

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 31D0118136	(X3) Date Survey Completed 06/21/2018
Name of Provider or Supplier Allied Gastrointestinal Associates Pa	Street Address, City, State 502 Centennial Blvd Ste 3, Voorhees, NJ	
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
D5407	<p>PROCEDURE MANUAL CFR(s): 493.1251(d)</p> <p>Procedures and changes in procedures must be approved, signed, and dated by the current laboratory director before use.</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Registered Nurse (RN), the laboratory failed to have an approved, signed and dated PM by the Laboratory Director (LD) from 12/28/16 to the date of the survey. The RN confirmed on 6/21/18 at 10:15 am the LD did not sign the PM.</p>
D5409	<p>PROCEDURE MANUAL CFR(s): 493.1251(e)</p> <p>The laboratory must maintain a copy of each procedure with the dates of initial use and discontinuance as described in 493.1105(a)(2).</p> <p>This STANDARD is not met as evidenced by: Based on surveyor review of the Procedure Manual (PM) and interview with the Registered Nurse (RN), the laboratory failed to maintain a copy of each procedure with initial use and discontinuance date from 12/28/16 to the date of survey. The finding includes: 1. The laboratory had two "Quality Assurance" procedures. 2. There was no discontinuance date on the procedure not in use. 3. The RN confirmed on 6/21/17 at 11:00 am that date was not on the procedure.</p>
D5603	<p>HISTOPATHOLOGY CFR(s): 493.1273(b)(f)</p>

(b) The laboratory must retain stained slides, specimen blocks, and tissue remnants as specified in 493.1105. The remnants of tissue specimens must be maintained in a manner that ensures proper preservation of the tissue specimens until the portions submitted for microscopic examination have been examined and a diagnosis made by an individual qualified under 493.1449(b), (l), or (m). (f) The laboratory must document all control procedures performed, as specified in this section.

This STANDARD is not met as evidenced by:

Based on review of Quality control (QC) log, and QC slides, and interview with the Registered Nurse (RN), the laboratory failed to retain QC slides from 12/28/16 to the date of survey. The findings include: 1. The QC log had Hematoxylin and Eosin (H&E) stain recorded as reviewed but had no H&E QC slide. 2. The RN confirmed at 10:10: am that the laboratory failed to retain QC slides for H&E.