Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0983714	11/18/2020
Name of Provider or Supplier	**Street Address, City, State**	
Luis A Rodriguez Md Pa	1400 E Ridge Rd Suite 8, Mcallen, 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 at the entrance and exit conferences. The facility representative was 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.
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 laboratory's temperature/humidity records from July 2020 to September 2020, review of the laboratory's maintenance records from July 2020 to September 2020, and staff interview, it was revealed the laboratory failed to have documentation on monitoring room temperature and humidity each day of patient testing. The findings were: 1. A review of the laboratory's room temperature/humidity

	records from July 2020 to September 2020 revealed the laboratory failed to have documentation of monitoring the temperature and humidity of the laboratory on the following days: a) July 2020 07/24/2020 b) August 2020 08/31/2020 c) September 2020 09/21/2020 09/22/2020 09/23/2020 09/24/2020 09/25/2020 09/30/2020 2. A review of the laboratory's maintenance records from July 2020 to September 2020 for the Coulter AcT diff 2 hematology analyzer revealed the instrument was in use each of the identified days. 3. The laboratory was asked to provide documentation of monitoring the room temperature and humidity on the listed days. No documentation was provided. 4. An interview with testing personnel number 1 (as listed on Form CMS 209) on 11/18/2020 at 1015 hours in the office - after her review of the records- 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 review of the manufacturer's instructions for the Coulter 4C Plus Controls, review of the manufacturer's instructions for the Coulter AcT diff 2 hematology analyzer, review of the laboratory's quality control records from May 2020 to October 2020, and staff interview, it was revealed the laboratory failed to ensure control material was not expired prior to use. The findings were: 1. A review of the manufacturer's instructions for the Coulter 4C Plus Controls (IVD 7504598-EB) revealed the controls were acceptable for use for 35 total days after opening or 20 days of use. 2. A review of the manufacturer's instructions for the Coulter AcT diff 2 hematology analyzer (PN A35926AB, December 2009) revealed: "An event occurs each time a vial is taken out of the refrigerator, warmed, and refrigerated again." "4C cell control has a maximum of 20 allowable events with 35 days." 3. A review of the laboratory's quality control records from August 2020 to October 2020 revealed the following: a) Low - Lot 067600 Normal - Lot 077600 High - Lot 087600 Crossover performed 5/26 and 5/27 Used for 23 days for patient testing thus, 5 days past expiration b) Low - Lot 068100 Normal - Lot 078100 High - Lot 088100 Crossover performed 7/27 Used for 23 days for patient testing thus, 4 days past expiration c) Low - Lot 068300 Normal - Lot 078300 High - Lot 088300 Crossover performed 8/27 and 8/28 Used for 20 days for patient testing thus, 2 days past expiration d) Low - Lot 068400 Normal - Lot 078400 High - Lot 088400 Crossover performed 09/24, 09/25, 09/30 Used 20 days for patient testing thus, 3 days past expiration 4. An interview with testing personnel number 1 (as listed on Form CMS 209) on 11/18/2020 at 1115 hours in the laboratory revealed the laboratory thought the controls were acceptable for use for 35 total days or 31 uses. She did not know about the 20 event rule. This confirmed the findings.
D5437	CALIBRATION AND CALIBRATION VERIFICATION CFR(s): 493.1255(a) Unless otherwise specified in this subpart, for each applicable test system the laboratory must perform and document calibration procedures-- (1) Following the manufacturer's test system instructions, using calibration materials provided or specified, and with at least the frequency recommended by the manufacturer; (2)

	Using the criteria verified or established by the laboratory as specified in 493.1253(b)(3)-- (2)(i) Using calibration materials appropriate for the test system and, if possible, traceable to a reference method or reference material of known value; and (2)(ii) Including the number, type, and concentration of calibration materials, as well as acceptable limits for and the frequency of calibration; and (3) Whenever calibration verification fails to meet the laboratory's acceptable limits for calibration verification. This STANDARD is not met as evidenced by: Based on review of the laboratory's Coulter AcT diff 2 calibration records from October 2019, May 2020 and November 2020, and staff interview, it was revealed the laboratory failed to have documentation of performing calibrations when calibration factors changed. The findings were: 1. A review of the laboratory's calibration records from October 2019, May 2020, and November 2020, revealed the following calibration factors were in use on the Coulter AcT diff 2 hematology analyzer: a) October 2019 Post calibration factors WBC - .9858 RBC - 1.063 Hgb - 1.039 MCV - .9256 Plt - 1.064 MPV - 1.032 b) May 2020 Pre-calibration factors (should match October 2019 post calibration) WBC - 1.036 RBC - 1.116 Hgb - 1.090 MCV - .9719 Plt - 1.000 MPV - 1.032 There was no documentation of a calibration being performed to justify the change in the calibration factors for WBC, RBC, Hgb, MCV and Plt. c) May 2020 Post calibration factors WBC - 1.003 RBC - 1.116 Hgb - 1.069 MCV - .9167 Plt - 1.056 MPV - 1.032 d) November 2020 Pre-calibration factors (should match May 2020 post calibration) WBC - 1.067 RBC - 1.116 Hgb - 1.086 MCV - .9167 Plt - 1.024 MPV - 1.032 There was no documentation of a calibration being performed to justify the change in the calibration factors for WBC, Hgb and Plt. 3. The laboratory was asked to provide documentation of performing calibrations to support the change in the calibration factors. No documentation was provided. 4. An interview with testing personnel number 1 (as listed on Form CMS 209) on 11/18/2020 at 1015 hours in the office - after her review of the records - confirmed the findings. Key WBC - white blood cell RBC - red blood cell Hgb - hemoglobin MCV - mean corpuscular volume Plt - platelet MPV - mean platelet volume