Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1035160	06/10/2021
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.
D1001	CERTIFICATE OF WAIVER TESTS CFR(s): 493.15(e) Laboratories eligible for a certificate of waiver must-- (1) Follow manufacturers' instructions for performing the test; and (2) Meet the requirements in subpart B, Certificate of Waiver, of this part. This STANDARD is not met as evidenced by: Based on review of manufacturer's instructions, patient test records, and confirmed in interview of facility personnel, the laboratory failed to follow the manufacturer's instructions to (a) include all authorized fact sheets when performing Covid testing using Quidel QuickVue test and (b) to ensure testing persons were trained prior to patient testing. The findings were: 1. Review of the manufacturer's instructions for use under, "Conditions of Authorization for Laboratory," it stated: "Authorized laboratories' using your product must include with test result reports, all authorized Fact Sheets. Under exigent circumstances, other appropriate methods for disseminating these Fact Sheets may be used, which may include mass media." and; "All operators using your product must be appropriately trained in performing and interpreting the results of your product, use appropriate personal protective equipment when handling this kit, and use your product in accordance with authorized labeling." 2. Review of 10 of 10 patient test results found the laboratory failed to follow the manufacturer's instructions to include the required fact sheets with the patient results and provide documentation of training testing personnel in performing and

	interpreting test results. 3. An interview with the primary testing person on June 10, 2021 at 09:55 hours in the office confirmed the findings. She revealed she was not aware of the requirement.
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 May 2021, 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. This is a repeat deficiency from the survey conducted October 10, 2018. 2. 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. 3. A review of patient test records from May 2021 identified the following sampling of patient results whose differential results had flags: Date Sequence # Flag 05-05-2021 893 BD 05-07-2021 909 BD 05-13-2021 955 BD 05-14-2021 970 BD 05-27-2021 1068 WBC Diff 05-27-2021 1073 WBC Diff 4. An interview with the testing personnel #1 (as listed on Form CMS-209) on June 10, 2021 at 1000 hours in the break room confirmed the findings. She confirmed the provider would look at the flags prior to invalidating and then scanning them into the patient medical record. This confirmed the findings. Key: CBC -complete blood count WBC - white blood cell