| **Statement of Deficiencies** | **(X1) Provider/Supplier/CLIA Identification Number** | **(X3) Date Survey Completed** |
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| | 45D2118697 | 01/31/2018 |
| **Name of Provider or Supplier** | **Street Address, City, State** | |
| Padre Dermatology Pllc | 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 |
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| **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 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 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. |
| **D1001** | CERTIFICATE OF WAIVER TESTS<br>CFR(s): 493.15(e)<br><br>Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part.<br><br>This STANDARD is not met as evidenced by:<br>Based on observations, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instruction for storage of urine pregnancy waived kits. The findings were: 1. Direct observation made on 01/31/2018 at 1310 hours revealed 1 box of Consult urine hCG (human chorionic gonadotropin) waived test kits stored at the nurse's station. 2. Further observations made at the time revealed no means of monitoring the temperature at the nurse's station. 3. Review of the manufacturer's instructions for storage of the test kit located on the package labeling stated, "36-86 degrees Fahrenheit." 4. The laboratory was asked to provide documentation of following the |

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| | manufacturer's instructions to store the kits at "36-86 degrees Fahrenheit" where the pregnancy kit was located. No documentation was provided. 5. An interview with the histotechnologist on 01/31/2018 at 1310 hours at the nurse's station confirmed the findings. |
| **D5217** | EVALUATION OF PROFICIENCY TESTING PERFORMANCE<br>CFR(s): 493.1236(c)(1)<br><br>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.<br><br>This STANDARD is not met as evidenced by:<br>Based on review of laboratory policy, the laboratory's quality assurance records from 2017, and staff interview, it was revealed the laboratory failed to have documentation of performing twice annual accuracy assessment for Mohs testing. Findings included: 1. The Mohs histopathological procedure is not included in Subpart I of the CLIA regulations. The laboratory is required to perform twice annual accuracy. 2. According to the laboratory's CMS-116 form, 437 Mohs procedures were performed annually for testing year 2017. 3. Review of the laboratory's policy, "Proficiency Testing" (no laboratory director approval date) stated, " ...Semi-annually, the tech or Risk Manager will send two cases containing the original slides, label it with only the surgical case number, and send it out for a microscopic examination by a Board Certified Dermatopatholgist. NO differential diagnosis will be offered with the specimen. The slide may be labeled, "Proficiency Test" by the sending laboratory for the records of the reference laboratory ..." 4. A review of the laboratory's quality assurance records from November 2016 to January 2018 revealed the laboratory failed to provide documentation of performing twice annual accuracy assessment for MOHS testing in 2017. 5. An interview with the histotechnologist on 01/31/2018 at 1600 hours in the laboratory confirmed the findings. He revealed that an accuracy assessment had recently been sent out but the results were not back yet. |
| **D5401** | PROCEDURE MANUAL<br>CFR(s): 493.1251(a)<br><br>A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.<br><br>This STANDARD is not met as evidenced by:<br>A. Based on review of the laboratory's procedure manual, manufacturer's instructions, review of the laboratory's maintenance records, and confirmed in interview, the laboratory failed to provide documentation of all maintenance procedures as defined by the laboratory's policy and the manufacturer's instructions. Findings included: 1. Review of the laboratory's policy "Quality Control Policies and Documentation" (no laboratory director approval date) stated, "The fly wheel and moving components on the cryostat are oiled, as recommended by the manufacturer, monthly. 2. Review of the manufacturer's instructions for the Leica CM1510S (Order-No. 0708-37111) under, "General maintenance instructions" stated, " ...From time to time - above all after the instrument has been dried repeatedly in a laboratory oven, apply a thin coat of cryostat oil onto ..." 3. Review of the laboratory's maintenance records from |

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| | January 2017 to December 2017 revealed no documentation of oiling the fly wheel and moving components of the cryostat. 4. The laboratory was asked to provide documentation of following its own policy to perform the oiling procedure. No documentation was provided. 5. An interview with the histotechnologist on 1/31/2018 at 1500 hours in the laboratory confirmed the findings. He confirmed that the procedure is done routinely but documentation needs to be added to the log sheet. B. Based on review of the laboratory's procedure manual, manufacturer's instructions, review of the laboratory's maintenance records, and confirmed in interview, the laboratory failed to provide documentation of all maintenance procedures as defined by the laboratory's policy and the manufacturer's instructions. Findings included: 1. Review of the laboratory's policy "Quality Control Policies and Documentation" (no laboratory director approval date) stated, "Air filter is cleaned as part of the maintenance monthly." 2. Review of the manufacturer's instructions for the Linistain Random Access Stainer (PN: 243603, 243604, 243605, 190601, 1903602, B100200, B100201) under, "Preventative Maintenance" stated, "B. Internal Cleaning: A vacuum cleaner is recommended for this type of cleaning. The nozzle should be made on non-metallic material, and care should be taken not to damage components with the nozzle." 3. Review of the laboratory's maintenance records from January 2017 to December 2017 revealed no documentation of vacuuming the internal components of the Linistain Random Access Stainer". 4. The laboratory was asked to provide documentation of following its own policy to perform the air filter cleaning procedure. No documentation was provided. 5. An interview with the histotechnologist on 1/31/2018 at 1500 hours in the laboratory confirmed the findings. C. Based on review of the laboratory's maintenance records, and confirmed in interview, the laboratory failed to provide documentation of all maintenance procedures as defined by the laboratory's policy and the manufacturer's instructions. Findings included: 1. Review of the laboratory's logsheet for "FUME HOOD/AIR VENT LOG" stated, "Replace filter as required by manufacturer, document." 2. Review of the laboratory's maintenance records from January 2017 to December 2017 revealed no documentation of replacing the air filter as stated on its logsheet. 3. The laboratory was asked to provide documentation of following its own policy to replace the air filter monthly. No documentation was provided. 4. An interview with the histotechnologist on 1/31/2018 at 1500 hours in the laboratory confirmed the findings. |
| **D5413** | TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT<br>CFR(s): 493.1252(b)<br><br>The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports.<br><br>This STANDARD is not met as evidenced by:<br>Observations, review of manufacturer's reagent labeling and interview of facility personnel found that the laboratory failed to ensure the proper storage of supplies in patient rooms. Findings included: 1. Observations made during the tour the facility conducted on January 31, 2018 found no means of measuring and recording the temperature of patient rooms where supplies are located. 2. Review of the manufacturer storage instructions as written on the reagent labels found: a. e-Swab |

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| | (quantity of 1): lot #171066400 "Store at 5-25 degrees Celsius" 3. Interview of the histotechnologist on 01/31/2018 at 1300 hours in patient exam room 1 revealed the laboratory did not monitor the temperature in the patient exam rooms. He further revealed the other patient exam rooms were set up in the same way. |