Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1018587	09/26/2019
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 representative(s) at the exit conference. The facility representative(s) 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.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: A. Based on surveyor observation, review of laboratory policy, manufacturer's instructions, patient records, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for performance of Consult Rapid Strep A testing. The findings were: 1. Surveyor observation made at 10:00 hours in the laboratory revealed Testing Personnel #2 (as listed on Form CMS-209) performing two Consult Rapid Strep A tests. While performing the test she swirled the swab 10 times and directly inoculated the test cartridge. 2. Review of the laboratory's policy titled, "Instrument Operation and Maintenance" approved by the laboratory director on November 27, 2005 stated, "This laboratory will follow procedures as the

	manufacturer describes for testing, reporting, calibrating, controls specialty protocols, and for performing/documenting remedial action." 3. Review of the manufacturer's instructions for Consult Rapid Strep A stated, "3. Immediately add the throat swab into the tube of pale yellow solution. Rotate the swab vigorously 10 times in the tube. Leave the swab in the tube for 1 minute. Then press the swab against the side of the tube and squeeze the bottom of the tube while removing the swab so that most of the liquid stays in the tube. Discard the swab." 4. The laboratory failed to follow the manufacturer's instructions to ensure the swab was maintained in the solution for 1 minute. 5. Review of patient records revealed the following: Patient Alias 3 Rapid Strep result: Positive Patient Alias 4 Rapid Strep result: Positive 6. Interview with the technical consultant on September 26, 2019 at 10:30 hours in the break room confirmed the findings. B. Based on surveyor observation, review of laboratory policy, manufacturer's instructions, patient records, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions for performance of BD Veritor Flu testing. The findings were: 1. Surveyor observation made on September 26, 2019 at 09:30 hours in the laboratory revealed Testing Personnel #3 (as listed on Form CMS-209) performing a waived BD Veritor Flu test. When asked how the test would be read, she revealed that it would be read visually for test and control lines. Patient Alias 1 Result read visually: Negative 2. Surveyor observation made on September 26, 2019 at 10:05 hours in the laboratory revealed Testing Personnel #2 (as listed on Form CMS-209) performing a waived BD Veritor Flu test. When asked if she used a reader to perform the interpretation, she revealed that the test would be read visually. Patient Alias 2 Result read visually: Negative 3. Review of the laboratory's policy titled, "Instrument Operation and Maintenance" approved by the laboratory director on November 27, 2005 stated, "This laboratory will follow procedures as the manufacturer describes for testing, reporting, calibrating, controls specialty protocols, and for performing/documenting remedial action." 4. Review of the manufacturer's instructions for BD Veritor System for Rapid Detection of Flu A & B (8087667(14), 2018-06) under, "Summary and Explanation" it stated, "All BD Veritor System Flu A & B test devices are interpreted by a BD Veritor System Instrument, either a BD Veritor Reader or BD Veritor Plus Analyzer (the "Analyzer")... and: "Step 7A: Timing development: NOTE:...Do not read device visually." 5. The laboratory failed to follow the manufacturer's instructions for test interpretation of the BD Veritor Flu test. The laboratory did not have a BD Veritor reader. 6. Interview with Testing Personnel #1 (as listed on Form CMS-209) on September 26, 2019 at 10:45 hours in the laboratory confirmed the findings. She revealed that when the kits were purchased they were told the readers were on back order. Key: BD - Becton Dickinson CMS - Centers for Medicare and Medicaid Services
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 policy, manufacturer's instructions, patient records and in interview with facility staff, it was revealed the laboratory failed to ensure abnormal flags on CBC results were resolved prior to their release to the healthcare provider.. The findings were: 1. 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." 2. 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." 3. A review of patient test records from 07/02/2019 to 07/19 /2019 revealed the following patient test results failed to have documentation of any verification of flags prior to releasing the results. ID = 111105 07/02/2019 ID = 07302018 07/17/2019 ID= 05112011 07/19/2019 4. An interview with the TP #1 (as listed on CMS Form-209) 09/26/2019 at 15:14 hours in the conference room after her review of the records confirmed the findings. Key: CBC - Complete Blood Count RBC - Red Blood Cell TP - Testing Personnel CMS- Centers for Medicare and Medicaid Services