

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 10D2002688	(X3) Date Survey Completed 07/18/2019
Name of Provider or Supplier Vivid Pathology, Pa	Street Address, City, State 7800 Us Hwy 98 W, Miramar Beach, 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 was conducted on July 18, 2019. Vivid Pathology clinical laboratory was not in compliance with 42 CFR 493, requirements for clinical laboratories.
D5413	<p>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Laboratory Director, the laboratory failed to document the room temperature and humidity for Microm HM 505 E Cryostat for 2 out of 2 years (2017-2019) reviewed. Findings Included: Review of maintenance records from 7/18/17 through 7/18/19 found no room temperature and humidity documented for the Microm HM 505 E Cryostat. Review of the manufacturer's instructions showed that the equipment required an environment operating conditions of 5 to 40 degrees Centigrade for temperature and a maximum relative humidity of 60 %. During an interview on 7/18/19 at 11:30 AM, the Laboratory Director confirmed that there were no room temperature and humidity documented.</p>