Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0988160	01/17/2020
Name of Provider or Supplier	**Street Address, City, State**	
Fort Worth Dermatology Associates	1200 W Rosedale, 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 Laboratory Director and Histotechnician were at the entrance conference conducted 01/17/2020. The survey process was discussed. An opportunity for questions and comments was given. Exit conference was held with the Laboratory Director on 01/17/2020. The laboratory was found to be in substantial compliance for the specialties/subspecialties for which it was surveyed. The standard level deficiency cited was 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.
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 laboratory policy, quality control (QC) logs, patient records, 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 15 of 15 days in 2018 (12/2018), 33 of 33 days in 2019 (11/2019, 12/2019) and 9 of 9 days in 2020 (01/2020). Findings: 1. Review of the laboratory's H&E staining policy revealed: "Quality Control: 1. Laboratory director shall review the first slide prepared each day for adequacy of stain." The procedure failed to define the staining characteristics for intended reactivity of the H&E stain. 2. A random review in 2018, 2019 and 2020 of "MOHS FORZEN SECTION DAILY TECHNICAL QUALITY ASSURANCE REPORT" revealed the following: The log had a row for "Stain Quality," each day

	stain quality was documented as "SATISFACTORY" or "UNSATISFACTORY" by placing a "checkmark" in the corresponding column. The bottom of the log was initialed by the laboratory director as the reviewer. The log did not specify if "SATISFACTORY" or "UNSATISFACTORY" was indicated for H&E intended reactivity to ensure predictable staining characteristics. The following dates were observed to be documented with "SATISFACTORY": 2018 December: 3, 4, 5, 6, 10, 11, 12, 13, 17, 18, 19, 20, 26, 27, 28 2019 November: 4, 5, 6, 7, 11, 12, 13, 14, 16, 18, 19, 20, 21, 26, 27 December: 2, 3, 4, 5, 9, 10, 11, 12, 14, 16, 17, 18, 19, 23, 26, 27, 30, 31 2020 January: 2, 6, 7, 8, 9, 13, 14, 15, 16 The laboratory failed to document the intended reactivity to ensure predictable H&E characteristics for the above dates. 3. The laboratory had an annual test volume of 1500 cases. 4. During an interview on 01 /17/2020 at 12:05 pm, the laboratory director confirmed the above findings.