

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  31D0867944	<b>(X3) Date Survey Completed</b>  10/08/2019
<b>Name of Provider or Supplier</b>  Cooper Gastroenterology At Fire Road	<b>Street Address, City, State</b>  3205 Fire Road, Egg Harbor Township, 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: Based on surveyor review of the Procedure Manual (PM), Biannual Assessment (BA) records and interview with the Office Manager (OM) , the laboratory failed to follow the procedure for BA in the calendar year 2019. The finding includes: 1. The PM stated that "two cases are to be reviewed by the Laboratory Director (LD) every six months" 2. There was no evidence that the LD had reviewed the slides in the calendar year 2019. 3 The BA records had the same physician referring and reviewing the slides. 4. The OM confirmed on 10/8/19 at 11:00 am that the laboratory did not follow the PM.</p>