Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D2240159	05/04/2023
Name of Provider or Supplier	**Street Address, City, State**	
Pathology Watch, Pllc	497 West 4800 South, Suite 201, Murray, UT	

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
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on record review of Standard Operating Procedures (SOPs) and interview with the compliance manager, the laboratory failed to have separate and distinct procedures for the laboratory Pathology Watch, PLLC located at 497 West 4800 South, Suite 201, Murray, UT, 84123 since starting patient testing on 10/18/2021. The laboratory shares this space with two other laboratories. The laboratory performs approximately 10,000 histopathology tests annually. Findings include: 1. Review of SOPs on 5/4/2023 at approximately 11:00 AM, revealed the laboratory failed to have separate and distinct procedures pertaining to Pathology Watch PLLC for the grossing process the laboratory performs. 2. Interview with compliance manager on 5/4/2023 at approximately 11:00 AM, revealed that the laboratory failed to show separate and distinct procedures for the grossing process for the laboratory Pathology Watch PLLC.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity.

	(4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on record review and interview with the compliance manager, the room temperature and humidity documentation did not contain the month or year the temperature and humidity was being measured where grossing examination using Cancer Diagnotstic Tissue Dye was used on specimens since 12/01/2022. Findings include: 1. Review of room temperature and humidity documentation on 5/4/2023 at approximately 11:30 AM, revealed the documentation did not specify the month or year the measurements were being recorded which is required for the Cancer Diagnostic Inc. Tissue Marking Dyes. 2. Interview with compliance manager on 5/4 /2023 at approximately 11:30 AM, confirmed that the temperature and humidity records for the room did not specify a month or a year which is a requirement for the Cancer Diagnostic Inc. Tissue Marking Dyes.