Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2260614	11/17/2022
Name of Provider or Supplier	**Street Address, City, State**	
Houston Dermatology Specialists	13114 Farm To Market 1960 Rd W Suite 119, Houston, 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 in compliance with applicable Conditions of Participation in the CLIA program, and certification 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 CMS Southern Operations Branch-Dallas for referral to the Office of Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
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 review of the laboratory's patient test log, review of laboratory's policies and procedures and staff interview, it was determined the laboratory failed to document Laboratory Director's approval (signature and date) of the laboratory's policies and procedures prior to implementation/use. Findings included: 1. Review of the laboratory's patient test log revealed the laboratory started testing patient samples on 09/27/2022. 2. Review of the laboratory's policies and procedures revealed the policy /procedure manual did not have Laboratory Director's approval (signature/date) documented. 3. In an interview on 11/17/2022 at 0930 hours in the office, the facility's RN (Registered Nurse) Manager confirmed the findings.

D5433	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(1) For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's quality control (QC) Stain Maintenance protocols for the Hematoxylin and Eosin (H&E) stain reagents, review of laboratory's patient test logs, review of laboratory's H&E stain reagent maintenance logs for September to November of 2022 and staff interview, it was determined the laboratory failed to document required stain reagent maintenance for 1 of 8 weeks reviewed. Findings included: 1. Review of the laboratory's quality control (QC) Stain Maintenance protocols for the Hematoxylin and Eosin (H&E) stain reagents revealed: "STAIN MAINTENANCE ... 7. The daily maintenance log will be signed off as documentation for completion of daily maintenance." 2. Review of laboratory's patient test logs revealed the laboratory performed patient testing once per week on the following days: 09/27/2022 10/04/2022 10/11/2022 10/18/2022 10/25/2022 11/01 /2022 11/08/2022 11/14/2022 3. Review of laboratory's H&E stain reagent maintenance logs for September to November of 2022 revealed there was no documentation of H&E reagent maintenance on 11/14/2022. 4. Further review of the laboratory's patient test logs revealed the following patient testing was performed on 11/14/2022, when H&E stain maintenance was not documented: Case# CD22-043 CD22-044 CD22-045 CD22-046 CD22-047 CD22-048 CD22-049 5. In an interview on 11/17/2022 at 1030 hours in the office, the facility's RN (Registered Nurse) Manager, after review of the data, confirmed the findings.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on review of the laboratory's Hematoxylin and Eosin (H&E) stain quality control (QC) records for September to November of 2022, review of laboratory's patient test logs and staff interview, it was determined the laboratory failed to document H&E stain acceptability/reactivity for 8 of 8 testing days. Findings included: 1. Review of the laboratory's Hematoxylin and Eosin (H&E) stain quality control (QC) records for September to November of 2022 revealed the QC was recorded as follows: QC Date QC Slide 09/27/2022 CD22-001 10/04/2022 CD22-006 10/11/2022 CD22-012 10/18/2022 CD22-017 10/25/2022 CD22-023 11/01/2022

	CD22-028 11/08/2022 CD22-039 11/14/2022 CD22-043 2. Further review of the above QC records revealed there was no documentation of stain acceptability /reactivity for the above 8 of 8 testing days. 3. Review of laboratory's patient test logs revealed the laboratory performed testing on 49 patients from September 27 to November 14 of 2022. 4. In an interview on 11/17/2022 at 1030 hours in the office, the facility's RN (Registered Nurse) Manager, after review of the data, confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of laboratory's policies and procedures, review of laboratory's quality assessment (QA) records for September to November of 2022 and staff interview, it was determined the laboratory failed to document Laboratory Director's monthly QA review as per laboratory policy for 3 of 3 months reviewed. Findings included: 1. Review of the laboratory's QA policies revealed: "QUALITY ASSURANCE ... The lab director will also review and sign off the checklist monthly." And "QUALITY ASSURANCE FOR ROUTINE STAINS ...The lab director will also review and sign off the checklist monthly." 2. Review of laboratory's QA records for September to November of 2022 revealed QA monthly checklists were documented on the following days: 09/27/2022 10/11/2022 11/01/2022 There was no documentation of Laboratory Director's review of the monthly checklists. 3. In an interview on 11/17 /2022 at 1045 hours in the office, the facility's RN (Registered Nurse) Manager, after review of the data, confirmed the findings.
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control 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 laboratory's policies and procedures, review of patient test logs, review of laboratory's H&E stain reagent maintenance logs and stain quality control records for September to November of 2022, and staff interview it was determined the Laboratory Director failed to ensure quality control was maintained. Refer to D5433 and D5601.