

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2049034	<b>(X3) Date Survey Completed</b>  06/28/2018
<b>Name of Provider or Supplier</b>  Total Gastroenterology Pa	<b>Street Address, City, State</b>  7441 Us Hwy 27 N, Sebring, FL	
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>D5209</b>	<p><b>PERSONNEL COMPETENCY ASSESSMENT POLICIES</b> CFR(s): 493.1235</p> <p>As specified in the personnel requirements in subpart M, the laboratory must establish and follow written policies and procedures to assess employee and, if applicable, consultant competency.</p> <p>This STANDARD is not met as evidenced by: Based on record review and interview with the Office Manager, the laboratory failed to have competency evaluations on one (#A) of two testing personnel for 2 out of 2 (2017-2018) years reviewed. Findings Included: Review of competency evaluations found that Testing Person #A did not have competency evaluations for each title ( Clinical Consultant, Technical Supervisor, General Supervisor, and Testing Personnel) completed for 2017 and 2018 . The Laboratory Director was Testing Person #B. Testing Person #B was responsible for completing the competency evaluations since they served in the position of Technical Supervisor. On 06/28/18 at 11:15 AM, the Office Manager confirmed that the competency evaluations were not completed in 2017 and 2018 for Testing Person #A.</p>
<b>D5407</b>	<p><b>PROCEDURE MANUAL</b> 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 record review and interview with the Office Manager, the Laboratory Director failed to sign the policies as reviewed after becoming the Laboratory Director on 08/08/16. Findings Included: Review of personnel records revealed that the</p>

laboratory had a change in Laboratory Director that was effective 08/08/16. Review of the Histology Policy & Procedure Manual revealed it was marked as reviewed on 3/16/16, 3/10/17, and 3/9/18 but contained no signatures by the Laboratory Director. Interview on 06/29/2018 at 10:30 AM with the Office Manager confirmed that the new Laboratory Director had not signed the manuals.