Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2137767	07/11/2019
Name of Provider or Supplier	**Street Address, City, State**	
Houston Skin Associates	10907 Memorial Hermann Drive, Suite 170, Pearland, 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.
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's records, and staff interview, it was revealed the laboratory director failed to ensure a quality assessment program was established for the laboratory. Findings include: 1. A review of the laboratory's records revealed the laboratory did not have a written quality assessment program. 2. The laboratory was asked to provide documentation of a quality assessment program. No documentation was provided. 3. An interview with the histotech on 7/11/19 at 09:20 in the conference room revealed a quality assessment program had not been established. This 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 review of the laboratory's submitted CMS 209 form, review of the laboratory's personnel files, and staff interview, it was revealed the laboratory director failed to ensure documentation of training for 1 of 1 testing personnel performing high complexity testing. Findings include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 7/11/19) revealed the the laboratory identified 1 testing person performing high complexity testing. 2. A review of the laboratory's personnel records revealed testing personnel #1 had no documentation of training prior to testing pateint's specimens. 3. An interview with the histotech on 7/11 /19 at 09:15 in the conference room revealed testing person #1 did not have documentation of training. This confirmed the above findings.
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 review of the laboratory's submitted CMS 209 form, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of responsibilities and duties for its clinical consultant, technical supervisor, and general supervisor. The findings were: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 07/11/19) revealed the laboratory identified 1 clinical consultant, 1 technical supervisor, and 1 general supervisor (all of these positions are assigned to testing person #1). 2. The laboratory did have a Quality Assurance Personnel Assessment form for testing person #1 performed in 2018. At the top of the form it states: Testing Person #1 Title: GS, CC, TS The Quality Assurance Personnel Assessment form does not specify the responsibilites and duties of the clinical consultant, technical supersivor or the general supervisor positions. The skills/competency being assessed on the Quality Assurance Personnel Assessment form are: -Biannual slide review -Testing personnel proficiency -Daily log review -Equipment serviced -Patient record review 3. An interview with the histotech on 07/11/19 at 09:30 in the conference room revealed the laboratory director did not specify in writing the responsibilities and duties of each consultant and supervisor. This confirmed the above findings.

D6127	TECHNICAL SUPERVISOR RESPONSIBILITIES CFR(s): 493.1451(b)(9) The technical supervisor is responsible for evaluating and documenting the performance of individuals responsible for high complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted CMS 209 form, review of the laboratory's personnel records, and staff interview, it was revealed the laboratory failed to have documentation of the technical supervisor performing semiannual competency assessments on 1 testing personnel during the first year of testing patient specimens. Finding include: 1. A review of the laboratory's submitted CMS 209 form (signed by the laboratory director on 7/11/19) revealed the laboratory identified 1 testing person. 2. A review of the laboratory's personnel records revealed testing person # 1 (as indicated on the CMS 209 form) started testing with the laboratory in May 2018. 3. Further review of the personnel records for testing person #1 revealed a competency assessment was performed on April 2, 2018. Another competency assessment was performed on June 7, 2019. The file did not contain a second competency assessment performed within testing person #1's first year of employment. 4. An interview with the histotech on 7/11/19 at 09:40 in the conference room confirmed the above findings.