Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1018060	(X3) Date Survey Completed 05/25/2022
Name of Provider or Supplier Sarasota Skin And Cancer Center Inc	**Street Address, City, State** 2179 S Tamiami Trl Ste 101, Osprey, 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 Sarasota Skin and Cancer Center Inc. on 05/25/22. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
D3011	FACILITIES CFR(s): 493.1101(d) Safety procedures must be established, accessible, and observed to ensure protection from physical, chemical, biochemical, and electrical hazards, and biohazardous materials. This STANDARD is not met as evidenced by: Based on observation and interview with the MOHS Tech, the laboratory failed to dispose of 95% Reagent Alcohol, 100% Reagent Alcohol, Hematoxylin Stain Solution, Eosin Y Stain Solution, and Histo-Clear according to manufacturer's instructions for 2 out of 2 (2020-2022) years reviewed. Findings Included: Observation of reagents in the flammable cabinet on 05/25/2022 at 10:00 a.m. revealed the labels on the 95% Reagent Alcohol, 100% Reagent Alcohol, Hematoxylin Stain Solution, Eosin Y Stain Solution, and Histo-Clear noted "Dispose of contents/container to an approved waste disposal plant." On 05/25/22 at 10:20 a.m., the MOHS Tech stated that the observed reagents were disposed of down the drain of the sink. The MOHS Tech reported she did not know she should follow the manufacturer's instructions. Photographic evidence was obtained.
D5209	PERSONNEL COMPETENCY ASSESSMENT POLICIES CFR(s): 493.1235 As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable,

	consultant competency. This STANDARD is not met as evidenced by: Based on record review and interview with Laboratory Staff, the laboratory failed to have documentation of competency assessments for three out of three (#B, #C, #D) Testing Personnel for two out of two years reviewed (2020-2022). Findings Included: Review of the CMS 209 signed by the Laboratory Director on 05/23/22 revealed three Testing Personnel (#B, #C, and #D). Review of the laboratory procedure titled "Initial and Annual Laboratory Employee Evaluation" revealed the Medical Director must perform the initial six month and annual competency. Review of Testing Personnel files revealed: Testing Personnel #B performed histopathology slide interpretation and had worked at the facility since the prior recertification survey conducted 2/13/20. Testing Personnel #B had only 1 competency assessment on file, dated 05/2022. Testing Personnel #C performed histopathology grossing and had had worked at the facility since the prior recertification survey conducted 2/13/20. Testing Personnel #C had only 1 competency assessment on file, dated 1/31/20. Testing Personnel #D performed histopathology grossing and had no competency assessments on file. A telephone interview on 05/25/22 at 11:10 AM with Testing Personnel #D confirmed no competency assessments had been performed on her. A telephone interview on 05 /25/22 at 12:10 PM with the Medical Assistant confirmed that Testing Personnel #C and #D did not have competency assessments performed for 2021 and 2022. On 05/25 /22 at 12:30 PM, Testing Personnel #B stated she thought the peer review was the competency assessment. This is a repeat deficiency.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and interview with Testing Personnel #D, the laboratory failed to follow the laboratory's policy for the temperature of the water bath for 432 days out of 432 days of testing from February 14, 2020 to May 25, 2022. Findings Included: Review of the laboratory's policy and procedure titled "Microtomy" revealed "Make sure water bath is at proper temperature which is 36 degrees Celsius to 42 degrees Celsius..." Review of the "Premier Water Bath Temperature and Maintenance log" and the "HT - 075 Water Bath Quality Control & Maintenance Log" revealed the temperature of the water bath had been documented as 44 degrees for 432 days out of 432 days of testing from February 14, 2020 to May 25, 2022 (date of survey). A telephone interview on 5/25/22 at 11:05 am with Testing Personnel #D confirmed the water bath temperatures were out of the range of 36 - 42 degrees Celsius.