

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2075815	(X3) Date Survey Completed 01/24/2022
Name of Provider or Supplier Dr Prosper Abitbol Pa	Street Address, City, State 801 Meadows Rd Ste 107, Boca Raton, 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 01/24/2022 found that clinical laboratory DR PROSPER ABITBOL PA was not in compliance with 42 CFR Part 493, Requirements for Laboratories.
D5415	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c)</p> <p>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.</p> <p>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 75 % and 95 % alcohol solutions used on the SAKURA TISSUE TEK VIP (Vacuum Infiltration Processor) from 03/10/2020 to 01/24/2022. The laboratory failed to document the making of the 95 % alcohol and 3 % Acetic Acid solutions used on the LEICA AUTOSTAINER XL from 03/10/2020 to 01/24/2022. Findings include: -Examination of the SAKURA TISSUE TEK VIP on 01/24/2022 at 10:30 AM, showed the processor used the following reagents: Alcohol 100 %, Alcohol 95 %, Alcohol 75 %, Formalin 10%, Safeclear and Paraffin. -Review of the SAKURA TISSUE TEK VIP Maintenance log, showed that the laboratory failed to record the preparation and expiration date for 95 % alcohol and 70 % alcohol and the lot number for the reagents used in the preparation. -Examination of the LEICA AUTOSTAINER XL on 01/24/2022 at 10:35 AM, showed that the stainer used the following reagents: Safeclear, Alcohol 100 % and 95 %, Hematoxylin, Eosin, Bluing, High Def and Acetic Acid 3 %. -Review of LEICA AUTOSTAINER XL Maintenance log, showed that the laboratory failed to record: Preparation and expiration date for 95 % alcohol and the Acetic Acid 3 % and the lot number for the</p>

reagents used in the preparation. During an interview on 01/24/2022 at 11:30 AM, the laboratory manager confirmed that the laboratory failed to keep record of the alcohol and acetic acid solutions preparation used on the SAKURA TISSUE TEK VIP and the LEICA AUTOSTAINER XL.