

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 25D0319945	(X3) Date Survey Completed 07/12/2018
Name of Provider or Supplier Digestive Health Center	Street Address, City, State 90 Industrial Park Circle, Ocean Springs, MS	
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	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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.</p> <p>This STANDARD is not met as evidenced by: Based on review of the Histology Policy and Procedure Manual, the laboratory's equipment maintenance records, and confirmation by Testing Personnel #6, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory failed to follow its written procedure for equipment maintenance from 7-2-15 until 7-5-18. Findings include: Review of the Histology Policy and Procedure Manual revealed the Equipment Maintenance policy states, "Yearly maintenance is performed on all equipment." Review of the laboratory's equipment maintenance records and confirmation by Testing Personnel #6 revealed there was no documentation of yearly maintenance on the following equipment from 7-2-15 until 7-5-18: Sakura Tissue-Tek Embedding Center Sakura SCA Coverslipper Sakura DRS 2000 Stainer Sakura VIP Tissue Processor Fisher-Scientific Tissue Prep Flotation Baths (2) Olympus CX31 Microscope Olympus BX45 Microscope</p>
D5429	<p>MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(1)</p> <p>For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document maintenance as defined by the manufacturer and with at least the frequency specified by the manufacturer.</p>

This STANDARD is not met as evidenced by:

Based on review of manufacturer's instructions for the Microm International Rotary HM 325 Microtome, the laboratory's equipment maintenance records, and confirmation by Testing Personnel #6, listed on the Centers for Medicare and Medicaid Services (CMS) 209 personnel form, the laboratory failed to perform and document annual routine maintenance, as defined by the manufacturer, for the two HM 325 Microtomes from 7-2-15 until 7-5-18. Findings include: Manufacturer's instructions for the Microm International Rotary HM 325 Microtome state, in the Annual Routine Maintenance section, "To secure section quality and functioning of the microtome, it is recommended that a routine maintenance be performed by a trained service technician once a year." Review of the laboratory's equipment maintenance records revealed there was no documentation of annual routine maintenance performed on the two HM 325 Microtomes, used for processing histopathology specimens, from 7-2-15 until 7-5-18. Testing Personnel #6 confirmed there was no documentation of routine maintenance on the two HM 325 Microtomes during this time frame.