

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2103965	(X3) Date Survey Completed 02/25/2019
Name of Provider or Supplier Orchid Dermatology Llc	Street Address, City, State 5301 4th Avenue Cir E, Bradenton, 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
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 facility failed to document corrective action when the room temperature was out of range for records reviewed from November 2017 to February 2019. Findings included: Record review of the "Mohs Laboratory Temperature and Humidity Log" revealed that the acceptable range for room temperature on the log was to be at or less than 72 degrees Fahrenheit and review of the "Mohs Laboratory Temperature and Humidity" procedure revealed the room temperature should not exceed 70 degrees Fahrenheit. The following dates (from November 2017 to February 2019) had room temperatures out of range with no corrective action documented: 1. 11/07/2017: documented room temperature of "75 degrees" 2. 11/14/2017: documented room temperature of "80 degrees" 3. 11/21/2017: documented room temperature of "78 degrees" 4 . 11/28/2017: documented room temperature of "80 degrees" 5. 12/06/2017: documented room temperature of "81 degrees" 6. 12/12/2017: documented room temperature of "85 degrees" 7 . 12/19 /2017: documented room temperature of "72 degrees" 8. 01/09/2018: documented room temperature of "75 degrees" 9. 01/16/2018: documented room temperature of "73 degrees" 10. 01/23/2018: documented room temperature of "82 degrees" 11. 01/30</p>

/2018: documented room temperature of "78 degrees" 12. 02/06/2018: documented room temperature of "72 degrees" 13. 02/13/2018: documented room temperature of "75 degrees" 14. 02/20/2018: documented room temperature of "74 degrees" 15. 02/27/2018: documented room temperature of "74 degrees" 16. 03/06/2018: documented room temperature of "74 degrees" 17. 03/13/2018: documented room temperature of "75 degrees" 18. 03/20/2018: documented room temperature of "73 degrees" 19. 03/27/2018: documented room temperature of "75 degrees" 20. 04/03/2018: documented room temperature of "77 degrees" 21. 04/05/2018: documented room temperature of "79 degrees" 22. 04/10/2018: documented room temperature of "75 degrees" 23. 04/17/2018: documented room temperature of "80 degrees" 24. 04/24/2018: documented room temperature of "79 degrees" 25. 04/30/2018: documented room temperature of "81 degrees" 26. 05/01/2018: documented room temperature of "78 degrees" 27. 05/08/2018: documented room temperature of "79 degrees" 28. 05/15/2018: documented room temperature of "80 degrees" 29. 05/22/2018: documented room temperature of "81 degrees" 30. 05/29/2018: documented room temperature of "80 degrees" 31. 06/05/2018: documented room temperature of "79 degrees" 32. 06/12/2018: documented room temperature of "79 degrees" 33. 06/19/2018: documented room temperature of "77 degrees" 34. 06/26/2018: documented room temperature of "81 degrees" 35. 07/03/2018: documented room temperature of "81 degrees" 36. 07/10/2018: documented room temperature of "77 degrees" 37. 07/17/2018: documented room temperature of "82 degrees" 38. 07/24/2018: documented room temperature of "78 degrees" 39. 07/31/2018: documented room temperature of "75 degrees" 40. 08/07/2018: documented room temperature of "74 degrees" 41. 08/14/2018: documented room temperature of "76 degrees" 42. 08/21/2018: documented room temperature of "75 degrees" 43. 08/28/2018: documented room temperature of "79 degrees" 44. 09/04/2018: documented room temperature of "80 degrees" 45. 09/11/2018: documented room temperature of "79 degrees" 46. 09/18/2018; documented room temperature of "79 degrees" 47. 09/25/2018: documented room temperature of "81 degrees" 48. 10/02/2018: documented room temperature of "76 degrees" 49. 10/09/2018: documented room temperature of "80 degrees" 50. 10/16/2018: documented room temperature of "82 degrees" 51. 10/23/2018: documented room temperature of "76 degrees" 52. 10/30/2018: documented room temperature of "83 degrees" 53. 11/06/2018: documented room temperature of "78 degrees" 54. 11/13/2018: documented room temperature of "79 degrees" 55. 11/20/2018: documented room temperature of "73 degrees" 56. 12/04/2018: documented room temperature of "76 degrees" 57. 12/11/2018: documented room temperature of "78 degrees" 58. 12/18/2018: documented room temperature of "79 degrees" 59. 01/08/2019: documented room temperature of "81 degrees" 60. 01/15/2019: documented room temperature of "74 degrees" 61. 01/22/2019: documented room temperature of "76 degrees" 62. 02/05/2019: documented room temperature of "81 degrees" 63. 02/12/2019: documented room temperature of "76 degrees" 64. 02/19/2019: documented room temperature of "78 degrees" Interview on 02/25/2019 at 10:30 AM with the Practice Manager confirmed that no corrective action was documented for out of range room temperatures for 2 out of 2 years (November 2017 to February 2019). The Practice Manager indicated that the laboratory had a floor air conditioner but was taking temperatures before room temperature was acceptable.