30 The laboratory failed to document the staining characteristics for the H&E stain. 3. During an interview on 11 /18/2019 at 12:10 pm, the histotechnician confirmed the above findings. II. Based on review of laboratory policy, Quality Control (QC) logs and confirmed in interview, the laboratory failed to document 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 1 of 12 days in 2018 (12/2018) and 4 of 29 days in 2019 (08/2019, 10/2019). 1. Review of laboratory policy Hematoxylin and Eosin Stain revealed: "Quality Control: Frozen sections have an internal control. There is a QC sheet that will be filled out daily (see last sheet in procedure. [sic] ... RESUTLS Nuclei Blue Erythrocytes and eosinophillic granules Bright pink to red Cytoplasm and other tissue elements Various shades of pink" 2. Review of the "Slide Quality & Maintenance" log in 2018 and 2019 revealed the following: The log had a column for "Stain 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 "H&E stain and section quality should be completed daily by the physician." The laboratory failed to document intended reactivity of the H&E stain on the following dates patients were tested in 2018 and 2019: 12/17/2018 Patient IDs: M18-1047, M18-1048, M18-1049, M18-1050, M18-1051, M18-1052 08/28/2019 Patient IDs: M19-763, M19-764, M19-765, M19-766, M19-767, M19-168 08/30/2019 Patient IDs: M19-769, M19-770, M19.770, M19-771, M19-772, M19-773, M19-774 10/09/2019 Patient IDs: M19-894, M19-895, M19-896, M19-897, M19-898 10/11/2019 Patient IDs: M19-899, M19-900, M19-901, M19-902, M19-903 The laboratory failed to document the staining characteristics for the H&E stain for each day of use. 3. During an interview on 11/18/2019 at 12:10 pm, the histotechnician confirmed the above findings.