

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 31D2152136	<b>(X3) Date Survey Completed</b> 12/04/2018
<b>Name of Provider or Supplier</b> Heymann, Manders, Green & Sommer, Llc	<b>Street Address, City, State</b> 10000 Sagemore Drive, Marlton, NJ	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

<b>(X4) ID Prefix Tag</b>	<b>Summary Statement of Deficiencies</b>
<b>D5401</b>	<p><b>PROCEDURE MANUAL</b> 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:  a) Based on surveyor review of the Procedure Manual (PM) and interview with the Testing Personnel (TP), the laboratory failed to have following procedures from September (Sept) 2018 to the date of survey. The findings include: 1. The laboratory did not have procedures for: Records and blocks retention Microscope maintenance Quality assurance Competency assessment 2. The TP # 1 listed on CMS form 209 confirmed on 12/4/18 at 10:00 am that above mentioned procedures were not available. b) Based on surveyor review of the PM and observation of the Staining Station (SS) and interview with the TP, the laboratory failed to follow Hematoxylin and Eosin Staining Procedure from Sept 2018 to the date of the survey. The finding includes: 1. The SS in the laboratory did not correspond with the staining procedure in the PM. a) The PM stated 95% alcohol for step 11, but the SS jar was for 100% alcohol. 2. The TP # 1 listed on CMS form 209 confirmed on 12/4/18 at 10:45 am that PM procedure did not match with SS. c) Based on surveyor review of the PM and interview with the TP, the laboratory failed to include Quality Control (QC) requirements in special stain procedures from Sept 2018 to the date of the survey. The TP # 1 listed on CMS form 209 confirmed on 12/4/18 at 10: 55 am that QC information was not in special stain procedures.</p>
<b>D5413</b>	<p><b>TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT</b> CFR(s): 493.1252(b)</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.

This STANDARD is not met as evidenced by:  
Based on surveyor review of the Temperature Charts (TC) and interview with the Testing Personnel (TP), the laboratory failed to define acceptable range for Tissue Processor, Embedding Center, Floatation Bath and Slide warmer from Sept 2018 to the date of survey. The TP # 1 confirmed on 12/4/18 at 10: 30 am that the range was not define on the TC.

**D5601**

**HISTOPATHOLOGY**  
CFR(s): 493.1273(a)(f)

(a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:  
Based on surveyor review of Quality Control (QC) records and interview with the Testing Personnel (TP), the laboratory failed to document the reaction of the Hematoxylin and Eosin stain and special stain from September 2018 to the date of the survey. The TP # 1 listed on CMS form 209 confirmed on 12/4/18 at 10:25 am that the laboratory did not document reaction of stains.