Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0874933	12/02/2020
Name of Provider or Supplier	**Street Address, City, State**	
Linda E Lopez-Rosario Md Pa	900 Plaza Drive Suite #2, Mission, 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.
D2007	TESTING OF PROFICIENCY TESTING SAMPLES CFR(s): 493.801(b)(1) The samples must be examined or tested with the laboratory's regular patient workload by personnel who routinely perform the testing in the laboratory, using the laboratory's routine methods This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted CMS 209, review of the laboratory's American Association of Bioanalysts' (AAB) proficiency testing records from 2018, 2019, and 2020, and staff interview, it was revealed the laboratory failed to have documentation of all testing personnel participating in proficiency testing. The findings were: 1. A review of the laboratory's submitted CMS 209 revealed the laboratory identified 3 testing personnel. 2. A review of the laboratory's American Association of Bioanalysts' proficiency testing records from 2018 (Non chemistry 1, 2, and 3) 2019 (Non chemistry 1, 2, and 3) and 2020 (Non chemistry (1, 2, and 3) revealed testing personnel did not participate in proficiency testing. The review

	showed the following personnel (as listed on Form CMS 209) testing each event: 2018 event 1 testing personnel number 2 2018 event 2 testing personnel number 3 2018 event 3 testing personnel number 3 2019 event 1 testing personnel number 3 2019 event 2 testing personnel number 2 2019 event 3 testing personnel number 3 2020 event 1 testing personnel number 2 2020 event 2 testing personnel number 2 2020 event 3 testing personnel number 2 3. The laboratory was asked to provide documentation of testing personnel number 1 participating in proficiency testing. No documentation was provided. 4. An interview with testing personnel number 1 (as listed on Form CMS 209) on 12/02/2020 at 0945 hours in the break room revealed she did not perform proficiency testing during the reviewed time frame. She stated she performed hematology testing everyday. This confirmed the findings.
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 the laboratory's American Association of Bioanalysts' proficiency testing records from 2018, 2019, and 2020, and staff interview, it was revealed the laboratory failed to have documentation of testing personnel signing the attestation statement for 2 of 9 events. The finding were: 1. A review of the laboratory's American Association of Bioanalysts' proficiency testing records from 2018 (Non chemistry 1, 2, and 3) 2019 (Non chemistry 1, 2, and 3) and 2020 (Non chemistry (1, 2, and 3) revealed testing personnel did sign 2 of 9 attestation statements. The events without documentation of the testing personnel signing the attestation statement were: 2019 event 1 2020 event 2 2. The laboratory was asked to provide documentation of testing personnel signing the attestation statements. No documentation was provided. 3. An interview with testing personnel number 1 (as listed on Form CMS 209) on 12 /02/2020 at 0945 hours in the conference room - after her review of the records- confirmed the findings.
D5791	ANALYTIC SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1289(a)(c) (a) The laboratory must establish and follow written policies and procedures for an ongoing mechanism to monitor, assess, and when indicated, correct problems identified in the analytic systems specified in 493.1251 through 493.1283. (c) The laboratory must document all analytic systems assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's CDS eCQAP reports, and staff interview, it was revealed the laboratory failed to have documentation of investigating flagged results of monthly quality control monitoring for hematology. The findings were: 1. A review of the laboratory's CDS eCQAP reports which compared the laboratory's monthly quality control results to the laboratory's peer group revealed the following flag: S1: SDI > +/- 2.0, results are outside of the defined reference limit Thus, the laboratory's results were shifted from its peer group and required investigation. 2. Further review of the CDS eCQAP reports from June 2020, July 2020 and August 2020 revealed the

	following parameters with S1 flags: a) June 2020 Plt low control MPV low control Lymp % low control Lymp % normal control Gran % low control MID # high control b) July 2020 MCHC normal control MCHC high control Lymph % normal control MID% normal control MID% high control c) August 2020 MPV high control Lymph% high control MID% high control 3. The laboratory was asked to provide documentation of investigating the identified flags. No documentation was provided. 4. An interview with testing personnel number 1 (as listed on Form CMS 209) on 12 /02/2020 at 1045 hours in the break room revealed the laboratory did not investigate the parameters with flags. This confirmed the findings.