

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D0295356	(X3) Date Survey Completed 06/22/2022
Name of Provider or Supplier Bliss Dermatology	Street Address, City, State 699 S Indiana Avenue, Englewood, 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 Pennie Dermatology and Skin Surgery Center LLC on 06/22/22. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5209	<p>PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Nurse Manager, the laboratory failed to perform competency assessments for five (B, C, D, E, and F) out of six (A, B, C, D, E, F) Testing Personnel for one (2021) out of two years reviewed (2021-2022). Findings included: Record review of the CMS 209, Laboratory Personnel Report, signed 06/22/22 by the Laboratory Director revealed Testing Personnel B performed high complexity histopathology testing, and Testing Personnel C, D, E, and F performed moderate complexity mycology and parasitology testing. Record review for Testing Personnel B, C, D, E, and F revealed no competency assessments were documented for 2021. On 06/22/22 at 10:55 AM, the Nurse Manager confirmed that Testing Personnel B did not have a competency assessment performed in 2021. On 06/22/22 at 11:35 AM, the Nurse Manager stated she did not know that the proficiency testing that Testing Personnel C, D, E, and F had performed was not the same as a competency assessment. This is a repeat deficiency.</p>
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p>

(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 Cryostat temperature was out of range for 169 days out of 212 test days for two out of two years reviewed (March 2020 - June 2022). Findings included: Review of the laboratory's "Cryostat Maintenance Policy and Procedure" last revised on 12/2020 revealed the Cryostat should be maintained at -20 degrees Celsius (C) to no colder than -30 degrees Celsius (C) for the best MOH's sectioning. Any variance out of the range will be recorded and reported to the supervisor, immediately. If the range variance cannot be repaired, the console will not be used until serviced. Record review of the Cryostat Maintenance Temperature logs from March 2020 through June 2022 revealed temperatures were out of the -20 degrees C to -30 degrees C with no corrective actions documented on: 1. June 16, 2020: "-31C" 2. June 23, 2020: "-31C" 3. July 13, 2020: "-31C" 4. July 14, 2020: "-31C" 5. July 20, 2020: "-31C" 6. July 27, 2020: "-31C" 7. August 10, 2020: "-32C" 8. August 11, 2020: "-31C" 9. August 17, 2020: "-31C" 10. August 18, 2020: "-31C" 11. September 1, 2020: "-31C" 12. September 21, 2020: "-31C" 13. September 28, 2020: "-31C" 14. October 5, 2020: "-33C" 15. October 6, 2020: "-33C" 16. October 12, 2020: "-32C" 17. October 14, 2020: "-32C" 18. October 19, 2020: "-34C" 19. October 20, 2020: "-33C" 20. October 26, 2020: "-34C" 21. October 27, 2020: "-35C" 22. November 2, 2020: "-34C" 23. November 3, 2020: "-31C" 24. November 9, 2020: "-34C" 25. November 10, 2020: "-35C" 26. November 16, 2020: "-32C" 27. November 17, 2020: "-31C" 28. November 24, 2020: "-31C" 29. November 30, 2020: "-35C" 30. December 7, 2020: "-34C" 31. December 8, 2020: "-35C" 32. December 14, 2020: "-32C" 33. December 15, 2020: "-34C" 34. December 21, 2020: "-31C" 35. December 22, 2020: "-32C" 36. January 4, 2021: "-32C" 37. January 5, 2021: "-34C" 38. January 11, 2021: "-34C" 39. January 12, 2021: "-34C" 40. January 18, 2021: "-35C" 41. January 19, 2021: "-36C" 42. January 21, 2021: "-35C" 43. January 25, 2021: "-34C" 44. January 26, 2021: "-34C" 45. February 1, 2021: "-34C" 46. February 8, 2021: "-32C" 47. February 9, 2021: "-34C" 48. February 15, 2021: "-35C" 49. February 16, 2021: "-33C" 50. February 18, 2021: "-34C" 51. March 1, 2021: "-32C" 52. March 2, 2021: "-32C" 53. March 8, 2021: "-32C" 54. March 9, 2021: "-32C" 55. March 11, 2021: "-32C" 56. March 22, 2021: "-34C" 57. March 23, 2021: "-34C" 58. March 25, 2021: "-34C" 59. March 29, 2021: "-35C" 60. March 30, 2021: "-34C" 61. April 5, 2021: "-35C" 62. April 6, 2021: "-35C" 63. April 12, 2021: "-35C" 64. April 13, 2021: "-34C" 65. April 19, 2021: "-34C" 66. April 20, 2021: "-34C" 67. April 22, 2021: "-34C" 68. April 26, 2021: "-35C" 69. April 27, 2021: "-35C" 70. April 29, 2021: "-35C" 71. May 3, 2021: "-35C" 72. May 4, 2021: "-35C" 73. May 10, 2021: "-35C" 74. May 11, 2021: "-35C" 75. May 17, 2021: "-35C" 76. May 18, 2021: "-35C" 77. May 24, 2021: "-35C" 78. May 25, 2021: "-35C" 79. June 3, 2021: "-33C" 80. June 7, 2021: "-33C" 81. June 8, 2021: "-35C" 82. June 21, 2021: "-35C" 83. June 22, 2021: "-35C" 84. June 28, 2021: "-35C" 85. June 29, 2021: "-35C" 86. July 2, 2021: "-35C" 87. July 7, 2021: "-35C" 88. July 8, 2021: "-35C" 89. July 21, 2021: "-35C" 90. July 22, 2021: "-35C" 91. July 28, 2021:

"-35C" 92. July 29, 2021: "-34C" 93. August 2, 2021: "-36C" 94. August 3, 2021: "-35C" 95. August 9, 2021: "-35C" 96. August 10, 2021: "-35C" 97. August 12, 2021: "-35C" 98. August 16, 2021: "-35C" 99. August 17, 2021: "-35C" 100. August 19, 2021: "-35C" 101. August 23, 2021: "-35C" 102. August 24, 2021: "-35C" 103. August 30, 2021: "-35C" 104. September 7, 2021: "-35C" 105. September 9, 2021: "-34C" 106. September 13, 2021: "-35C" 107. September 14, 2021: "-36C" 108. September 20, 2021: "-36C" 109. September 21, 2021: "-35C" 110. September 27, 2021: "-36C" 111. September 28, 2021: "-35C" 112. October 5, 2021: "-31C" 113. October 7, 2021: "-31C" 114. October 11, 2021: "-34C" 115. October 12, 2021: "-33C" 116. October 14, 2021: "-34C" 117. October 18, 2021: "-34C" 118. October 19, 2021: "-34C" 119. October 25, 2021: "-34C" 120. October 26, 2021: "-34C" 121. November 1, 2021: "-34C" 122. November 2, 2021: "-35C" 123. November 4, 2021: "-35C" 124. November 8, 2021: "-35C" 125. November 9, 2021: "-35C" 126. November 15, 2021: "-34C" 127. November 18, 2021: "-35C" 128. November 21, 2021: "-34C" 129. November 22, 2021: "-34C" 130. November 29, 2021: "-34C" 131. November 30, 2021: "-34C" 132. December 1, 2021: "-35C" 133. December 6, 2021: "-34C" 134. December 7, 2021: "-34C" 135. December 13, 2021: "-34C" 136. December 14, 2021: "-34C" 137. December 16, 2021: "-34C" 138. December 20, 2021: "-34C" 139. December 27, 2021: "-34C" 140. December 28, 2021: "-34C" 141. January 3, 2022: "-34C" 142. January 4, 2022: "-34C" 143. January 24, 2022: "-35C" 144. January 25, 2022: "-35C" 145. February 1, 2022: "-36C" 146. February 3, 2022: "-35C" 147. February 7, 2022: "-33C" 148. February 8, 2022: "-35C" 149. February 14, 2022: "-35C" 150. February 15, 2022: "-35C" 151. February 17, 2022: "-35C" 152. February 21, 2022: "-35C" 153. March 1, 2022: "-33C" 154. March 8, 2022: "-33C" 155. March 9, 2022: "-33C" 156. March 14, 2022: "-33C" 157. March 15, 2022: "-33C" 158. March 21, 2022: "-34C" 159. April 4, 2022: "-34C" 160. April 5, 2022: "-34C" 161. April 11, 2022: "-34C" 162. April 12, 2022: "-34C" 163. April 18, 2022: "-35C" 164. April 19, 2022: "-35C" 165. April 25, 2022: "-36C" 166. April 26, 2022: "-35C" 167. May 9, 2022: "-34C" 168. May 10, 2022: "-34C" 169. May 16, 2022: "-33C" On 6/22/22 at 11:40 AM, the Nurse Manager stated she did not know why the temperatures were out of range without corrective action.