Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 45D2074576	**(X3) Date Survey Completed** 05/25/2018
Name of Provider or Supplier Houston Skin Cancer Associates Pllc	**Street Address, City, State** 20320 Nw Freeway Suite 700, Jersey Village, 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 was found out of compliance with the CLIA regulations. The conditions not met were: D6168 - 42 C.F.R. 493.1487 Condition: Laboratories performing high complexity testing; testing personnel; The facility representative was given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit.
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 procedures and laboratory records and confirmed in an interview, the laboratory failed to document at least twice annually the accuracy of 1 of 1 tests. (Hematoxylin and eosin stain) Findings were: 1. Review of the laboratory procedure Mohs Lab Biannual revealed "biannually; each calendar year. Four Mohs cases are randomly selected to be pulled and reviewed by an outside dermapathologist. They will evaluate the slides and list if they are acceptable and concur with the Mohs surgeon's findings." 2. A review of laboratory proficiency testing records from 2017 revealed documentation of the laboratory verifying the accuracy for the Hematoxylin and eosin stain on 1/13/17. The laboratory was asked for documentation of the 2nd accuracy assessment for Hematoxylin and eosin stain for 2017. No documentation was provided. 3. An interview with the histotechnician via phone on 5/25/18 at 0925 hours in the office manager's office confirmed the above findings. She stated that she has been unable to coordinate with the Mohs surgeon to select the slides for the 2nd accuracy assessment for 2017.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d)

	Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by: Based on observations, review of laboratory records, and confirmed in interview, the laboratory failed to ensure the laboratory did not use expired materials for histopathology testing. Findings were: 1. Surveyor observation on 5/25/18 at 0940 hours revealed the following expired reagents in the laboratory flammable cabinet: 1 opened Eosin-y Alcoholic 0.25% (SL98-1) lot #043181, exp 12/17 2. Surveyor observations on 5/25/18 at 0940 hours revealed the following expired reagents in the laboratory: 7 unopened Submount mounting media (57006-4) lot # 6105 exp 4/13/18 1 opened Submount mounting media (57006-4) lot # 6105 exp 4/13/18 3. Random review of the laboratory case log sheet for 2018 revealed documentation that the laboratory performed patient testing using the above expired reagents. date case # 1/12 /18 TF18-C1 1/26/18 TF18-C13 2/09/18 TF18-C26 3/09/18 TF18-C45 3/30/18 TF18-C51 4/03/18 WW18-C62 5/8/18 WW18-C70 4. An interview with the office manager on 5/25/18 at 0945 hours in the laboratory confirmed the above findings.
D6094	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on review of the laboratory policies, laboratory records, and confirmed in interview, the laboratory director failed to establish and maintain a quality assessment policy to identify and detect problems in the laboratory. Findings were: 1. The laboratory director failed to ensure the laboratory documented at least twice annually the accuracy of 1 of 1 tests. (refer to D5217) 2. The laboratory director failed to ensure the laboratory did not use expired materials for histopathology testing. (refer to D5417)
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 review of the laboratory personnel records and confirmed in interview, the Laboratory Director failed to ensure 1 of 1 Testing Personnel had documentation of qualifying education prior to testing patients' samples for high complexity testing. Refer to D6171

D6107	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(15) The laboratory director must specify, in writing, the responsibilities and duties of each consultant and each supervisor, as well as each person engaged in the performance of the preanalytic, analytic, and postanalytic phases of testing, that identifies which examinations and procedures each individual is authorized to perform, whether supervision is required for specimen processing, test performance or result reporting and whether supervisory or director review is required prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on a review of the laboratory's personnel records and confirmed in interview, the laboratory director failed to specify, in writing, the responsibilities and duties of 1 of 1 testing person, engaged in the performance or oversight of high complexity histopathology testing. Findings were: 1. A review of the facility's personnel files, revealed that at the time of the survey, a job description was unavailable for 1 of 1 testing personnel (TP#1) performing high complexity histopathology testing. 2. Random review of the laboratory case log sheet for 2018 revealed documentation that the TP#1 performed patient testing. date case # 4/03/18 WW18-C62 5/8/18 WW18-C70 3. An interview with the histotechnician via phone on 5/25/18 at 0925 hours in the office manager's office confirmed the above findings. She stated that she has the documentation but has been unable to update the laboratory records.
D6168	TESTING PERSONNEL CFR(s): 493.1487 The laboratory has a sufficient number of individuals who meet the qualification requirements of 493.1489 of this subpart to perform the functions specified in 493. 1495 of this subpart for the volume and complexity of testing performed. This CONDITION is not met as evidenced by: Based on review of the laboratory personnel records and confirmed in interview, the laboratory failed to ensure 1 of 1 Testing Personnel had documentation of qualifying education prior to testing patients' samples for high complexity testing. Refer to D6171
D6171	TESTING PERSONNEL QUALIFICATIONS CFR(s): 493.1489(b) (b) Meet one of the following requirements: (b)(1) Be a doctor of medicine, doctor of osteopathy, or doctor of podiatric medicine licensed to practice medicine, osteopathy, or podiatry in the State in which the laboratory is located or have earned a doctoral, master's or bachelor's degree in a chemical, physical, biological or clinical laboratory science, or medical technology from an accredited institution; (b)(2)(i) Have earned an associate degree in a laboratory science, or medical laboratory technology from an accredited institution or-- (b)(2)(ii) Have education and training equivalent to that specified in paragraph (b)(2)(i) of this section that includes-- (b)(2)(ii)(A) At least 60 semester hours, or equivalent, from an accredited institution that, at a minimum, include either-- (b)(2)(ii)(A)(1) 24 semester hours of medical laboratory technology courses; or (b)(2)(ii)(A)(2) 24 semester hours of science courses that include-- (b)(2)

(ii)(A)(2)(i) Six semester hours of chemistry; (b)(2)(ii)(A)(2)(ii) Six semester hours of biology; and (b)(2)(ii)(A)(2)(iii) Twelve semester hours of chemistry, biology, or medical laboratory technology in any combination; and (b)(2)(ii)(B) Have laboratory training that includes either of the following: (b)(2)(ii)(B)(1) Completion of a clinical laboratory training program approved or accredited by the ABHES, the CAHEA, or other organization approved by HHS. (This training may be included in the 60 semester hours listed in paragraph (b)(2)(ii)(A) of this section.) (b)(2)(ii)(B)(2) At least 3 months documented laboratory training in each specialty in which the individual performs high complexity testing. (b)(3) Have previously qualified or could have qualified as a technologist under 493.1491 on or before February 28, 1992; (b)(4) On or before April 24, 1995 be a high school graduate or equivalent and have either-- (b)(4)(i) Graduated from a medical laboratory or clinical laboratory training program approved or accredited by ABHES, CAHEA, or other organization approved by HHS; or (b)(4)(ii) Successfully completed an official U.S. military medical laboratory procedures training course of at least 50 weeks duration and have held the military enlisted occupational specialty of Medical Laboratory Specialist (Laboratory Technician); (b)(5)(i) Until September 1, 1997-- (b)(5)(i)(A) Have earned a high school diploma or equivalent; and (b)(5)(i)(B) Have documentation of training appropriate for the testing performed before analyzing patient specimens. Such training must ensure that the individual has-- (b)(5)(i)(B)(1) The skills required for proper specimen collection, including patient preparation, if applicable, labeling, handling, preservation or fixation, processing or preparation, transportation and storage of specimens; (b)(5)(i)(B)(2) The skills required for implementing all standard laboratory procedures; (b)(5)(i)(B)(3) The skills required for performing each test method and for proper instrument use; (b)(5)(i)(B)(4) The skills required for performing preventive maintenance, troubleshooting, and calibration procedures related to each test performed; (b)(5)(i)(B)(5) A working knowledge of reagent stability and storage; (b)(5)(i)(B)(6) The skills required to implement the quality control policies and procedures of the laboratory; (b)(5)(i)(B)(7) An awareness of the factors that influence test results; and (b)(5)(i)(B)(8) The skills required to assess and verify the validity of patient test results through the evaluation of quality control values before reporting patient test results; and (b)(5)(i)(B)(8)(ii) As of September 1, 1997, be qualified under 493.1489(b)(1), (b)(2), or (b)(4), except for those individuals qualified under paragraph (b)(5)(i) of this section who were performing high complexity testing on or before April 24, 1995; (b)(6) For blood gas analysis-- (b)(6)(i) Be qualified under 493.1489(b)(1), (b)(2), (b)(3), (b)(4), or (b)(5); (b)(6)(ii) Have earned a bachelor's degree in respiratory therapy or cardiovascular technology from an accredited institution; or (b)(6)(iii) Have earned an associate degree related to pulmonary function from an accredited institution; or (b)(7) For histopathology, meet the qualifications of 493.1449 (b) or (l) to perform tissue examinations.

This STANDARD is not met as evidenced by:
Based on a review of the laboratory personnel records and confirmed in interview, the laboratory failed to have documentation to qualify 1 of 1 testing personnel to perform high complexity histopathology testing for macroscopic (gross) examinations and interpretation. The findings included: 1. A review of facility personnel files revealed that 1 of 1 testing personnel had no documentation available for review at the time of the survey to qualify him to perform high complexity histopathology testing for macroscopic (gross) examinations and interpretation. 2. An interview with the histotechnician via phone on 5/25/18 at 0925 hours in the office manager's office confirmed the above findings. She stated that she has the documentation but has been unable to update the laboratory records.