Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D1082478	06/17/2020
Name of Provider or Supplier	**Street Address, City, State**	
Broward Plastic Surgery Pa	2818 E Oakland Park Blvd, Fort Lauderdale, 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	A recertification survey conducted on 6-17-2020, found that Broward Plastic Surgery PA clinical laboratory was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
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, the laboratory failed to create job responsibility policies for technical supervisor (TS), Clinical Consultant (CC), and Laboratory director (LD) in the procedure manual. Findings Included: A review of the procedure manual revealed no job responsibility policies for TS, CC and LD. During an interview on 6/17/2020 at 12:11pm, Laboratory director confirmed the procedure manual had no job responsibility policies for LD, CC and TS
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 observation, record review and interview, the laboratory failed to monitor room temperature, humidity and internal temperature from November 2018 to May 2020 for Lecia 1800 Cryocut. Findings Include: An observation of the Histopathology Room revealed no thermometer is available that records humidity and room temperature. A review of the 1800 Cryocut instrument manual showed for optimal operating conditions, it is best to position in an area that will be free from air current draughts from open windows and air conditioning. Room temperature must not exceed 35C and humidity must not exceed 60%. A review of the Cryostat Temperature Log displayed that internal temperature Cryocut was not recorded for November 2018 through December 2019. There was no documentation for Humidity and room temperature. During an interview on 6/17/2020 at 12:11pm, Laboratory director confirmed no documentation for room temperature, humidity and internal temperature from November 2018 to May 2020 for Cryocut.