Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1035160	10/10/2018
Name of Provider or Supplier	**Street Address, City, State**	
Jorge L Flores Md Pa	1885 E Price Road Suite A, 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 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.
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 studies performed on the Medonic M-series hematology analyzer, review of patient normal ranges currently in use, and staff interview, it was revealed the laboratory failed to have documentation of verifying patient normal ranges. The findings were: 1. A review of the laboratory's verification studies performed on the Medonic M-series hematology analyzer (serial number

	294690) in December 2017 revealed the laboratory failed to have documentation of verifying patient normal ranges. 2. A review of patient normal ranges currently in use by the laboratory revealed the following 8 patient normal ranges: a) 2 - 6 months WBC 6.0 - 17.5 LYM 2.6 - 13.0 MID 0.2 - 2.3 GRAN 1.5 - 6.7 LYM% 44.0 - 74.0 MID% 4.0 - 13.0 GRA% 25.0 - 38.0 RBC 3.80 - 5.20 HGB 13.0 - 16.5 HCT 39.0 - 52.0 MCV 82.0 - 100.0 MCH 28.0 - 38.0 MCHC 32.0 - 34.0 RDW% 11.7 - 15.0 PLT 140 - 440 MPV 8.0 - 11.0 b) 7 - 11 months WBC 6.0 - 17.5 LYM 2.6 - 13.0 MID 0.2 - 2.3 GRAN 1.5 - 7.1 LYM% 44.0 - 74.0 MID% 4.0 - 13.0 GRA% 25.0 - 41.0 RBC 3.70 - 5.20 HGB 12.0 - 14.0 HCT 35.0 - 45.0 MCV 77.0 - 98.0 MCH 24.0 - 32.0 MCHC 27.0 - 30.0 RDW% 11.7 - 15.0 PLT 140 - 440 MPV 8.0 - 11.0 c) 1 - 2 years WBC 6.0 - 17.0 LYM 2.9 - 13.3 MID 0.2 - 2.2 GRAN 1.5 - 7.1 LYM% 48.0 - 78.0 MID% 4.0 - 13.0 GRA% 25.0 - 42.0 RBC 3.50 - 4.90 HGB 10.0 - 14.0 HCT 30.0 - 42.0 MCV 75.0 - 96.0 MCH 24.0 - 32.0 MCHC 28.0 - 30.0 RDW% 11.7 - 15.0 PLT 140 - 440 MPV 8.0 - 11.0 d) 3 - 4 years WBC 5.0 - 14.5 LYM 1.8 -9.4 MID 0.2 - 1.9 GRAN 1.5 - 7.1 LYM% 63.0 - 65.0 MID% 4.0 - 13.0 GRA% 30.0 - 49.0 RBC 3.7 - 5.00 HGB 11.2 - 14.5 HCT 32.0 - 44.0 MCV 75.0 - 96.0 MCH 23.0 - 33.0 MCHC 28.0 - 30.0 RDW% 11.7 - 15.0 PLT 140 - 440 MPV 8.0 - 11.0 e) 5 - 11 years WBC 4.0 -13.5 LYM 1.1 -6.5 MID 0.2 - 1.8 GRAN 1.5 - 7.8 LYM% 28.0 - 48.0 MID% 4.0 - 13.0 GRA% 38.0 - 58.0 RBC 3.9 - 5.10 HGB 11.5 - 14.5 HCT 33.0 - 45.0 MCV 78.0 - 96.0 MCH 23.0 - 33.0 MCHC 28.0 - 30.0 RDW% 11.7 - 15.0 PLT 140 - 440 MPV 8.0 - 11.0 f) 12 - 17 years WBC 4.0 -12.5 LYM 1.1 - 5.9 MID 0.2 - 1.6 GRAN 1.5 - 7.8 LYM% 27.0 - 47.0 MID% 4.0 - 13.0 GRA% 38.0 - 63.0 RBC 3.8 - 5.20 HGB 11.6 - 14.8 HCT 34.0 - 46.0 MCV 80.0 - 98.0 MCH 27.0 - 34.0 MCHC 28.0 - 36.0 RDW% 11.0 - 16.0 PLT 140 - 440 MPV 8.0 - 11.0 g) Adult female WBC 3.5 - 10.0 LYM 0.5 - 5.0 MID 0.1 - 1.5 GRAN 1.2 - 8.0 LYM% 15.0 - 50.0 MID% 2.0 - 15.0 GRA% 35.0 - 80.0 RBC 3.5 - 5.50 HGB 11.5 - 16.5 HCT 35.0 - 55.0 MCV 75.0 - 100.0 MCH 25.0 - 35.0 MCHC 31.0 - 38.0 RDW% 11.0 - 16.0 PLT 100 - 440 MPV 8.0 - 11.0 h) Adult male WBC 3.5 - 10.0 LYM 0.5 - 5.0 MID 0.1 - 1.5 GRAN 1.2 - 8.0 LYM% 15.0 - 50.0 MID% 2.0 - 15.0 GRA% 35.0 - 80.0 RBC 3.5 - 5.50 HGB 11.5 - 16.5 HCT 35.0 - 55.0 MCV 75.0 - 100.0 MCH 25.0 - 35.0 MCHC 31.0 - 38.0 RDW% 11.0 - 16.0 PLT 100 - 440 MPV 8.0 - 11.0 3. The laboratory was asked to provide documentation of verifying the patient normal ranges currently in use. No documentation was provided. 4. An interview with the technical consultant on 10/10 /2018 at 1045 hour in the break room - after his review of the records - confirmed the findings. KEY WBC - white blood cell LYM - lymphocytes MID - monocytes and basophils GRAN - granulocytes LYM% - percent lymphocytes MID% - percent monocytes and basophils GRA% - percent granulocytes RBC - red blood cell HGB - hemoglobin HCT - hematocrit MCV - mean corpuscular volume MCH - mean corpuscular hemoglobin MCHC - mean corpuscular hemoglobin concentration RDW% - red blood cell distribution width PLT - platelet MPV - mean platelet volume
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 manufacturer's instructions for the Medonic M-series hematology analyzer, review of patient test records from August 2018 and September

	2018, and staff interview, it was revealed the laboratory's quality assessment plan failed to identify that differential results with flags were reported to providers without documentation of the laboratory performing any corrective actions. The findings were: 1. A review of the manufacturer's instructions for the Medonic M-series hematology analyzer (PN 2031698 R03.14.14) under the section titled "Interpretation of Results" revealed: " - The following flags cover abnormalities in the WBC differential and indicate a possible problem with the accuracy of the results: BD NM OM TM - Refer to the Medonic M-series User's manual for detailed information regarding the messages, their descriptions, and suggested actions for resolving them. - Performing a slide review (which is recommended by the manufacturer) or referring the specimen for further study when flags are attached to the differential WBC is left to the discretion of the ordering provider. 2. A review of patient test records from August 2018 and September 2018 identified the following sampling of patient results whose differential results had flags, however the laboratory staff entered the flagged results into the progress notes for the physician to review without performing any corrective actions: Date ID Flag 08/18 11653 BD 08/30 13608 OM 08/31 13646 OM 09/10 12206 OM 09/15 12379 BD 3. Further review of the identified patient records revealed the laboratory scanned in the original CBC instrument printouts as well as the printouts which had the differential portion of the CBC crossed out. 4. An interview with the technical consultant on 10/10/2018 at 1215 hours in the break room revealed he was unaware testing personnel were reporting out the flagged results in the progress notes for patients. He stated the provider would look at the progress notes for the CBC results. This confirmed the findings. KEY CBC -complete blood count WBC - white blood cell
D6055	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 whenever test methodology or instrumentation changes. The individual's performance must be reevaluated to include the use of the new test methodology or instrumentation prior to reporting patient test results. This STANDARD is not met as evidenced by: Based on review of the laboratory's verification records for the Medonic M-series hematology analyzer, 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 prior to testing personnel performing patient testing. The findings were: 1. A review of the laboratory's verification records for the Medonic M-series hematology analyzer revealed the laboratory was placed into use in December 2017. 2. A review of the laboratory's personnel records revealed the technical consultant had performed competency assessments for testing personnel for hematology testing the following date: a) Testing personnel number 1 03/2017 03 /2018 b)Testing personnel number 2 02/2017 02/2018 c) Testing personnel number 3 11/2017 05/2018 3. The laboratory was asked to provide documentation of the technical consultant performing competency assessments prior to testing personnel performing patient testing. No documentation was provided. 4. An interview with the technical consultant on 10/10/2018 at 1015 hours in the break room revealed he was unaware competency assessments were required prior to testing personnel performing testing on a newly installed analyzer. This confirmed the findings.