

<b>Statement of Deficiencies</b>	<b>(X1) Provider/Supplier/CLIA Identification Number</b>  45D0982856	<b>(X3) Date Survey Completed</b>  10/21/2020
<b>Name of Provider or Supplier</b>  Luis Morales Md	<b>Street Address, City, State</b>  5235 Southmost Road Suite B, Brownsville, 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>D0000</b>	<p>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.</p>
<b>D5401</b>	<p>PROCEDURE MANUAL CFR(s): 493.1251(a)</p> <p>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 laboratory policy, review of manufacturer's instructions, and confirmed in interview of facility personnel, the laboratory failed to follow its own policy for resolving flags for 5 of 7 CBC results prior to their release to the healthcare provider. The findings were: 1. Review of the laboratory's policy titled "Policy for Handling Flagged CBC Differentials" approved by the laboratory director on October 12, 2017 stated, " ...If the flags disappear, then report that result. If the flag persists, then it will be considered an abnormal differential and will be invalidated and/or should be sent or analysis." 2. Review of the manufacturer's instructions for the</p>

Medonic M hematology analyzer (February 2016, Article no: 1504472) stated, "Abnormalities: 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 toward 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." And, BD - WBC DIFF: high interference between populations: Blood sample too old or pathological sample. Action: Follow laboratory's protocol for verification of results. OM - WBC DIFF: only one WBC population found; slide review advised. Action: Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results. TM - WBC Diff: too many WBC populations found; slide review advised. Action: Blood sample too old or pathological sample. Follow the laboratory's protocol for verification of results. 3. Review of patient test records from August 3, 2020 to October 21, 2020 found the following 5 of 7 CBC results with flags that were not invalidated and/or sent out for confirmation: Sequence #: 162 Date: 08/12/2020 Flag: OM Sequence #: 190 Date: 08/17/2020 Flag: OM Sequence #: 231 Date: 08/21/2020 Flag: BD Sequence #: 336 Date: 09/10/2020 Flag: OM Sequence #: 335 Date: 09/10/2020 Flag: OM 4. The laboratory was asked to provide documentation of verifying flags on CBC results prior to the release to the healthcare provider. No documentation was provided. 5. The findings were confirmed in interview of the technical consultant on October 21, 2020 at 16:45 hours in the break room.

**D5421**

**ESTABLISHMENT AND VERIFICATION OF PERFORMANCE**  
 CFR(s): 493.1253(b)(1)

Each laboratory that introduces an unmodified, FDA-cleared or approved test system must do the following before reporting patient test results: (1)(i) Demonstrate that it can obtain performance specifications comparable to those established by the manufacturer for the following performance characteristics: (1)(i)(A) Accuracy. (1)(i)(B) Precision. (1)(i)(C) Reportable range of test results for the test system. (1)(ii) Verify that the manufacturer's reference intervals (normal values) are appropriate for the laboratory's patient population.

This STANDARD is not met as evidenced by:  
 Based on review of the laboratory's verification records for the Medonic M Series hematology analyzer and staff interview, it was revealed the laboratory failed to ensure verification studies were complete prior to performing patient testing. The findings were: 1. This is a repeat deficiency from the survey dated July 26, 2018. 2. Review of the laboratory's instrument verification records for the Medonic M Series hematology analyzer revealed the laboratory director approved the instrument for patient testing on August 1, 2018. 3. Direct observation on October 21, 2020 in the laboratory revealed that the testing person demonstrated that the following patient normal ranges were available for patient testing in the analyzer: Newborn 1-23 months 2-9 years 10-17 years female 10-17 years male Adult male Adult female 4. Review of the manufacturer's instructions for the Medonic M Series hematology analyzer (PN 203129B R03.14.14) stated, "All new instruments must be tested to validate the manufacturer's claims for Accuracy, Precisions, Reportable Range (linearity), and Reference Range..." 5. Review of the laboratory's verification records for the Medonic M Series hematology analyzer revealed the reference range study was incomplete. Each range had not been verified. 6. An interview with the technical consultant at 16:00 hours in the break room confirmed the findings.

## CORRECTIVE ACTIONS

CFR(s): 493.1282(b)(2)

(b) The laboratory must document all corrective actions taken, including actions taken when any of the following occur: (b)(2) Results of control or calibration materials, or both, fail to meet the laboratory's established criteria for acceptability. All patient test results obtained in the unacceptable test run and since the last acceptable test run must be evaluated to determine if patient test results have been adversely affected. The laboratory must take the corrective action necessary to ensure the reporting of accurate and reliable patient test results.

This STANDARD is not met as evidenced by:

Based on review of laboratory policy, review of the laboratory's quality control records, patient test records, and confirmed in interview of facility personnel, the laboratory failed to provide documentation of performing corrective action when 2 out of 3 levels of quality control failed for 1 of 24 testing days in April 2019 and 1 of 23 testing days in May 2019. The findings were: 1. Based on review of the laboratory's policy titled "Control Policy" approved by the laboratory director on June 21, 2016, it stated, " ...Patient testing must not be performed or reported when control results are outside the expected range for two of three controls per analyte." 2. Review of the laboratory's quality control records from April 2019 to October 2020 found the following testing days when 2 or more out of 3 levels of quality control failed: April 22, 2019 Lot #2190231 Low Control Run for Platelets: 72(L) Lot#2190232 Normal Control Run for Platelets: 182(L) May 22, 2019 Lot #2190231 (Low Control) RBC: 2.62 (H) HCT: 18.5% (H) HGB: 6.6 (H) WBC: 7.9 (H) Lot #290232 (Normal Control) HCT: 65.1 (H) HGB: 21.8 (H) WBC: 31.0 (H) PLT: 283 (H) Lot #2190233 (High Control) RBC: 6.49 (H) HCT: 60.6 (H) HGB: 20.2 (H) WBC: 28.0 (H) PLT: 613 (H) 3. Review of patient records revealed the following patients were testing on April 22, 2019 and May 22, 2019 when at least 2 out of three levels of quality control failed: April 22, 2019 Sequence #1244 @ 10:48 hours Sequence #1245 @ 1245 hours May 22, 2019 Sequence #1510 @ 10:41 hours Sequence #1511 @ 12:28 hours Sequence #1512 @ 12:38 hours Sequence #1513 @ 13:26 hours Sequence #1514 @ 17:17 hours Sequence #1515 @ 18:28 hours 4. The laboratory was asked to provide documentation of performing corrective action when at least two of three levels of quality control failed on April 22, 2019 and May 22, 2019. No documentation was provided. 5. The findings were confirmed in interview of the technical consultant on October 21, 2020 at 16:30 hours in the break room. Key: H - high RBC - red blood cell HCT - hematocrit HGB - hemoglobin