

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D1018587	<b>(X3) Date Survey Completed</b>  07/22/2025
<b>Name of Provider or Supplier</b>  Martin Garza Md Pa	<b>Street Address, City, State</b>  3521 W Freddy Gonzalez Suite B, Edinburg, TX	
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>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens.</p> <p>This STANDARD is not met as evidenced by: Based on review of the laboratory's policies, review of patient test records from April 2025 to July 2025, and staff interview, the laboratory failed to follow it's policies for: A) repeat testing of samples, B) addressing flags, and C) the notification of panic values. The findings included: A) Repeat of samples 1. A review of the laboratory's policy titled "Repeat Criteria for CBC's with Critical Values (approved September 2023) determined the laboratory defined criteria for the repeat testing of complete blood counts. They were: WBC: less than 2 or greater than 20 HGB: less than 8 or greater than 18 HCT: less than 24 or greater than 55 PLT: less than 80 or greater than 500 2. A review of patient test records from April 2025 to July 2025 identified the following patient samples which met the laboratory's criteria repeat testing however repeat testing was not performed: a) Date: 05/22/2025 ID: 02192024 Result: PLT - 508 b) Date: 06/16/2025 ID: 12032013 Result: WBC - 24.1 c) Date: 07/17/2025 ID: 03162021 HGB - 5.4 HCT - 14.9 3. The technical consultant confirmed the findings after her review of the records on 07/22/2025 at 1100 hours in the break room. B) Addressing flags 1. A review of the laboratory's policy titled "Policy for Handling Flagged CBC's" (approved 2/17/2022) determined: "It will be the policy of this laboratory to rerun flagged CBC results. If the second run still shows flags, then the lab will evaluated flagged differentials according to procedures in the unit's operators manual. Lab procedures must ensure sample requirements are met, that the unit is in good condition order, and that the testing procedure is correctly followed. Sometimes the flags will disappear when the sample is allowed to equilibrate at room temperature</p>

for 15 to 20 minutes, or by recollecting the sample. If the flags disappear, then report that result. If the flags persist, then the laboratory will confirm abnormal differential by sending out to a reference laboratory or crossing out the flagged values. Crossing out of the flagged parameters has to occur prior to handing the results to the provider. These results cannot be used to diagnose the condition of the patient. Flagged results will not be reported at any time." 2. A review of patient test records from April 2025 to July 2025 identified the following flagged patient results which were reported to the provider: a) Date: 05/07/2025 ID: 04152024 Flag: OM - not repeated - flagged results reported to provider b) Date: 05/27/2025 ID: 08202024 Flag: BD - not repeated - flagged results not crossed out c) Date: 06/04/2025 ID: 08292024 Flag: OM - not repeated - flagged results reported to provider 3. The technical consultant confirmed the findings after her review of the records on 07/22/2025 at 1100 hours in the break room. C) Notification of critical values 1. A review of the laboratory's policy titled "Repeat Criteria for CBC's with Critical Values (approved September 2023) determined the laboratory defined criteria for the identification of critical values. They were: WBC: less than 2 or greater than 20 HBG: less than 8 or greater than 18 HCT: less than 24 or greater than 55 PLT: less than 80 or greater than 500 2. A review of the laboratory's policy titled "Reporting Panic Values" (no approval date) determined: "It is the policy of this laboratory to document the reporting of panic values. Document: - who was notified - when was the person notified - by whom was the person notified 3. A review of patient test records from April 2025 to July 2025 identified the following patient samples which met the laboratory's critical values however the laboratory's policies were not followed: a) Date: 05/01/2025 ID: 05122023 WBC: 20.1 - notification time not documented b) Date: 05/22/2025 ID: 02192024 PLT: 506 - not repeated - notification time not documented c) Date: 05/27/2025 ID: 08202024 PLT: 522 - not repeated - notification time not documented d) Date: 06/16/2025 ID: 12032013 WBC: 24.1 - not repeated - notification time not documented e) Date: 07/17/2025 ID: 3162021 HGB: 5.4 HCT: 14.9 - not repeated - notification time not documented 4. The technical consultant confirmed the findings after her review of the records on 07/22/2025 at 1100 hours in the break room. Key WBC - white blood cell HGB - hemoglobin HCT - hematocrit PLT - platelet