

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2176088	(X3) Date Survey Completed 01/04/2022
Name of Provider or Supplier Clear Skin Dermatology, P.A.	Street Address, City, State 2454 N McMullen Booth Road Suite 424, Clearwater, 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 Clear Skin Dermatology PA on 01/04/2022. 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 interview with the Licensed Practical Nurse (LPN), the laboratory failed to document corrective action when the humidity room temperature for the cryostat was out of range for 35 out of 82 days from June 1, 2020 to December 31, 2021. Findings included: Record review of the Avantik QS12 cryostat instrument manual revealed the relative humidity was a maximum of 60%. Record review of the "Room Temperature" logs showed the acceptable humidity range was less than 60%. The following humidity percentages were documented: 1. 06/10/2020: "64%" 2. 06/17/2020: "64%" 3. 06/24/2020: "63%" 4. 07/15/2020: "63%" 5. 07/16/2020: "65%" 6. 07/23/2020: "63%" 7. 07/24/2020: "61%" 8. 07/29/2020: "69%" 9. 08/12/2020: "64%" 10. 08/19/2020: "63%" 11. 08/26/2020: "64%" 12. 09/16/2020: "68%" 13. 10/01</p>

/2020: "61%" 14. 10/08/2020: "61%" 15. 01/26/2021: "64%" 16. 02/09/2021: "70%"
17. 02/16/2021: "76%" 18. 02/23/2021: "69.%" 19. 03/01/2021: "61%" 20. 03/16
/2021: "76%" 21. 03/23/2021: "69%" 22. 03/30/2021: "69%" 23. 04/13/2021: "62%"
24. 04/20/2021: "70%" 25. 04/27/2021: "63%" 26. 06/01/2021: "66%" 27. 06/08
/2021: "68%" 28. 06/22/2021: "61%" 29. 08/17/2021: "63%" 30. 09/21/2021: "63%"
31. 10/11/2021: "64%" 32. 10/12/2021: "65%" 33. 12/07/2021: "72%" 34. 12/15
/2021: "68%" 35. 12/21/2021: "74%" On 01/04/22 at 11:35 a.m., the LPN confirmed
the humidity percentages were out of range and no corrective action was documented.