

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  01D2267539	<b>(X3) Date Survey Completed</b>  05/03/2023
<b>Name of Provider or Supplier</b>  Gmpc Gastroenterology And Hepatology	<b>Street Address, City, State</b>  2415 Central Parkway, Montgomery, AL	
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>D5473</b>	<p>CONTROL PROCEDURES CFR(s): 493.1256(e)(2)(g)</p> <p>(e) For reagent, media, and supply checks, the laboratory must do the following: (e) (2) Each day of use (unless otherwise specified in this subpart), test staining materials for intended reactivity to ensure predictable staining characteristics. Control materials for both positive and negative reactivity must be included, as appropriate. (g) The laboratory must document all control procedures performed.</p> <p>This STANDARD is not met as evidenced by: Based on a review of the Staining Quality Control (QC) logs, an interview with the Pathologist/Testing Personnel, and a review of an email and QC records sent to the CLIA office, the laboratory failed to implement a mechanism to document the on-site assessment of staining quality of Histopathology slides for each day of processing /staining performed at the reference laboratory. The findings include: 1. During the entrance tour on 5/3/2023 at 8:30 AM, the surveyor confirmed this laboratory performed "read-only" assessments on Histopathology slides from Gastroenterology biopsies. The Pathologist/Testing Personnel stated he performed the on-site reading /assessments usually on Thursdays, and occasional Wednesdays, depending on the workload. The surveyor then asked how and where the biopsy specimens were processed. The reference laboratory representative stated biopsies were transported to Memphis for processing daily via couriers; then, the stained slides were transported back to the laboratory via the couriers, usually the next day. 2. A review of the "QC /IHC [Immuno-Histo Chemistry] Batch Control" records revealed the daily assessments of special stains only. There was no documentation of the Hematoxylin and Eosin (H&amp;E) stain quality. 3. During an interview on 5/3/2023 at 9:00 AM, the surveyor asked how the H&amp;E stain quality was assessed and documented. The Pathologist/Testing Personnel stated he had forgotten those records, but he would email the documents to the CLIA office. 4. The records were received via email on 5/4 /2023 at 10:30 AM. The Pathologist/Testing Personnel had forwarded the Reference</p>

Lab's "H&E STAINER ROTATION/QC LOG" sheets; the stain QC was initialed by a reference lab pathologist each day. The Pathologist/ Testing Personnel had utilized the reference lab's records as his documentation for H&E stain quality, and initialed next to the reference lab pathologist on Thursdays, and occasional Wednesdays when he performed his on-site readings. 5. In an e-mail and during a phone conversation on 5/4/2023, the surveyor explained the documents were unacceptable. The Testing Personnel at a read-only laboratory must document their on-site assessment of the stain quality for each day patient biopsies are processed and stained. For example, there may be several QC slides assessed during the one day of on-site reading. In addition, each laboratory should have a mechanism to document the quality of the H&E staining for each day of specimen processing at the reference laboratory.

SURVEYOR ID# 32558 Licensure and Certification Surveyor