Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1025956	12/03/2020
Name of Provider or Supplier	**Street Address, City, State**	
Enrique Caceres Md Pa	4236 N Mccoll Rd Ste B, 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.
D5221	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(d) All proficiency testing evaluation and verification activities must be documented. This STANDARD is not met as evidenced by: Based on review of the laboratory's American Proficiency Institute's proficiency testing records from 2018, 2019, and 2020, and staff interview, it was revealed the laboratory failed to have documentation of the laboratory director reviewing 2 of 9 proficiency testing results. The findings were: 1. A review of the laboratory's American Proficiency Institute's hematology proficiency testing records from 2018 (events 1, 2, and 3), 2019 (events 1, 2, and 3) and 2020 (events 1, 2, and 3) revealed the laboratory failed to have documentation of the review of the results for 2 of 9 events. The events missing documentation of review were: 2019 event 2 - laboratory director's name printed by someone else 2019 event 3 - laboratory director's name typed 2. The laboratory was asked to provide documentation of the laboratory director review the identified results. No documentation was provided. 3. An interview with

	testing personnel number 1 (as listed on Form CMS 209) on 12/03/2020 at 1130 hours in the break room - 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 Beckman Coulter 4C hematology controls, review of the laboratory's hematology quality control records from September - November 2020, and staff interview, it was revealed the laboratory failed to ensure expired control were not used. The findings were: 1. A review of the manufacturer's instructions for the Beckman Coulter 4C hematology controls (7504598-EB) revealed the controls were acceptable for use for 20 uses or 35 days after opening. 2. A review of the laboratory's hematology quality control records from September 15 - October 13, 2020 and October 16 - November 13, 2020 revealed during each identified period the hematology control were utilized for 21 uses. Thus the controls exceeded their stability on October 13, 2020 and November 13, 2020. 3. An interview with testing personnel number 1 (as listed on Form CMS 209) on 12/03 /2020 at 1130 hours in the break room - after her review of the records- 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 manufacturer's instructions for the Beckman Coulter AcT diff 2, review of the laboratory's calibration records from 2019 and 2020, and staff interview, it was revealed the laboratory failed to perform calibration every six months as required. The findings were: 1. A review of the manufacturer's instructions for the Beckman Coulter AcT diff 2 hematology analyzer under the section titled "Calibration Procedures" revealed: "Calibration Frequency Calibrate at least once every six months....." 2. A review of the laboratory's calibration records from 2019 and 2020 revealed the laboratory performed calibrations at the following times: April 2019 September 2019 (5 months later) June 2020 (9 months later) 3. The laboratory was asked to provide documentation of performing a calibration within 6 months of the September 2019 calibration. No documentation was provided. 4. An interview

	with testing personnel number 1 (as listed on Form CMS 209) on 12/03/2020 at 1130 hours in the break room - after her review of the records- confirmed the findings.
D5469	CONTROL PROCEDURES CFR(s): 493.1256(d)(10)(g) Unless CMS Approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub. 7), that provides equivalent quality testing, the laboratory must--Establish or verify the criteria for acceptability of all control materials. (i) When control materials providing quantitative results are used, statistical parameters (for example, mean and standard deviation) for each batch and lot number of control materials must be defined and available. (ii) The laboratory may use the stated value of a commercially assayed control material provided the stated value is for the methodology and instrumentation employed by the laboratory and is verified by the laboratory. (iii) Statistical parameters for unassayed control materials must be established over time by the laboratory through concurrent testing of control materials having previously determined statistical parameters. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: Based on review of the laboratory's hematology quality control records and staff interview, it was revealed the laboratory failed to have documentation of verifying 6 of 6 new lots of control material prior to use. The findings were: 1. A review of the laboratory's hematology quality control records from 2020 revealed the following lots were placed into use: a) lot 069100 b) lot 069400 c) lot 067600 d) lot 079400 e) lot 068100 f) lot 068700 2. The laboratory was asked to provide documentation of verifying the manufacturer's control ranges prior to placing the lots into use. No documentation was provided. 3. An interview with testing personnel number 1 (as listed on Form CMS 209) on 12/03/2020 at 1115 hours in the laboratory revealed the facility did not verify new lots control control material. The controls were placed into use without this being done. This confirmed the findings.
D6053	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(9) The technical consultant is responsible for evaluating and documenting the performance of individuals responsible for moderate complexity testing at least semiannually during the first year the individual tests patient specimens. This STANDARD is not met as evidenced by: Based on review of the laboratory's personnel records and staff interview, it was revealed the laboratory failed to have documentation of the technical consultant performing competency assessments semiannually within the first year for 1 of 2 testing personnel. The findings were: 1. A review of the laboratory's personnel records revealed two testing personnel required documentation of competency assessments being performed semiannually within the first year of employment. 2. Further review revealed testing personnel number 2 (as listed on Form CMS 209) was hired in June 2019. Competency assessments were documented as being performed in June 2019 and July 2020. 3. The laboratory was asked to provide documentation of a second competency assessment being performed semiannually for testing personnel number 2. No documentation was provided. 4. An interview with testing personnel number 1

	(as listed on Form CMS 209) on 12/03/2020 at 1130 hours in the break room - after her review of the records - confirmed the findings.