

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D1024988	(X3) Date Survey Completed 01/07/2022
Name of Provider or Supplier Us Path Labs Llc	Street Address, City, State 4910 Communication Ave Suite 175, 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 US PATH LABS 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 on the Tissue Tek VIP (Vacuum Infiltration Processor) and for the making of the 70 %, 80 % and 95 % alcohol solutions used on the Tissue Tek VIP from 01/07/2020 to 01/07/2022. Findings include: -Examination of the Tissue Tek VIP on 01/07/2022 at 11:30 AM, showed the Tissue Tek used the following reagents: Xylene, Alcohol 100 %, Alcohol 95 %, Alcohol 80 %, and Alcohol 70 %. -Review of the Tissue Tek Maintenance log, showed that the laboratory failed to record: a) Lot numbers and expiration dates for Xylene and Alcohol 100 %. b) Preparation and expiration date for the following solutions: 95 % alcohol, 80 % alcohol and 70 % alcohol and the lot number for the reagents used in the preparation. During an interview on 01/07/2022 at 01.00 PM, the laboratory manager confirmed that the laboratory failed to keep record of the lots used and failed to document the alcohol solutions preparation used on the Tissue Tek VIP.</p>
D6120	TECHNICAL SUPERVISOR RESPONSIBILITIES

CFR(s): 493.1451(b)(7)(8)

(7) The technical supervisor is responsible for identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; (8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.

This STANDARD is not met as evidenced by:

Based on record review and staff interview, the Technical Supervisor (TS) failed to do annual competency assessment for 1 out of 6 Testing Personnel (TP) in 2020 and 2021. Findings include: -Review of CMS 209 Laboratory Personnel Report dated and signed by the Laboratory Director (LD) on 01/11/2022 revealed that: - LD was TS, GS and TP F. -The laboratory had 4 TP that were Grosser (TP B, TP C, TP D and TP E) and TP A was a Pathologist. -Personnel records review revealed that the TS failed to do annual competency for TP A for year 2020 and 2021. During an interview on 01/07/2022 at 1:25 PM, with Laboratory Manager, she confirmed that the TS failed to do the annual competency assessment of reference.