

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2037121	(X3) Date Survey Completed 01/07/2022
Name of Provider or Supplier Jag Lab Llc	Street Address, City, State 4910 Communication Ave Suite 176, 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 01/07/2022 found that the JAG LAB LLC clinical laboratory 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 lot numbers and expiration dates of the reagents used for the Hematoxylin and Eosin (H&E) and the making of the 95 % alcohol, 100 % acid alcohol and 95 % acid alcohol solutions for the H&E staining process on the Sakura Tissue Tek DRS 2000 Stainer from 01/07/2020 to 01/07/2022. Findings include: - Examination of the Tissue Tek DRS 2000 on 01/07/2022 at 10:00 AM, showed the Tissue Tek used the following reagents: Xylene, Alcohol 100 %, Alcohol 95 %, Hematoxylin, Acid Alcohol 100 %, 95 % Alcohol, 95 % Acid Alcohol and Eosin. - Review of the Tissue Tek Maintenance log, showed that the laboratory failed to record: a) Lot numbers and expiration dates for Xylene, Alcohol 100 %, Hematoxylin and Eosin. b) Preparation and expiration date for 95 % alcohol, 100 % acid alcohol and 95 % acid alcohol and the lot number for the reagents used. During an interview on 01/07/2022 at 11:30 AM, the laboratory manager confirmed that the laboratory failed to keep record of the lots used and failed to document the alcohol solutions preparation used in the H&E stainer.</p>