Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0982856	07/26/2018
Name of Provider or Supplier	**Street Address, City, State**	
Luis Morales Md	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.

(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) shou1ld be notified immediately.
D2009	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The individual testing or examining the samples and the laboratory director must attest to the routine integration of the samples into the patient workload using the laboratory's routine methods. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's American Proficiency Institute (API) proficiency testing records, review of attestation sheets, and confirmed in interview of facility personnel, the laboratory failed to ensure 1 of 6 attestation statements were signed by the laboratory director. The findings were: 1. Review of the laboratory's policy titled, "Proficiency Testing" approved by the laboratory director on September 24, 2002, stated, " ...The lab should document all steps taken in PT performance ..." 2. Review of the laboratory's API records for 2016 (event 3), 2017 (events 1, 2, and 3), and 2018 (events 1 and 2) revealed the attestation statement for 2018 (event 2) was not signed by the laboratory director. 3. Review of the attestation

	statement for 2018 (event 2) stated, "Signatures Required: Testing personnel and the laboratory director must physically sign an attestation statement for all PT results, and retain the signed statement (or a copy) for a minimum of 2 years. Either the paper worksheet or a printed copy of this online attestation statement can be used for this purpose." 4. An interview with the technical consultant on September 20, 2018 at 1420 hours in the break room confirmed the findings.
D2010	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(2) The laboratory must test samples the same number of times that it routinely tests patient samples. This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's American Proficiency Institute (API) proficiency testing records, and confirmed in interview of facility personnel, the laboratory failed to ensure proficiency testing samples were tested the same number of times as patient samples. The findings were: 1. Review of the laboratory's policy titled, "Proficiency Testing" approved by the laboratory director on September 24, 2002, stated, " ...PT specimens are to be treated the same as patient samples ..." 2. According to the primary testing person on September 20, 2018 at 13: 34 hours in the laboratory, part of the laboratory's verification process for CBCs (complete blood counts) with flagged results is to perform repeat testing. 3. Review of the laboratory's API records for 2016 (event 3), 2017 (events 1, 2, and 3), and 2018 (events 1 and 2) revealed the following proficiency testing samples were not tested the same number of times as patient samples. The PT samples with flags were not verified by repeat testing. 2017 (event 1) Sample ID: Hemo01 Flag: L5 Sample ID: Hem02 Flag: L5 Sample ID: Hemo03 Flag: L5 Sample ID: Hemo04 Flag: L2, L5 Sample ID: Hem05 Flag: L5, R1 2017 (event 2) Sample ID: Hem 06 Flag: L5 Sample ID: Hem 07 Flag: L2, L5 Sample ID: Hem 8 Flag: L5 Sample ID: Hem 09 Flag: L5 Sample ID: Hem 10 Flag: L5 2017 (event 3) Sample ID: Hem 11 Flag: L5, R1 Sample ID: Hem12 Flag: L5 Sample ID: Hem13 Flag: L5 Sample ID: Hem14 Flag: L2, L5 Sample ID: Hem15 Flag: L5, R1 2018 (event 1) Sample ID: H01 Flag: L5, R1 Sample ID: H2 Flag: L5 Sample ID: 03 Flag: L5 Sample ID: 04 Flag: L5, R1 Sample ID: H5 Flag: L2, L5 2018 (event 2) Sample ID: Hem06 Flag: L5 Sample ID: Hem07 Flag: L5 Sample ID: Hem08 Flag: L5 Sample ID: Hem09 Flag: L2, L5 4. An interview with the technical consultant on September 20, 2018 at 1420 hours in the break room confirmed the findings.
D2015	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(5)(6) (5) The laboratory must document the handling, preparation, processing, examination, and each step in the testing and reporting of results for all proficiency testing samples. The laboratory must maintain a copy of all records, including a copy of the proficiency testing program report forms used by the laboratory to record proficiency testing results including the attestation statement provided by the PT program, signed by the analyst and the laboratory director, documenting that proficiency testing samples were tested in the same manner as patient specimens, for a minimum of two years from the date of the proficiency testing event. (6) PT is required for only the test system, assay, or examination used as the primary method for patient testing during the PT event.

	This STANDARD is not met as evidenced by: Based on review of laboratory policy, review of the laboratory's American Proficiency Institute (API) proficiency testing records, review of attestation sheets, and confirmed in interview of facility personnel, the laboratory failed to ensure 1 of 6 attestation statements were retained for 2 years. The findings were: 1. Review of the laboratory's policy titled, "Proficiency Testing" approved by the laboratory director on September 24, 2002, stated, " ...All records and reports will be maintained for two years." 2. Review of the laboratory's API records for 2016 (event 3), 2017 (events 1, 2, and 3), and 2018 (events 1 and 2) revealed the attestation statement for 2016 (event 3) was not available for review at the time of the survey on September 20, 2018. 3. Review of the attestation statement for 2018 (event 2) stated, "Signatures Required: Testing personnel and the laboratory director must physically sign an attestation statement for all PT results, and retain the signed statement (or a copy) for a minimum of 2 years. Either the paper worksheet or a printed copy of this online attestation statement can be used for this purpose." 4. An interview with the technical consultant on September 20, 2018 at 1420 hours in the break room confirmed the findings.
D5413	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(b) The laboratory must define criteria for those conditions that are essential for proper storage of reagents and specimens, accurate and reliable test system operation, and test result reporting. The criteria must be consistent with the manufacturer's instructions, if provided. These conditions must be monitored and documented and, if applicable, include the following: (1) Water quality. (2) Temperature. (3) Humidity. (4) Protection of equipment and instruments from fluctuations and interruptions in electrical current that adversely affect patient test results and test reports. This STANDARD is not met as evidenced by: Based on review of the manufacturer's instructions for the Medonic M Series (Serial Number 46351) hematology analyzer, review of the laboratory's environmental monitoring records from August 2018 and September 2018, and staff interview, it was revealed the laboratory failed to establish a humidity range that was within manufacturer's specifications. The findings were: 1. Review of the manufacturer's instructions (P/N 203089B, R01.30.12) revealed the operating humidity for the Medonic M Series hematology analyzer is less than 80%. 2. A review of the laboratory's environmental monitoring records from August and September 2018 revealed the laboratory had an established humidity range of 20% - 88%. 3. An interview with the technical consultant on 09/20/2018 at 1600 hours in the break room confirmed the findings.
D5417	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(d) Reagents, solutions, culture media, control materials, calibration materials, and other supplies must not be used when they have exceeded their expiration date, have deteriorated, or are of substandard quality. This STANDARD is not met as evidenced by:

	Based on direct observation, review of laboratory policy, and confirmed in interview of facility personnel, the laboratory failed to ensure expired items were not available for use in patient testing. The findings were: 1. Based on direct observation in the laboratory on September 20, 2018 at 13:10 hours during the initial tour of the laboratory the following expired items were found: a. Modified Stuart's Medium (Lot 5K21A) - expiration date 4-21-17: quantity of 8 b. Modified Stuart's Medium (Lot 5K06A) - expiration date 4-6-17: quantity of 20 c. Cary Blair Transport Medium (Lot 919240) - expiration date 2-26-18: quantity of 10 2. The above findings were confirmed in interview of the primary testing person on September 20, 2018 at 13: 15 hours. She agreed the items were expired but revealed that the supplies were not in use and should have been discarded.
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. 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. 2. Direct observation on September 20, 2018 in the laboratory revealed the primary testing person demonstrate 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 3. 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..." 4. 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. 5. An interview with the technical consultant at 1530 hours in the break room confirmed the findings. She revealed the laboratory was still in the process of collecting data.
D6023	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(6) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(6) Ensure the establishment and maintenance of acceptable levels of analytical performance for each test system;

	This STANDARD is not met as evidenced by: Based upon review of the laboratory's verification studies for the Medonic M Series hematology analyzer, and staff interview, it was revealed the laboratory director failed to provide a policy to address patient results when a result is out of the verified linearity range of the instrument. The findings were: 1. A review of the laboratory's verification records for the Medonic M Series hematology analyzer approved by the laboratory director on August 1, 2018, revealed the laboratory had established its linearity ranges as follows: WBC: 0.8 - 80.0 x 10^9/L RBC: 0.50 - 7.00 x 10^12/L HGB: 2.0 - 23.0 x g/dL PLT: 30 - 1000 x 10^9/L 2. The primary testing person was asked what she would do with a patient result of a WBC of 100,000, and she stated she would repeat the result because it would be a panic, and then she, "Would report it to the provider." 3. The laboratory director failed to implement a policy that instructed testing persons on how to report patient results outside of the laboratory established linearity range of the analyzer. 4. An interview with the technical consultant on September 20, 2018 at 1600 hours in the break room confirmed the findings. Key: L - liter g - gram dL - deciliter WBC - white blood cell RBC - red blood cell HGB - hemoglobin PLT - platelet
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 the manufacturer's instructions for the Medonic M Series hematology analyzer, review of patient results, and confirmed in interview of facility personnel, the technical consultant failed to ensure that testing personnel's training on the Medonic M Series hematology analyzer included how to resolve patient results for CBCs with flags prior to patient testing. The findings were: 1. Review of the laboratory's verification records for the Medonic M Series hematology analyzer revealed that the laboratory director approved the for use on August 1, 2018. 2. A review of the Medonic M-series Operator's guide section 9.2 titled "System Information and Messages" pages 70 -73 revealed the following 27 flags: AF, DE, FD, HF, HH, HL, HN, HO, HS, OR, SE, TE, EC, ER, NR, DF, DP, LF, LP, ST, TB, TL,TU, BD, NM, OM and TM. The Operator's guide states, that for flags BD, NM, OM and TM, the required action is: "Blood sample too old or pathological sample. Follow laboratory's protocol for verification of results". 3. Random review of patient results revealed the following patient results were reported when flags had not been verified: Sequence #: 42 Date: 08/02/2018 Flag: OM Sequence #: 163 Date: 08/16 /2018 Flag: OM Sequence #: 217 Date: 08/22/2018 Flag: OM Sequence #: 226 Date: 08/23/2018 Flag: OM Sequence #: 234 Date: 08/24/2018 Flag: OM Sequence #: 280 Date: 08/30/2018 Flag: BD Sequence #: 292 Date: 08/31/2018 Flag: OM 4. The above findings were confirmed in interview with the primary testing person on September 20, 2018 at 16:15 hours in the break room. When shown the results with flags and asked how she resolves patient results with flags, she stated that she, "Did not realize what the flags looked like on the patient results." She confirmed that she was looking for flags such as L2 and L5, "Like on the previous analyzer."