

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 45D2118697	(X3) Date Survey Completed 01/22/2020
Name of Provider or Supplier Padre Dermatology Plc	Street Address, City, State 14650 Compass St Ste 1, Corpus Christi, 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	<p>Noted deficiencies and plans of correction were discussed with the laboratory representative at the entrance and exit conferences. 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. 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.</p>
D5793	<p>ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(b)(c)</p> <p>(b) The analytic systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of analytic systems quality assessment reviews with appropriate staff. (c) The laboratory must document all analytic systems assessment activities.</p> <p>This STANDARD is not met as evidenced by: Based on review of quality assurance records from 2018 and 2019, review of laboratory environmental logs, and confirmed in interview of facility personnel, the laboratory' quality assurance plan failed to identify that the laboratory documented out of range room temperatures for 2 out of 150 days in 2018 and 7 out of 141 days in 2019. The findings were: 1. Review of quality assurance records from 2018 and 2019 found no documentation of the laboratory identifying and correcting that the laboratory documented out of range room temperatures for 2 of 150 days in 2018 and</p>

7 of 141 days in 2019. 2. Review of the laboratory's environmental records from 2018 and found the following days when the laboratory documented out of range room temperatures: 2018 Room Temperature Range: 65 - 75 degrees Fahrenheit January 3, 2018: 64.5 degrees Fahrenheit January 17, 2018: 63.5 degrees Fahrenheit 2019 Room Temperature Range: 68 - 76 degrees Fahrenheit January 2, 2019: 66.9 degrees Fahrenheit January 29, 2019: 67.7 degrees Fahrenheit February 5, 2019: 67 degrees Fahrenheit March 4, 2019: 65.2 degrees Fahrenheit March 5, 2019: 67 degrees Fahrenheit November 12, 2019: 60.8 degrees Fahrenheit November 16, 2019: 67.2 degrees Fahrenheit 3. The findings were confirmed in interview with the surgical assistant on January 22, 2020 at 15:15 hours in the laboratory.