Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2141099	03/30/2022
Name of Provider or Supplier	**Street Address, City, State**	
Us Dermatology Partners Houston South	1327 Lake Pointe Pkwy, Ste 416, Sugar Land, 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	Noted deficiencies and plans of correction were discussed with the laboratory representative(s) at the exit conference. The facility representative(s) 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 in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 a review of the laboratory's policies, the KOH Quality Assurance logs, and staff interview, it was revealed that the laboratory failed to verify the accuracy of KOH procedures at least twice annually for three of three testing personnel in 2021. Findings include: 1. A review of the laboratory's policy titled "KOH Quality Assurance" revealed the following: "Each provider who performs KOH must have two cases reviewed by another provider in the practice twice per year." 2. A review of the KOH Quality Assurance logs for 2021 revealed no documentation of verifying the accuracy of the KOH procedures for the following three testing personnel: Testing

	person #1 Testing person #3 Testing person #4 3. An interview with the Administrator on 3/30/22 at 11:25 a.m. in her office, after review of the records, confirmed the above findings. Key: KOH = Potassium Hydroxide
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 a review of laboratory's procedure manual and staff interview, it was revealed that the laboratory failed to have a written procedure for how it will ensure the accuracy, at least twice annually, for MOHS slides. Findings include: 1. A review of the laboratory's procedure manual revealed the laboratory failed to have a written procedure for how it will perform the twice annual accuracy assessments for MOHS slides. 2. An interview with the Administrator on 3/30/22 at 9:50 a.m. in her office, after review of the records, confirmed the above findings.
D5407	PROCEDURE MANUAL CFR(s): 493.1251(d) Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies and staff interview, it was revealed that the laboratory failed to ensure the laboratory director signed and approved six of six procedures before use. Findings include: 1. A review of the laboratory's policies revealed the laboratory failed to ensure the laboratory director signed and approved the following 6 procedures before use: - Procedures for the Test Performed - Patient Test Management - Quality Control - Quality Assurance - Laboratory Manual for Provider Performed Microscopy - Mohs Laboratory Procedure Manual 2. An interview with the Administrator on 3/30/22 at 11:40 a.m. in her office, after review of the records, confirmed the above findings.

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 surveyor observation, a review of the operations manual for the Olympus BX46 Instructions, and staff interview it was revealed the laboratory failed to have documentation of monitoring the temperature and humidity in one of one office of testing personnel where laboratory equipment was stored. Findings include: 1. During a tour of the facility on 3/30/22 at 11:15 a.m. an Olympus BX46 System Microscope was found in the office of testing person #1. 2. A review of the Instruction Manual for Olympus BX46 revealed the manufacturer required the following conditions for operation: Olympus BX46 System Microscope "Ambient temperature: 5C to 40C (41 to 104 F) Maximum relative humidity: 80% for temperatures up to 31C (88F) , decreasing linearly through 70% at 34C (93F), to 60% at 37C (99F), to 50% relative humidity at 40C (104F)." 3. The laboratory was asked to provide documentation of monitoring the temperature and humidity in the office for compliance with the manufacturer's instructions. No documentation was provided. 4. An interview with the Administrator on 3/30/22 at 11:30 a.m. in her office, revealed the facility did not monitor the temperature or humidity in the office. 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: Based on a review of laboratory's policies, the laboratory's Quality Control Analysis Log Sheets, a review of patient test records, and staff interview, it was revealed that the laboratory failed to document the intended reactivity of Hematoxylin & Eosin (H&E) stain for Mohs histopathology slides each day of use for one of 15 days reviewed from March 2021 to November 2021. Findings: 1. A review of the laboratory's policy titled "CLIA Compliance Procedure Manual Moh's Microscopic Surgery" revealed the following: "It is the policy of US Dermatology Partners to maintain a quality control program to ensure that accuracy is reported and documented. A positive and or negative control will be used as indicated by staining protocol. Control slides are ran daily to check the validity of the stain." 2. A review of the laboratory's Quality Control Analysis Log Sheets from March 2021 to November 2021 revealed no documentation of the intended reactivity for the H&E stain on November 29, 2021. 3. A review of patient test records revealed the following 8

	patients were tested on November 29, 2021 when the intended reactivity of the H&E slide was not documented: Patient Case Numbers: 107 108 109 110 111 112 113 114 4. An interview with the Administrator on 3/30/22 at 11:15 a.m. in her office, after review of the records, confirmed the above findings.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(1) Test systems do not meet the laboratory's verified or established performance specifications, as determined in 493.1253(b), which include but are not limited to-- (b)(1)(i) Equipment or methodologies that perform outside of established operating parameters or performance specifications; (b)(1)(ii) Patient test values that are outside of the laboratory's reportable range of test results for the test system; and (b)(1)(iii) When the laboratory determines that the reference intervals (normal values) for a test procedure are inappropriate for the laboratory's patient population. This STANDARD is not met as evidenced by: Based on a review of the laboratory's policies, the laboratory's Room Temperature logs, the laboratory's patient test records, and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions when the room temperature or humidity were documented outside the laboratory's acceptable range for two of 13 times from October 2021 to March 2022. Findings include: 1. A review of the laboratory's policy titled "CLIA Compliance Procedure Manual" revealed the following: "Temperatures will be recorded each surgery day by the laboratory technician. If the temperature is outside the desired range, the laboratory supervisor will be notified, as soon as possible, so that appropriate corrective action may be taken." 2. A review of the laboratory's Room Temperature logs from October 2021 to March 2022 revealed the following acceptable temperature and humidity ranges: Room Temperature 15 - 25C (59 - 77F) Humidity should not be greater than 60% 3. Further review of the Room Temperature logs from October 2021 to March 2022 revealed the following 2 days where the documented room temperature or humidity were outside the laboratory's acceptable range and no corrective action was documented: Date: 10/4/21 Humidity 64% Date: 2/7/22 Room Temperature: 79.9F 4. A review of the laboratory's patient test records revealed the following 10 patient's specimens were processed when the room temperature or humidity were outside of the acceptable ranges: Patient Case Number: 083 084 085 018 019 020 021 022 023 024 5. An interview with the Administrator on 3/30/22 at 10:50 a.m. in her office, after review of the records, confirmed the above findings.
D6102	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(12) The laboratory director must ensure that prior to testing patients' specimens, all personnel have the appropriate education and experience, receive the appropriate training for the type and complexity of the services offered, and have demonstrated that they can perform all testing operations reliably to provide and report accurate results. This STANDARD is not met as evidenced by:

	Based on a review of the laboratory's submitted CMS 209 form, the laboratory's personnel records, and staff interview, it was revealed that the laboratory director failed to ensure one of one testing personnel had documentation of on-site training to perform high complexity testing- Mohs. Findings include: 1. A review of the CMS 209 form revealed the laboratory identified one testing personnel performing high complexity testing- Mohs. 2. A review of the laboratory's personnel records revealed testing person #2 failed to have documentation of on-site training for performing Mohs. 3. An interview with the Administrator on 3/30/22 at 9:20 a.m. in her office, after review of the records, confirmed the above findings.