Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0686719	10/02/2020
Name of Provider or Supplier	**Street Address, City, State**	
Heights Dermatology And Aesthetic Center	2120 Ashland, 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 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.
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 MOHS Temperature and Humidity logs for 2019 and 2020 and staff interview, it was revealed the laboratory failed to have documentation of performing corrective actions when the laboratory temperature was

	documented outside the laboratory's acceptable range for 10 of 10 times from January 2019 to September 2020. Findings include: 1. A review of the laboratory's MOHS Temperature and Humidity logs from January 2019 to September 2020 revealed the following acceptable temperature range: "Temperature Range for the lab 67F - 71F." 2. Further review of the MOHS Temperature and Humidity logs for 2019 and 2020 revealed the following days where the documented laboratory temperature was outside the laboratory's acceptable range: Date Recorded Temperature 3/26/19 72F 5/1 /19 73F 5/2/19 72F 5/15/19 72F 6/18/19 73F 6/19/19 72F 6/20/19 72F 8/27/19 72F 10 /1/19 72F 10/29/19 72F 3. The laboratory was asked to provide documentation of performing corrective actions when the laboratory temperature was outside of the acceptable range. No documentation was provided. 4. An interview with laboratory director on 10/2/20 at 9:35 a.m. in the laboratory, after review of the records, confirmed the above 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 a review of the laboratory's records and staff interview, it was revealed the laboratory failed to have a quality assessment program that could identify and correct problems in analytic systems. Findings include: 1. The quality assessment program failed to identify that the laboratory did not have documentation of corrective actions when the laboratory temperature was outside of the laboratory's acceptable range. (refer to D5781)
D6022	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that the quality control and quality assessment programs are established and maintained to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a review of the laboratory's quality assessment program, a review of the laboratory's records, and staff interview, it was revealed the laboratory director failed to ensure the laboratory's quality assessment program identified failures in quality. Findings include: 1. The laboratory's quality assessment program failed to identify that the laboratory did not have documentation of corrective actions when the laboratory temperature was outside of the laboratory's acceptable range. (refer to D5781)