Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	46D0662893	04/13/2022
Name of Provider or Supplier	**Street Address, City, State**	
Professional Diagnostics Inc Jordan Valley Mc	3460 Pioneer Parkway, West Valley City, 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 and interview with the laboratory staff, the laboratory failed to follow the procedure for performing deep cleaning for the Tissue - Tek Cryo3 Microtome/Cryostat. The laboratory performs approximately 3,500 tests annually. Findings include: 1. The Cryostat - Deep Cleaning, Disinfecting and Maintenance procedure stated that the "Cryostat will be defrosted and deep cleaned/disinfected every 6 months". 2. Record review of maintenance logs revealed the laboratory failed perform deep cleanings in the years of 2022, 2021, and 2020. 4. In an interview on 04 /13/2022 at 10:30 AM, the laboratory staff confirmed the laboratory failed to follow the procedure for performing deep cleaning.
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, direct observation, and interview with the lab technician, room temperature and humidity of the laboratory was not monitored. The laboratory performs approximately 3,500 tests annually. Findings include: 1. Record review did not include recorded room temperature and humidity on the maintenance log. There was no written policy for the monitoring room temperature of room humidity. 2. No thermometer or hygrometer was present in the laboratory during observation on 04/13 /2022 at approximately 10:00 AM 3. The Tissue-Tek Cryostat requires an operating environment of 15C to 35C and relative humidity of 30% to 85%. 4. In an interview on 04/13/2022 at approximately 10:10 AM, the technician confirmed room temperature and humidity was not monitored.