Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 10D0725831	**(X3) Date Survey Completed** 05/10/2022
Name of Provider or Supplier Paul F Rockley Md	**Street Address, City, State** 17101 Ne 19th Ave Ste 101, North Miami Beach, 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 05/10/2022 found the PAUL F ROCKLEY clinical laboratory not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation, record review and staff interview, the laboratory failed to document the making of the 95 percentage (%) alcohol solution used on the SAKURA TISSUE TEK Vacuum Infiltration Processor (VIP) from 09/01/2020 to 05/10/2022. Findings include: -Examination of the SAKURA TISSUE TEK VIP on 05/10/2022 at 01:45 PM, showed the processor had the following reagents: Alcohol 100 %, Alcohol 95 %, Formalin 10%, Pro-Par Clearant and Paraffin. -Review of the reagent log from 09/01/2020 to 05/10/2022 revealed that the laboratory used alcohol 100 % during the period of reference. - Review of the procedure manual policy "Alcohol Dilutions Procedure for Tissue Processor" revealed the following: "The histology technician will maintain a log documenting the production of a new mixture set. This log will state the date the mixture was made, the percentage of the dilution, the expiration date of the alcohol 100 % used and the lot number of the 100 % alcohol." -The laboratory had no documentation for the preparation of the 95 % alcohol solution from 09/01 /2020 to 05/10/2022. During an interview on 05/10/2022 at 2:00 PM, the laboratory consultant confirmed that the laboratory failed to keep record of the 95 % alcohol preparation used on the SAKURA TISSUE TEK VIP for the period of reference.