Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2111811	01/07/2021
Name of Provider or Supplier	**Street Address, City, State**	
Richardson Dermatology, Pllc	7000 Bryant Irivn Road, Suite 100, 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	An entrance conference was held with the laboratory representatives. The survey process was discussed, and survey forms were provided. An opportunity for questions and comments was given. Noted deficiencies and plans of correction were discussed with the laboratory representatives at the exit conference. The laboratory representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be NOT in compliance with the CLIA conditions for specialties /subspecialties surveyed for 42 CFR 493.1441 Laboratory Director, (high complexity) CMS form 2567 will be emailed from the Texas State Health and Human Services Commission, Health Facility Compliance Arlington Group.
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 the laboratory's procedure manual, "Proficiency Testing" records, and in interview with staff, the laboratory failed to ensure accuracy was verified for Mohs procedure for 2 or 2 events in 2018, 2 of 2 events in 2019 and 1 of 1 event in 2020 (not included in subpart I of this part). Findings: 1. Review of the laboratory's procedure manual (page 8) stated, "Since there do not seem to be any suitable, commercially available control materials for this procedure, randomly-selected sample slides will be sent every 6 months for peer review to another CLIA-certified laboratory (see Appendix D). Twice yearly the Director of operations (via calendar reminder) will initiate a peer review. The Clinical Coordinator or lab technician will ensure that the slides are sent. The Lab Director will compare results. The slides will be submitted to [Dr. Name]. Results will be kept in the front pocket of the instrument Control Log Binder." 2. Review of the laboratory's "Mohs Micrographic Surgery Skin

	Specimens Proficiency Testing" records revealed the following: 08/21/2018 Patient #MV18-920 record stated, "Slide Interpretation: Agree with original dx; Additional Comments: Excellent sections; good staining" Mohs maps were included with diagnosis and stages. 11/26/2018 Patient #MV18-1353 record stated, "Slide Interpretation: Agree with original interpretation; Additional Comments: Very nice sections/staining quality" Mohs maps were included with diagnosis and stages. 07/15 /2019 Patient #MV19-787 record stated, "Slide Interpretation: Agree original interpretation; Additional Comments: Great sections" Mohs maps were included with diagnosis and stages. 12/20/2019 Patient #MV19-1661 record stated, "Slide Interpretation: Agree with original interpretation; Additional Comments: Excellent staining & complete sections" Mohs maps were included with diagnosis and stages. 07 /27/2020 Patient #MV20-780 record stated, "Slide Interpretation: Agree with original interpretation; Additional Comments: Excellent quality sections" Mohs maps were included with diagnosis and stages. The slide interpretation and additional comments were documented by the outside laboratory doctor. The outside doctor had access to the original interpretation of the Mohs slides. The laboratory did not ensure verification of accuracy with blind patient samples when submitted to an outside laboratory. 3. According to records, the laboratory's annual volume was 1600 histopathology tests. 4. During an interview on 01/07/2018 at 2:36 pm, the Medical Assistant (MA) was asked what was submitted to the outside doctor for twice annual verification, she stated, "The slides and Mohs map with patient demographics blacked out." The Mohs maps included diagnosis of patient Mohs slides, the diagnosis was not blacked out. Note this was a repeat deficiency from recertification survey conducted on 05/22/2018.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on review of the laboratory's procedure manual, "Proficiency Testing" records, and in interview with staff, the laboratory director failed to provide overall management and direction of the laboratory services. Refer to D6082.
D6082	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(1) The laboratory director must ensure that testing systems developed and used for each of the tests performed in the laboratory provide quality laboratory services for all aspects of test performance, which includes the preanalytic, analytic, and postanalytic phases of testing. This STANDARD is not met as evidenced by: Based on review of the laboratory's procedure manual, "Proficiency Testing" records, and in interview with staff, the laboratory director failed to ensure that testing systems performed in the laboratory provided quality laboratory services for all aspects of test performance as evidenced by: 1. The laboratory failed to ensure accuracy was verified for Mohs procedure for 2 or 2 events in 2018, 2 of 2 events in 2019 and 1 of 1 events

	in 2020 (not included in subpart I of this part). Refer to D5217. Note this was a repeat deficiency from recertification survey conducted on 05/22/2018.