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| Statement of Deficiencies | (X1) Provider/Supplier/CLIA Identification Number 10D1011557 | (X3) Date Survey Completed 03/16/2023 |
| Name of Provider or Supplier Francis A Caban Md Pa D/B/A Caban Skin Institute | Street Address, City, State 4164 N Armenia 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 |
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| D0000 | An announced CLIA recertification survey was conducted at Francis A Caban MD PA dba Caban Skin Institute on 03/16/2023. 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 16 days out of 39 days (January 1, 2021 - March 16, 2023) reviewed. Findings included: Record review of the laboratory's policy and procedure signed by the Laboratory Director and dated 08/11/22 revealed that the acceptable range for the Cryostat was -20 to -25 degrees Celsius (C). Record review of the cryostat temperature logs revealed Cryostat temperatures were out of range with no corrective action for the following dates: 1. July 20, 2021: -18 C 2. November 9, 2021: -19 C 3. January 11, 2022: -19 C 4. February 22, 2022: -18 C 5. March 22, 2022: -17 C 6. April 5, 2022: -18 C 7. May 17, 2022: -19 C 8. June 14, 2022: -18 C 9. July 13, 2022 : -16 C 10. July 19, 2022: -19 C 11. August 16, 2022: -18 C 12. August 29, 2022: -18 C 13. September 13, 2022: -18 C</p> |

14. January 17, 2023: -18 C 15. January 31, 2023: -16 C 16. February 28, 2023: -18 C
On 03/16/2023 at 11:00 AM, the Regional Manager confirmed Cryostat temperatures were out of range and no corrective action was completed.