Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2036772	11/19/2020
Name of Provider or Supplier	**Street Address, City, State**	
Dfw Skin Surgery Center, Pllc	1115 W Randol Mill Road, Suite 200, Arlington, 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 Laboratory Director was present at the entrance conference conducted 11/19 /2020. The survey process was discussed. An opportunity for questions and comments was given. The exit conference was held with the Laboratory Director on 11/19/2020. 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.
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory policy, patient records and confirmed in interview, the laboratory failed to follow their own written policy for labeling Mohs slides for 27 of 27 patients in 2019 (random review) and 27 of 27 patients in 2020 (random review). Findings: 1. Review of the laboratory's "Policies and Procedures Manual - Mohs Surgery" page 3 stated: "Specimen Handling, Storage, Transport, Preservation and Identification ... Laboratory technician cuts frozen sections and stains slides. Slides are labeled with accession number, patient name, and date." 2. A random review of patient Mohs slides from 2019 and 2020 were observed to labeled with patient name, accession number, stage, section number and slide number as follows: 04/02/2019 Patient ID: M19-0375, M19-0376, M19-0377, M19-0378, M19-0379 04/03/2019 Patient ID: M19-0380, M19-0381, M19-0382, M19-0383, M19-0384, M19-0385, M19-0386, M19-0387, M19-0388, M19-0389, M19-

	0390 04/08/2019 Patient ID: M19-0391, M19-0392, M19-0393, M19-0394, M19-0395, M19-0396, M19-0397, M19-0398, M19-0399, M19-0400, M19-0401 11/02/2020 Patient ID: M20-1046, M20-1047, M20-1048, M20-1049, M20-1050, M20-1051, M20-1052, M20-1053, M20-1054 11/03/2020 Patient ID: M20-1055, M20-1056, M20-1057, M20-1058, M20-1059, M20-1060, M20-1061, M20-1062, M20-1063, M20-1064 11/04/2020 Patient ID: M20-1065, M20-1066, M20-1067, M20-1068, M20-1069, M20-1070, M20-1071, M20-1072 The laboratory failed to follow their own written policy for labeling Mohs slides with accession number, patient name, and date. 3. During an interview on 11/19/2020 at 2:50 pm, the laboratory director 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: Based on review of the laboratory's policy, Quality Control (QC) logs, and confirmed in interview, the laboratory failed to define intended reactivity for staining material each day of use to ensure predictable staining characteristics for the Hematoxylin and Eosin (H&E) QC for 177 of 177 days in 2019 (01/02/2019 through 12/20/2019) and 73 of 73 days in 2020 (01/06/2020 through 09/23/2020). Findings: 1. Review of the laboratory's "Policies and Procedures Manual - Mohs Surgery" page 7 stated: "Frequency and Record of Quality Control Analyses Each day that this procedure is performed, a positive control sample will be analyzed in exactly the same manner as patient samples prior to the first case of the day (see Appendix C). Any discrepancy in staining of the control sample will be logged in the Quality Control Log, as will be any other noted abnormality in tissue processing, together with the subsequent corrective action, as directed by the Laboratory Director (see Appendix E)." The policy did not define intended reactivity of the H&E stain to ensure predictable characteristics. 2. Review of the "Staining Quality Control Log for Mohs Surgery" revealed the following: The log had columns for "Date", "Staining Quality", "Issue, if not "Good"", "Corrective Measure", and "Signature". Each day QC was documented under the "Staining Quality" column with the word "Good". The log failed to specify what the word "Good" meant. The following dates in 2019 and 2020 were observed to be documented with "Good": 2019 January: 2, 7, 8, 9, 14, 15, 16, 21, 22, 23, 28, 29, 30 February: 4, 5, 6, 11, 12, 13, 18, 19, 20, 25, 26, 27 March: 4, 5, 6, 11, 12, 13, 18, 19, 20, 25, 26, 27 April: 1, 2, 3, 8, 9, 10, 15, 16, 17, 22, 23, 24, 29, 30 May: 1, 6, 7, 8, 13, 14, 15, 20, 21, 22, 28, 29 June: 3, 4, 5, 10, 11, 12, 17, 18, 19, 24, 25, 26 July: 1, 2, 3, 8, 9, 10, 15, 16, 17, 22, 23, 24, 29, 30, 31 August: 5, 6, 7, 13, 14, 19, 20, 21, 26, 27, 28 September: 3, 4, 9, 10, 11, 16, 17, 18, 23, 24, 25, 30 October: 1, 2, 7, 8, 9, 14, 15, 16, 21, 22, 23, 28, 30 November: 4, 5, 6, 11, 12, 13, 18, 19, 20, 25, 26, 27 December: 2, 3, 4, 9, 10, 11, 16, 17, 18, 23, 26, 27, 30 2020 January: 6, 7, 8, 13, 14, 15, 20, 21, 22, 27, 28, 29 February: 10, 11, 12, 17, 18, 19, 24, 25, 26 March: 2, 3, 4, 10, 11, 16, 17, 18, 23, 24, April: 7, 16, 27, 28, 29 May: 4, 5, 6, 11, 12, 13, 18, 19, 20, 26, 27 July: 28, 29 August: 3, 4, 5, 10, 11, 12, 17, 18, 19, 24, 25, 26, 31 September: 1, 2, 8, 9, 14, 15, 16, 21, 22, 23 The laboratory failed to document the staining characteristics for the H&E stain. 3. The laboratory had an annual volume of 1400 histology patients. 4.

	During an interview on 11/19/2020 at 1:45 pm, the laboratory director confirmed the above findings.