Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1018587	12/16/2021
Name of Provider or Supplier	**Street Address, City, State**	
Martin Garza Md Pa	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.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	Noted deficiencies and plans of correction were discussed with the laboratory representatives at the entrance and exit conferences. The facility representatives were given an opportunity to provide evidence of compliance with the noted deficiencies, and no such evidence was provided prior to survey exit. The facility was found to be in compliance with applicable Conditions of Participation in the CLIA program, and recertification is recommended. Note: The CMS-2567 (Statement of Deficiencies) is an official, legal document. All information must remain unchanged except for entering the plan of correction, correction dates, and the signature space. Any discrepancy in the original deficiency citation(s) will be reported to the Dallas Regional Office (RO) for referral to the Office of the Inspector General (OIG) for possible fraud. If information is inadvertently changed by the provider/supplier, the State Survey Agency (SA) should be notified immediately.
D5403	PROCEDURE MANUAL CFR(s): 493.1251(b) The procedure manual must include the following when applicable to the test procedure: (1) Requirements for patient preparation; specimen collection, labeling, storage, preservation, transportation, processing, and referral; and criteria for specimen acceptability and rejection as described in 493.1242. (2) Microscopic examination, including the detection of inadequately prepared slides. (3) Step-by-step performance of the procedure, including test calculations and interpretation of results. (4) Preparation of slides, solutions, calibrators, controls, reagents, stains, and other materials used in testing. (5) Calibration and calibration verification procedures. (6) The reportable range for test results for the test system as established or verified in 493.1253. (7) Control procedures. (8) Corrective action to take when calibration or control results fail to meet the laboratory's criteria for acceptability. (9) Limitations in the test methodology, including interfering substances. (10) Reference intervals (normal values). (11) Imminently life-threatening test results, or panic or alert values. (12) Pertinent literature references. (13) The laboratory's system for entering results in the patient record and reporting patient results including, when appropriate, the

	protocol for reporting imminently life threatening results, or panic, or alert values. (14) Description of the course of action to take if a test system becomes inoperable. This STANDARD is not met as evidenced by: Based on review of laboratory inservice dated December 6, 2019, review of manufacturer's instructions, patient records and confirmed in interview with laboratory staff, the laboratory failed to ensure abnormal flags on CBC results were resolved prior to their release to the healthcare provider. The findings included: 1. This is a repeat deficiency from surveys dated 06-20-2017 and 09-26-2019. 2. A review of the laboratory's policy titled "Policy for Abnormal Differentials" approved by the laboratory director on 03/13/2012 stated: "It will be the policy of this laboratory to send out abnormal differentials to the reference lab based on the Laboratory Directors (sic) discretion. The Laboratory Director will determine if an abnormal differential is required post evaluating CBC results and assessing the patient's clinical findings. A normal differential will be described as having only normal cells: Lymphocytes, Monocytes, Basophils, Neutrophils and normal size and shape RBC and Platelets. If your CBC instrumentation is showing alarms (R1, R2, M#, etc) in the differential section of the report, it will be considered and abnormal differential and Laboratory Director must be notified for further instruction." The laboratory could not locate their current flag policy. 3. A review of the laboratory's inservice dated December 6, 2019, it stated, "The laboratory will follow their policy for abnormal differentials. When flags are noted, the laboratory personnel will acknowledge, repeat, follow manufacturer required actions/instructions on handling flag/alert identified and resolve it. If abnormal differential requires to be sent out for a manual differential, documentation and send out result report will be attached to patient's chart." 4. A review of the manufacturer's instructions for the Medonic hematology analyzer (May 2009 Article no: 1504248) under the section titled "9.1 Out-of-Range and Information Message Indicators" under "Abnormalities" revealed: "Follow your laboratory's protocol for verification on all samples with anomalies and /or abnormal distributions signaled by the instrument. Pathological cells may vary in their stability towards lysing of their cytoplasmic membranes compared to normal cells, which may cause aberrations in the automated analysis. This also applies to the presence of normal non-pathological cells that have been subjected to chemotherapy or other treatments." 5. A review of patient test records from October and November 2021 found the following patient CBC results with flags that were not resolved prior to their release to the healthcare provider: Date: 10-04-2021 Sequence Number: 205 Date: 10-08-2021 Sequence Number: 241 Date: November 04-2021 Sequence Number: 417 6. An interview with the technical consultant on December 16, 2021 at 10:45 hours in the break room confirmed the findings. After she reviewed the records, she agreed the flags were not resolved.
D6045	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(7) (b) The technical consultant is responsible for-- (b)(7) Identifying training needs and assuring that each individual performing tests receives regular in-service training and education appropriate for the type and complexity of the laboratory services performed; This STANDARD is not met as evidenced by: Based on review of laboratory records, manufacturer's instructions, patient reports,

	and confirmed in interview of laboratory personnel, the technical consultant failed to identify that testing personnel needed training or a regular inservice regarding resulting of flags on CBCs (complete blood count). (Refer to D5403)