Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1081226	02/04/2020
Name of Provider or Supplier	**Street Address, City, State**	
Palm Harbor Dermatology	4197 Woodlands Pkwy 2nd Fl, Palm Harbor, 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 Palm Harbor Dermatology PA on 02/04/2020. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Supervisor, the laboratory failed to ensure the twice a year accuracy verification testing in 2019 for Scabies testing in the subspecialty of Parasitology for 4 out 4 Testing Personnel (#B, #C, #D, and #E) and for KOH testing in the subspecialty of Mycology for 2 (#B and #D) out of 4 Testing Personnel. Findings included: Review of Proficiency Testing records revealed: No documentation of the peer review for Scabies test, Parasitology for Testing Personnel #B, #AC, #D, and #E for 2019. No documentation of the peer review for KOCH test, Mycology for Testing Personnel #B and #D for 2019. During an interview on 02/04/20 at 10:15 AM, the Laboratory Supervisor confirmed that she did not have the missing 2019 peer reviews for the Scabies and KOCH tests.
D5781	CORRECTIVE ACTIONS CFR(s): 493.1282(b)(1) (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 29 out 616 days (February 2018 - January 2020) reviewed. Findings included: Record review of the "Procedure for Sectioning the Specimen" revealed that the acceptable range for the cryostat was -20 to -30 degrees Celsius. Record review of the "Temperature Monitor Log for Refrigerators, Cryostats" revealed that a red circle was to be drawn around out of range temperatures and then a "Request for Corrective Action" form was to be completed. Further review of the "Temperature Monitor Log for Refrigerators, Cryostats" revealed the cryostat temperatures were out of range, with no corrective action documented, on the following dates: 1. Cryostat #2 - February 5, 2018: documented temperature of -31 degrees Celsius 2. Cryostat #2 - February 6, 2018: documented temperature of -31 degrees Celsius 3. Cryostat #2 - February 19, 2018: documented temperature of -31 degrees Celsius 4. Cryostat #2 - February 21, 2018: documented temperature of -31 degrees Celsius 5. Cryostat #2 - February 23, 2018: documented temperature of -31 degrees Celsius 6. Cryostat #2 - February 27, 2018: documented temperature of -31 degrees Celsius 7. Cryostat #2 - May 3, 2018: documented temperature of -31 degrees Celsius 8. Cryostat #2 - May 7, 2018: documented temperature of -31 degrees Celsius 9.. Cryostat #2 - May 8, 2018: documented temperature of -31 degrees Celsius 10. Cryostat #2 - May 18 , 2018: documented temperature of -31 degrees Celsius 11. Cryostat #2 - May 23, 2018: documented temperature of -31 degrees Celsius 12. Cryostat #2 - June 15, 2018: documented temperature of -31 degrees Celsius 13. Cryostat #2 - July 12, 2018: documented temperature of -31 degrees Celsius 14. Cryostat #2 - July 19, 2018: documented temperature of -31 degrees Celsius 15. Cryostat #2 - August 6, 2018: documented temperature of -31 degrees Celsius 16. Cryostat #2 - August 16, 2018: documented temperature of -31 degrees Celsius 17. Cryostat #2 - October 16, 2018: documented temperature of -31 degrees Celsius 18. Cryostat #2 - November 27, 2018: documented temperature of -31 degrees Celsius 19. Cryostat #2 - January 7, 2019: documented temperature of -31 degrees Celsius 20. Cryostat #2 - January 8, 2019: documented temperature of -31 degrees Celsius 21. Cryostat #2 - January 15, 2019: documented temperature of -31 degrees Celsius 22. Cryostat #1 - September 18, 2019: documented temperature of -31 degrees Celsius 23. Cryostat #1 - October 3, 2019: documented temperature of -31 degrees Celsius 24. Cryostat #1 - October 10, 2019: documented temperature of -31 degrees Celsius 25. Cryostat #1 - October 11, 2019: documented temperature of -31 degrees Celsius 26. Cryostat #1 - November 22, 2019: documented temperature of -31 degrees Celsius 27. Cryostat #1 - January 6, 2020: documented temperature of -31 degrees Celsius 28. Cryostat #1 - January 22, 2020: documented temperature of -31 degrees Celsius 29. Cryostat #1 - January 27, 2020: documented temperature of -31 degrees Celsius Interview on 02/04/20 at 11:20 AM with the Moh's Laboratory Supervisor revealed that she thought the temperature range went to -32 degrees Celsius so corrective action was not documented.