Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	10D2108734	11/01/2021
Name of Provider or Supplier	**Street Address, City, State**	
Woodruff Institutue Llc, The	9776 Bonita Beach Road Se Suite 202-C, Bonita Springs, 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 recertification survey was conducted on 11/1/21 at The Woodruff Institute a clinical laboratory in Fort Myers, Florida. The Woodruff Institute is not in compliance with Code of Federal Regulations (CFR) 42, Part 493, Laboratory Requirements. 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 direct observation, review of Material Safety Data Sheets (MSDS), and interview with the Office Manager, the laboratory failed to store flammable liquid in an approved flammable liquids storage area for two (Cancer Diagnostics Reagent Alcohol, 200 Proof and StatLab Eosin - Y, Alcoholic 0.25%) out of five (Cancer Diagnostics Reagent Alcohol, 200 Proof, Zero Xylene, Acetone, StatLab Eosin - Y, Alcoholic 0.25% , and Citra - Clear) flammable liquids. The findings included: During observations taken on 11/1/21 at approximately 10:45 a.m., it was revealed Cancer Diagnostics Reagent Alcohol, 200 Proof, Zero Xylene, and Acetone, and StatLab Eosin - Y, Alcoholic 0.25% Gill Hematoxylin , and Citra - Clear were stored under the laboratory's sink. Record review of the MSDS for the Cancer Diagnostics Reagent Alcohol, 200 proof revealed the MSDS states "Inside storage should be in a National Fire Protection Association (NFPA) approved flammable liquid storage or cabinet". Review of the MSDS sheets for the StatLab Eosin - Y, Alcoholic 0.25% revealed the statement "Keep in fireproof place". Interview on 11/1/21 at 10:50 a.m.,

	the Office Manager did not know that the laboratory needed to store Cancer Diagnostics Reagent Alcohol, 200 proof in a flammable cabinet and StatLab Eosin - Y, Alcoholic 0.25% in a fireproof place.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on histopathology twice annual verification of accuracy record review and interview with the Office Manager, the Laboratory Director failed to ensure that corrective action was documented when the laboratory's histopathology twice annual verification of accuracy activity was unsuccessful for 1 (October 19, 2020 - March 3, 2021) out 5 (April 23, 2019 through September 16, 2019, November 12, 2019 through March 9, 2020, April 7, 2020 through September 14, 2020, October 19, 2020 through March 3, 2021 and April 27, 2020 through September 20, 2021) verification activities. The findings included: Record review of the laboratory's policy revealed the procedure "Internal Proficiency Testing of Mohs Micrographic Slides" (revision date 3 /5/2018) which stated, "It is the responsibility of the Laboratory Director and the Office Manager to monitor compliance and assure that proficiency testing is performed according to instructions." Record review of the histopathology twice annual verification of accuracy activities revealed that 1 (October 19, 2020 - March 3, 2021) out of 5 (April 23, 2019 through September 16, 2019, November 12, 2019 through March 9, 2020, April 7, 2020 through September 14, 2020, October 19, 2020 through March 3, 2021 and April 27, 2020 through September 20, 2021) verification activities were unsuccessful and corrective action was not performed and documented for the disagreement between the Moh's surgeons for diagnosis of the M20 -146 case. Interview on 11/1/21 at 11:15 PM., the Office Manager stated that she did not know that the laboratory must perform and document corrective action for failed histopathology twice annual verification of accuracy.