

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  10D2049034	<b>(X3) Date Survey Completed</b>  09/30/2022
<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>D0000</b>	An announced CLIA recertification survey was conducted at Total Gastroenterology PA on 09/26/22 - 09/30/2022. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiency:
<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 staff interview, the laboratory failed to perform semi - annual competency assessments on one (#C) out of three Testing Personnel (#A, #B, and #C) for the year 2021 and 2022. The findings included: A review of the CMS 209, Laboratory Personnel Report, signed and dated 09/23/22 by the Laboratory Director revealed Staff #C worked as Testing Personnel (TP). A review of TP #C's personnel record revealed a hire date of April 2021. TP #C had no evidence of any competency assessments. A review of the facility procedure titled "Education: Training and Evaluation of Competency" sent by the laboratory on 09/30/22 revealed, "Lab staff will be evaluated for competency before reporting lab results (after training), 6 months after initial training, and thereafter yearly. Competency will be pertinent to his /her working area." On 09/26/22 at 10:30 a.m., the Office Manager stated she did not know the laboratory was to complete semi - annual competency assessments the first year of employment for TP #C.</p>