

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1037280	(X3) Date Survey Completed 09/29/2020
Name of Provider or Supplier Academic Alliance In Dermatology Inc	Street Address, City, State 4238 W Kennedy Ave, Tampa, 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 Academic Alliance in Dermatology Inc. on 09/29/20. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5781	<p>CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1)</p> <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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and staff interview, the laboratory failed to document corrective action when the Cryostat temperature was out of range for 91 days out of 111 days (January 2019 - September 2020) reviewed. Findings included: Record review of the " V. MOHS TECHNICIAN'S DAILY PROCEDURES" revealed that the acceptable range for the cryostat was -18 to -22 degrees Celsius. Record review of the "MOH'S Q/A AND Q/C CHECKLIST" revealed that the cryostat temperatures were out of range with no corrective action for the following dates: 1. January 11, 2019: documented temperature of "23C" 2. January 16, 2019: documented temperature of "23C" 3. January 25, 2019: documented temperature of "23C" 4. January 30, 2019: documented temperature of "23C" 5. March 1, 2019: documented temperature of "23C" 6. March 13, 2019: documented temperature of "23C" 7. March</p>

15, 2019: documented temperature of "23C" 8. March 22, 2019: documented temperature of "23C" 9. April 5, 2019: documented temperature of "24C" 10. April 10, 2019: documented temperature of "23C" 11. April 12, 2019: documented temperature of "24C" 12. April 26, 2019: documented temperature of "23C" 13. May 1, 2019: documented temperature of "23C" 14. May 10, 2019: documented temperature of "23C" 15. May 17, 2019: documented temperature of "24C" 16. May 24, 2019: documented temperature of "25C" 17. May 29, 2019: documented temperature of "23C" 18. June 5, 2019: documented temperature of "25C" 19. June 7, 2019: documented temperature of "23C" 20. June 19, 2019: documented temperature of "24C" 21. June 21, 2019: documented temperature of "24C" 22. July 12, 2019: documented temperature of "25C" 23. July 17, 2019: documented temperature of "24C" 24. July 26, 2019: documented temperature of "25C" 25. August 2, 2019: documented temperature of "25C" 26. August 9, 2019: documented temperature of "24C" 27. August 14, 2019: documented temperature of "24C" 28. August 16, 2019: documented temperature of "24C" 29. August 23, 2019: documented temperature of "23C" 30. August 28, 2019: documented temperature of "23C" 31. September 4, 2019: documented temperature of "24C" 32. September 13, 2019: documented temperature of "24C" 33. September 20, 2019: documented temperature of "24C" 34. September 27, 2019: documented temperature of "23C" 35. October 2, 2019: documented temperature of "24C" 36. October 4, 2019: documented temperature of "24C" 37. October 11, 2019: documented temperature of "24C" 38. October 16, 2019: documented temperature of "23C" 39. October 18, 2019: documented temperature of "24C" 40. October 25, 2019: documented temperature of "23C" 41. November 6, 2019: documented temperature of "23C" 42. November, 8 2019: documented temperature of "23C" 43. November 15, 2019: documented temperature of "23C" 44. November 20, 2019: documented temperature of "23C" 45. November 27, 2019: documented temperature of "23C" 46. December 11, 2019: documented temperature of "23C" 47. December 13, 2019: documented temperature of "23C" 48. December 27, 2019: documented temperature of "23C" 49. January 8, 2020: documented temperature of "23C" 50. January 10 2020: documented temperature of "23C" 51. January 17, 2020: documented temperature of "23C" 52. January 22, 2020: documented temperature of "23C" 53. January 24, 2020: documented temperature of "23C" 54. January 29, 2020: documented temperature of "23C" 55. February 7, 2020: documented temperature of "23C" 56. February 12, 2020: documented temperature of "23C" 57. February 14, 2020: documented temperature of "23C" 58. February 26, 2020: documented temperature of "23C" 59. March 6, 2020: documented temperature of "23C" 60. March 11, 2020: documented temperature of "23C" 61. March 13, 2020: documented temperature of "24C" 62. March 19, 2020: documented temperature of "23C" 63. March 25, 2020: documented temperature of "23C" 64. April 4, 2020: documented temperature of "23C" 65. April 22, 2020: documented temperature of "23C" 66. April 24, 2020: documented temperature of "23C" 67. April 29, 2020: documented temperature of "23C" 68. May 1, 2020: documented temperature of "23C" 69. May 13, 2020: documented temperature of "23C" 70. May 15, 2020: documented temperature of "23C" 71. May 22, 2020: documented temperature of "23C" 72. May 27, 2020: documented temperature of "23C" 73. May 29, 2020: documented temperature of "23C" 74. June 3, 2020: documented temperature of "23C" 75. June 12, 2020: documented temperature of "23C" 76. June 17, 2020: documented temperature of "23C" 77. July 1, 2020: documented temperature of "23C" 78. July 10, 2020: documented temperature of "23C" 79. July 15, 2020: documented temperature of "23C" 80. July 17, 2020: documented temperature of "23C" 81. July 22, 2020: documented temperature of "23C" 82. July 24, 2020: documented temperature of "23C" 83. August 7, 2020: documented temperature of "23C" 84. August 12, 2020: documented temperature of "23C" 85. August 21, 2020:

documented temperature of "23C" 86. August 26, 2020: documented temperature of "23C" 87. September 4, 2020: documented temperature of "23C" 88. September 9, 2020: documented temperature of "23C" 89. September 11, 2020: documented temperature of "23C" 90. September 18, 2020: documented temperature of "23C" 91. September 23, 2020: documented temperature of "23C" Interview on 09/29/20 at 11: 30 AM with the Laboratory Manager confirmed and stated she had overlooked the documented cryostat temperatures that were out of range because she was focusing on the room temperature and humidity documentation.