Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2111811	05/22/2018
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 05/22/2018 with the Medical Assistant (MA) and the Laboratory Director. The survey process was discussed. An opportunity for questions and comments was given. Based upon the onsite survey conducted 05/22 /2018, this facility was found to be in substantial compliance for the specialties /subspecialties in which it was surveyed. An exit conference was held 05/22/2018 with the MA and the Laboratory Director. The standard level deficiencies cited were discussed. The process for submitting the corrections was explained. An opportunity for questions and comments was provided.
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 in 11/2017 and 12/2017 (not included in subpart I of this part). Findings included: 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: 11/27/2017 - Patient #MV17-1064 record stated, "Slide Interpretation: Agree with original interpretation (BCC on Stage I; clear

	margins on Stage II); Additional Comments: Excellent overall quality." Patient #MV17-1062 record stated, "Slide Interpretation: BCC present on Stage I, Margins clear on Stage II; Additional Comments: Agree with outside/original interpretation, great quality slides." Mohs maps were included with diagnosis and stages. 12/18/2017 - Patient #MV17-1183 record stated, "Slide Interpretation: Agree BCC present on Stage I, margins clear on Stage II; Additional Comments: Good quality slides, Agree with original interpretation." Patient #MV17-1181 record stated, "Slide Interpretation: Agree with outside interpretation (BCC on Stage I; clear margins on Stage II); Additional Comments: Excellent staining/quality." 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 1200 histopathology tests. 4. During an interview on 05/22/2018 at 2:20 pm, the Medical Assistant (MA) was asked what was submitted to the outside doctor for twice annual verification, she stated, "The slides, Mohs map, and op notes." The Mohs maps and operation notes included diagnosis of patient Mohs slides.
D5311	SPECIMEN SUBMISSION, HANDLING, AND REFERRAL CFR(s): 493.1242(a) The laboratory must establish and follow written policies and procedures for each of the following, if applicable: (1) Patient preparation. (2) Specimen collection. (3) Specimen labeling, including patient name or unique patient identifier and, when appropriate, specimen source. (4) Specimen storage and preservation. (5) Conditions for specimen transportation. (6) Specimen processing. (7) Specimen acceptability and rejection. (8) Specimen referral. This STANDARD is not met as evidenced by: Based on direct observation, review of laboratory policy manual, patient slides and confirmed in interview with MA, the laboratory failed to follow its own written policy for labeling patient slides with the collection date for 12 of 12 randomly selected MOHS patient slides for 2016, 2017 and 2018. (Note: Multiple slides were prepared for each individual patient case.) Findings include: 1. Review of the laboratory's policy manual stated, "Slides are labeled with accession number, patient name, date and specimen source (if applicable)." 2. Review of selected patient slides from 11 /2016, 09/2017, 12/2017, 02/2018, 03/2018, 04/2018, 05/2018 revealed the laboratory failed to follow its own written policy for labeling patient slides with collection date for the following identified patients: BX18-020 MV18-481 MV18-488 MV18-429 MV18-430 MV18-335 MV18-336 MV18-148 MV17-1216 MV17-808 E17-010 MV16-027 3. According to records, the laboratory's annual volume was 1200 histopathology tests. 4. During an interview on 05/22/18 at 04:20 PM, the MA confirmed the above findings.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic

	examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of the laboratory's policy manual, Quality Control records, and confirmed in interview with MA, the laboratory failed to implement a written policy /procedure that defined the intended reactivity to ensure predictable staining characteristics of Hematoxylin & Eosin (H&E) stain. Findings included: 1. Review of the laboratory's policy manual did not include an H&E stain procedure that defined the intended reactivity of the stain to ensure predictable characteristics. 2. Review of the "Slide Quality Control" logs for 01/2018 through 04/2018 did not define the intended stain reactivity to ensure predictable characteristics. 3. According to records, the laboratory's annual volume was 1200 histopathology tests. 4. During an interview on 05/22/18 at 04:20 PM, the MA confirmed there was not a policy that defined the intended reactivity of the stain to ensure predictable characteristics.
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: I. Based on review of the manufacturer's instructions, the laboratory policy manual, and confirmed in interview with MA, the laboratory failed to monitor and document humidity of the room in which the cryostat and stainer were stored and were used to process patient specimens for 3 of 3 months in 2016, 12 of 12 months in 2017 and 4 of 4 months in 2018. Findings include: 1. Review of the Thermo Linistat Stainer manufacturer's instructions stated, "Relative Humidity-Max. 80%." 2. Review of the "Automatic Stainer Quality Control/Maintenance" logs for 10/2016 through 12/2016, 01/2017 through 12/2017 and 01/2018 through 04/2018 revealed the humidity range was not defined and humidity was not documented. 3. Review of the Thermo Scientific HM525NX Cryostat manufacturer's instructions stated, "Relative Humidity Max. 60%." 4. Review of the "Cryostat Maintenance" logs for 10/2016 through 12 /2016, 01/2017 through 12/2017 and 01/2018 through 04/2018 revealed the humidity

	range was not defined and was not documented. 5. According to records, the laboratory's annual volume was 1200 histopathology tests. 6. During an interview on 05/22/18 at 03:15PM, the MA confirmed the laboratory failed to follow manufacturer's instructions for monitoring and documentation of humidity conditions. II. Based on review of the laboratory policy manual and confirmed in interview of testing personnel, the laboratory failed to properly monitor and document room temperatures of the room in which the cryostat was stored and used to process patient specimens for 6 of 34 days from 10/2016 through 12/2016, for 189 of 189 days from 01/2017 through 12/2017 and for 51 of 62 days from 01/2018 through 04/2018. Findings include: 1. Review of the "Cryostat Maintenance" logs from 10/2016 through 12/2016, 01/2017 through 12/2017 and from 01/2018 through 04/2018 stated, "Optimal room temperature: 68 to 72 F." 2. Review of the Cryostat Maintenance" logs for 10/2016 through 12/2016, 01/2017 through 12/2017 and 01/2018 through 04/2018 revealed the following random sampling of days were not within the defined range (68 to 72 F): 12/15/2016; -69 12/20/2016; -69 12/21/2016; -70 12/22/2016; -69 12/27 /2016; -69 12/29/2016; -69 02/01/2017; -69 02/08/2017; -70 02/28/2017; -70 06/15 /2017; -69 06/28/2017; -69 10/03/2017; -70 10/24/2017; -68 12/06/2017; -68 12/19 /2017; -69 12/21/2017; -68 02/08/2018; -69 02/20/2018; -68 03/05/2018; -68 03/27 /2018; -68 04/03/2018; -69 04/30/2018; -68 3. During an interview on 05/22/18 at 04: 20 PM, the MA confirmed the temperatures were not documented correctly.
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 Quality Control records and confirmed in interview with MA, the laboratory failed to document staining materials for intended reactivity to ensure predictable staining characteristics of Hematoxylin & Eosin (H&E) stain for 15 of 15 months from 10/24/2016 through 12/31/2017. 1. Review of the "Slide Quality Control" log revealed "H&E Quality" for stain reactivity failed to define the intended stain reactivity to ensure predictable characteristics. (Refer to D5403) 2. When asked for logs from 2016 and 2017, none were provided and H&E reactivity was not documented. (The laboratory began testing in 10/24/2016.) The laboratory implemented "Slide Quality Controls" logs 01/2018. Logs from 01/2018 through 04 /2018 included: "Date", "H&E Quality, "Section Quality" and "Physical Initials". The logs did not include documentation of the H&E intended stain reactivity to ensure predicatable staining chararacterisitics. (Refer to D5403) 3. According to records, the laboratory's annual volume was 1200 histopathology tests. 4. During an interview on 05/22/2018 at 02:39 PM, the MA stated, "We don't have slide quality control for 2016 or 2017. This was an oversight." The MA confirmed the laboratory failed to document Hematoxylin & Eosin (H&E) stain for intended reactivity to ensure predictable staining characteristics