

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b> 10D2049034	<b>(X3) Date Survey Completed</b> 07/10/2020
<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 07/10/2020. The laboratory is not in compliance with 42 CFR Part 493, Requirements for Laboratories. The following is a description of the standard level deficiencies:
<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 follow the laboratory's procedure for competency assessment to perform competency assessment semi - annually for the histopathology technical component that was started in January 2019 for three (#C, #D, and #E) out of three Testing Personnel (#C, #D, and #E). Findings included: Review of the CMS 209 Laboratory Personnel Report revealed Personnel #C, #D, and #E held the position of Testing Person. Review of the laboratory's procedure "General Competency Program" dated 7/25/18 revealed "Competency must be reassessed for all tasks/workbench(s) being performed by the employee six months after the first initial task competency, at one year from the initial task competency, and annually thereafter. Record review of competency assessments revealed that the 2019 1st 6 month competency assessments had not been performed for Testing Personnel #C, #D, and #E. Interview on 07/10/2020 at 11:45 AM with the Office Manager confirmed that the first 6 month competency assessment had not been performed for Testing Person #C, #D, and #E for 2019.</p>
<b>D5217</b>	<b>EVALUATION OF PROFICIENCY TESTING PERFORMANCE</b>

CFR(s): 493.1236(c)(1)

At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.

This STANDARD is not met as evidenced by:

Based on record review and interview with the Office Manager, the laboratory failed to verify the accuracy histopathology testing for one (2019) of two years reviewed (2019-2020) for 3 out 3 Testing Personnel (#C, #D, and #E). Findings included: Peer review records for histopathology for Testing Personnel #C, #D, and #E were requested but could not be provided by the laboratory for 2019. Interview on 07/10/20 at 01:00 PM with the Office Manager confirmed that the laboratory did not have the 2019 peer reviews for the histopathology testing.

**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 record review and interview, the laboratory failed to prepare a negative control slide for the Immunohistochemical (IHC) stain for Helicobacter pyloric from January 2019 to date of survey. Findings included: Review of the log titled, "Staining Quality Control Review Summary" showed the laboratory failed to document a negative control slide for Helicobacter pyloric stain from January 2019 to date of survey. Phone interview on 7/10/20 at 12:30 PM with Testing Personnel D confirmed that the negative control slide had not been prepared.