

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2095045	(X3) Date Survey Completed 01/27/2023
Name of Provider or Supplier Innovative Dermatology And Mohs Surgery Llc	Street Address, City, State 3507 Lee Blvd Ste 107, Lehigh Acres, FL	
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	An announced CLIA recertification survey was conducted at Innovative Dermatology and Mohs (Micrographic oriented histologic surgery }LLC on 01/27/23. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Markow, Denise L. Based on record review and interview with the Laboratory Director, the laboratory failed to verify the accuracy of mycology (fungi) for two (2021 - 2022) out of two (2021 - 2022) years for one Testing Personnel (#B) out of 2 Testing Personal (#A and #B) , and failed to verify the accuracy of parasitology (scabies), virology (herpes simplex virus and varicella zoster virus) testing for two (2021 - 2022) out of two (2021 - 2022) years for two Testing Personnel (#A and #B) out of two Testing Personnel (#A and #B), and failed to verify the accuracy of histopathology (hematoxylin and eosin) testing twice annually for two (2021 - 2022) out of two years reviewed (2021 - 2022) for one Testing Personnel (#A) out of one Testing Personnel (#A). Findings included: Record review of the Laboratory Personnel Report (Form CMS 209) completed and signed by the Laboratory Director on 1/26/2023 revealed that the Laboratory Director (Testing Personnel #A) performed high complexity testing (hematoxylin and eosin testing, and includes fungi, scabies, herpes simplex virus and varicella zoster testing and Testing Personnel #B performed moderate complexity (fungi, scabies, herpes simplex virus, and varicella zoster virus. Record review of the "Proficiency Testing/Verification of Accuracy" revealed "Provider Performed Microscopy (PPM) Proficiency testing (PT) will be performed every 6 months by using a Clinical Laboratory Improved Amendment (CLIA)</p>

approved outside organization such as American Academy of Family Practitioners (AAFP)....." Record review of the AAFP proficiency testing revealed the laboratory was enrolled in "Clinical Microscopy" proficiency testing for two (2021 - 2023) out two (2021 - 2022) years and one (Testing Personnel #A) out of two (Testing Personnel #A and #B) Testing Personnel #A performed the testing for 6 (A, B, and C Events 2021, and A, B, and C Events 2022) out of 6 (A, B, and C Events 2021, and A, B, and C Events 2022) proficiency testing events. Record review of the AAFP revealed that the "Clinical Microscopy" proficiency testing only tested for scabies for two proficiency testing events (2021 B Event and 2022 A Event) out of 6 A, B, and C Events 2021, and A, B, and C Events 2022) and 6 (A, B, and C Events 2021, and A, B, and C Events 2022) out of 6 (A, B, and C Events 2021, and A, B, and C Events 2022) did not test for herpes simplex or varicella zoster virus. Record review of the "Proficiency Testing/Verification of Accuracy" revealed "Mohs surgery (PT) will be done by sending at least 2 cases semi - annually (every 6 months) to an outside Mohs surgeon or Pathologist for proficiency testing review. Record review of the "MOHS PT Cases for Review (Bi-Annual)" logs revealed 2 (both logs dated 12/20/22 but one log had specimens from 2021 and the other had specimens from 2022) out 4 (two for 2021 and two for 2022) bi - annual proficiency testing had been performed. On 01/27/2023 at 9:30 a.m., the Certified Nursing Assistant stated this office had the same deficient practice regarding twice annual verification of precision and accuracy as her other office that was surveyed 01/26/23.

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 record review and staff interview, the facility failed to document corrective action when the room temperature of the laboratory, in which the cryostats were located, was out of range for 137 days out of 148 from January 2021 to January 27, 2023. Findings included: Record review of the "Leica CM 1510-Cryostat Instruction Manual" revealed "Room temperature always below 22 degrees Celsius" (22 degrees Celsius = 71.6 degrees Fahrenheit (F)). The record review of the "Temperature" logs revealed the following temperatures were documented: 1. 01/05/2021 - 76 degrees F 2. 01/12/2021 - 76 degrees F 3. 01/19/2021 - 73 degrees F 4. 01/26/2021 - 75 degrees F 5. 02/02/2021 - 76 degrees F 6. 02/09/2021 - 75 degrees F 7. 02/16/2021 - 76 degrees F 8. 02/23/2021 - 76 degrees F 9. 03/02/2021 - 76 degrees F 10. 03/09/2021 - 76 degrees F 11. 03/16/2021 - 76 degrees F 12. 03/23/2021 - 76 degrees F 13. 03/30/2021 - 76 degrees F 14. 04/06/2021 - 76 degrees F 15. 04/13/2021 - 76 degrees F 16. 04/16/2021 - 76 degrees F 17. 04/20/2021 - 76 degrees F 18. 04/27/2021 - 76 degrees F 19. 05/04/2021 - 75 degrees F 20. 05/11/2021 - 76 degrees F 21. 05/14/2021 - 76 degrees F 22. 05/18/2021 - 76 degrees F 23. 05/25/2021 - 76 degrees F 24. 06/01/2021 - 75 degrees F 25. 06/08/2021 - 72 degrees F 26. 06/15/2021 - 76 degrees F 27. 06/22

/2021 - 76 degrees F 28. 06/27/2021 - 76 degrees F 29. 07/06/2021 - 76 degrees F 30. 07/27/2021 - 76 degrees F 31. 08/03/2021 - 76 degrees F 32. 08/10/2021 - 73 degrees F 33. 08/17/2021 - 76 degrees F 34. 08/24/2021 - 76 degrees F 35. 08/31/2021 - 76 degrees F 36. 09/07/2021 - 76 degrees F 37. 09/14/2021 - 76 degrees F 38. 09/21/2021 - 76 degrees F 39. 11/02/2021 - 76 degrees F 40. 11/03/2021 - 76 degrees F 41. 01/04/2022 - 76 degrees F 42. 01/11/2022 - 76 degrees F 43. 01/12/2022 - 76 degrees F 44. 01/14/2022 - 76 degrees F 45. 01/18/2022 - 76 degrees F 46. 01/19/2022 - 76 degrees F 47. 01/25/2022 - 76 degrees F 48. 01/26/2022 - 76 degrees F 49. 02/01/2022 - 76 degrees F 50. 02/02/2022 - 76 degrees F 51. 02/08/2022 - 76 degrees F 52. 02/09/2022 - 76 degrees F 53. 02/11/2022 - 76 degrees F 54. 02/15/2022 - 76 degrees F 55. 02/16/2022 - 76 degrees F 56. 02/22/2022 - 76 degrees F 57. 02/23/2022 - 76 degrees F 58. 03/01/2022 - 76 degrees F 59. 03/02/2022 - 76 degrees F 60. 03/08/2022 - 76 degrees F 61. 03/09/2022 - 76 degrees F 62. 03/11/2022 - 76 degrees F 63. 03/15/2022 - 76 degrees F 64. 03/16/2022 - 76 degrees F 65. 03/29/2022 - 76 degrees F 66. 03/30/2022 - 76 degrees F 67. 04/05/2022 - 76 degrees F 68. 04/06/2022 - 76 degrees F 69. 04/08/2022 - 76 degrees F 70. 04/12/2022 - 74 degrees F 71. 04/13/2022 - 76 degrees F 72. 04/19/2022 - 76 degrees F 73. 04/20/2022 - 76 degrees F 74. 04/22/2022 - 76 degrees F 75. 04/26/2022 - 76 degrees F 76. 04/27/2022 - 76 degrees F 77. 05/03/2022 - 76 degrees F 78. 05/04/2022 - 76 degrees F 79. 05/10/2022 - 74 degrees F 80. 05/11/2022 - 76 degrees F 81. 05/20/2022 - 76 degrees F 82. 05/24/2022 - 73 degrees F 83. 05/25/2022 - 75 degrees F 84. 06/01/2022 - 74 degrees F 85. 06/07/2022 - 74 degrees F 86. 06/08/2022 - 74 degrees F 87. 06/10/2022 - 75 degrees F 88. 06/14/2022 - 73 degrees F 89. 06/15/2022 - 74 degrees F 90. 06/21/2022 - 73 degrees F 91. 06/22/2022 - 72 degrees F 92. 06/24/2022 - 74 degrees F 93. 06/28/2022 - 76 degrees F 94. 06/29/2022 - 74 degrees F 95. 07/26/2022 - 72 degrees F 96. 07/27/2022 - 72 degrees F 97. 07/29/2022 - 76 degrees F 98. 08/02/2022 - 76 degrees F 99. 08/03/2022 - 76 degrees F 100. 08/05/2022 - 76 degrees F 101. 08/09/2022 - 72 degrees F 102. 08/10/2022 - 72 degrees F 103. 08/19/2022 - 73 degrees F 104. 08/23/2022 - 76 degrees F 105. 08/24/2022 - 76 degrees F 106. 08/30/2022 - 73 degrees F 107. 08/31/2022 - 72 degrees F 108. 09/02/2022 - 76 degrees F 109. 09/07/2022 - 73 degrees F 110. 09/20/2022 - 72 degrees F 111. 09/21/2022 - 74 degrees F 112. 09/27/2022 - 76 degrees F 113. 10/04/2022 - 76 degrees F 114. 10/05/2022 - 76 degrees F 115. 10/12/2022 - 72 degrees F 116. 10/14/2022 - 75 degrees F 117. 10/18/2022 - 72 degrees F 118. 10/19/2022 - 74 degrees F 119. 10/25/2022 - 73 degrees F 120. 10/26/2022 - 73 degrees F 121. 11/01/2022 - 74 degrees F 122. 11/02/2022 - 72 degrees F 123. 11/08/2022 - 73 degrees F 124. 11/09/2022 - 73 degrees F 125. 11/11/2022 - 74 degrees F 126. 11/15/2022 - 74 degrees F 127. 11/16/2022 - 76 degrees F 128. 11/22/2022 - 76 degrees F 129. 11/23/2022 - 76 degrees F 130. 11/29/2022 - 76 degrees F 131. 11/30/2022 - 76 degrees F 132. 12/14/2022 - 76 degrees F 133. 12/20/2022 - 76 degrees F 134. 01/04/2022 - 74 degrees F 135. 01/18/2022 - 72 degrees F 136. 01/20/2022 - 76 degrees F 137. 01/24/2022 - 75 degrees F On 01/27/2023 at 10:35 a.m., the Certified Nursing Assistant stated she was unaware that the room temperature was suppose be less than 71.6 degrees Fahrenheit.