Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D0942248	07/18/2019
Name of Provider or Supplier	**Street Address, City, State**	
Juan F Montalvo Md Pa	10410 Medical Loop Bldg 3b, Laredo, 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
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 Form CMS-209, API (American Proficiency Institute) proficiency testing (PT) records and confirmed in interview of facility personnel, the laboratory failed to ensure PT samples were rotated between all testing persons. The findings were: 1. Review of the laboratory's submitted Form CMS-209 signed by the laboratory director on July 18, 2019 revealed the laboratory identified four testing persons as performing moderate complexity testing. 2. Review of the PT records for Microbiology 2018 (events 1, 2, and 3) revealed the attestation sheets were signed as follows: 2018 (event 1) testing personnel one 2018 (event 2) testing personnel two 2018 (event 3) testing personnel two 3. The laboratory was asked to provide documentation of each of the testing persons participating in proficiency testing for 2018. No documentation was provided. 4. Interview with testing personnel one (as listed on Form CMS-209) on July 18, 2019 at 10:15 hours in the break room confirmed the findings. She revealed that the other two testing persons were not in the lab as much as herself and testing person two. Key: CMS - Centers for Medicare and Medicaid Services
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 BD MicroProbe Processor Instrument User's Manual, laboratory environmental records (01/2018 through 07/2019), and confirmed in interview, the laboratory failed to ensure humidity level requirements were within the operating specifications for the BD MicroProbe Processor analyzers for 19 of 19 months. Findings included: 1. Review of the BD MicroProbe Processor Instrument User's Manual page 2-2 stated the following: "Environmental Indoor Use ... Ambient Humidity: 10-85 %" 2. Review of the laboratory environmental records from 01/2018-07/2019 revealed the laboratory failed to document humidity measurements. 3. During an interview on 07/18/2019 at 11:44 am, Testing person #1 (as listed on Form CMS-209) stated that she was unaware that humidity had to be monitored, confirming the above findings. Key: CMS - Centers for Medicare and Medicaid Services BD - Becton Dickinson
D5445	CONTROL PROCEDURES CFR(s): 493.1256(d)(1)(2)(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--(d)(1) Perform control procedures as defined in this section unless otherwise specified in the additional specialty and subspecialty requirements at 493.1261 through 493.1278. (d)(2) For each test system, perform control procedures using the number and frequency specified by the manufacturer or established by the laboratory when they meet or exceed the requirements in paragraph (d)(3) of this section. (g) The laboratory must document all control procedures performed. This STANDARD is not met as evidenced by: I. Based on review of the laboratory's Individualized Quality Control Plan (IQCP), and confirmed in interview of facility personnel, the laboratory failed to provide documentation that the QA (quality assessment) portion of the IQCP included procedures for ongoing monitoring of the effectiveness of its IQCP for Serum HCG. Findings: 1. Review of the laboratory's IQCP for Serum HCG revealed it was approved by the laboratory director on May 17, 2017. 2. Review of the quality assessment portion of the IQCP failed to include procedures for ongoing monitoring of the IQCP. 3.During an interview on 07/18/2019 at 11:36 am, testing person 1 (as listed on form CMS-209) confirmed the above findings. II. Based on review of the laboratory's Individualized Quality Control Plan (IQCP), and confirmed in interview of facility personnel, the laboratory failed to provide documentation that the QA (quality assessment) portion of the IQCP included procedures for ongoing monitoring of the effectiveness of its IQCP for BD Affirm. Findings: 1. Review of the laboratory's IQCP for BD Affirm revealed it was approved by the laboratory director on May 17, 2017. 2. Review of the quality assessment portion of the IQCP failed to include procedures for ongoing monitoring of the IQCP. 3.During an interview on 07/18/2019 at 11:36 am, testing person 1 (as listed on form CMS-209) confirmed the above findings. III. Based on review of laboratory's Individualized Quality Control Plan (IQCP), quality control (QC) records, patient test records, and staff interview the

	laboratory failed to test at least two levels of quality control materials for serum HCG, at the frequency defined in their IQCP approved May 17, 2017. Findings: 1. Review of the laboratory's written IQCP revealed the laboratory defined a frequency of testing external quality control materials every 30 days and upon opening a new box of test cassettes. 2. Review of QC records revealed the laboratory tested external QC for each new box of test cassettes opened only and not every 30 days. The laboratory failed to test external QC for serum HCG as defined in their IQCP. 3. Review of QC records revealed the laboratory performed external QC upon opening a new box of test cassettes on the following dates: 10/18/2017 Lot# hcg7020113, expiration date: 12/31 /2019 The following patients were tested with this box of test cassettes after the 30-day expiration date of the QC: ID 21657 test date 11/21/2017 ID 22846 test date 11/27 /2017 ID 8998 test date 11/29/2017 01/30/2018 Lot# hcg7050031, expiration date: 04 /30/2019 The following patients were tested with this box of test cassettes after the 30-day expiration date of the QC: ID 22372 test date 03/01/2018 IDs 22790, 14072 test date 03/06/2018 ID 20058 test date 03/07/2018 IDs 20495, 14587 test date 03/08 /2018 03/08/2018 Lot# hcg7050031, expiration date: 04/30/2019 The following patients were tested with this box of test cassettes after the 30-day expiration date of the QC: ID 22581 test date 04/09/2018 IDs 15999, 18334, 18419 test date 04/10/2018 IDs 17338, 16184 test date 04/11/2018 06/04/2018 Lot# hcg8010037, expiration date: 12/31/2019 The following patients were tested with this box of test cassettes after the 30-day expiration date of the QC: IDs 21531, 22688 test date 07/10/2018 ID 13781 test date 07/12/2018 IDs 22779, 23348, 21948 test date 07/17/2018 IDs 22205, 9666, 19487 test date 07/18/2018 IDs 23004, 8370 test date 07/24/2018 ID 21249 test date 08/01/2018 11/01/2018 Lot# hcg8050024, expiration date: 04/30/2020 The following patients were tested with this box of test cassettes after the 30-day expiration date of the QC: IDs 23566, 15211, 10915 test date 12/06/2018 ID 17213 test date 12/11/2018 ID 23197 test date 12/12/2018 ID 23329 test date 12/17/2018 IDs 13934, 23210 test date 12/20/2018 ID 17907 test date 12/26/2018 03/06/2019 Lot# hcg8080031, expiration date: 07/31/2020 The following patients were tested with this box of test cassettes after the 30-day expiration date of the QC: ID 10389 test date 04/08/2019 ID 18233 test date 04/09/2019 ID 20672 test date 04/11/2019 ID 13733 test date 04/16 /2019 05/16/2019 Lot# hcg8100083, expiration date: 09/30/2020 The following patients were tested with this box of test cassettes after the 30-day expiration date of the QC: ID 22206 test date 06/17/2019 ID 21240 test date 06/20/2019 ID 22548 test date 06/24/2019 ID 23105 test date 06/25/2019 4. During an interview on 07/18/2019 at 9:43 am, testing person 1 (as listed on Form CMS-209) stated that external quality control was only performed for each new box of serum HCG cassettes and not every 30 days as stated in the laboratory's IQCP.
D6051	TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)(v) The procedures for evaluation of the competency of the staff must include, but are not limited to assessment of test performance through testing previously analyzed specimens, internal blind testing samples or external proficiency testing samples. This STANDARD is not met as evidenced by: Based on review of the laboratory's submitted Form CMS-209, review of personnel records, review of API (American Proficiency Institute) proficiency testing (PT) records, and confirmed in interview of facility personnel, the technical consultant failed to evaluate each testing person's competency through testing previous specimens, blind test samples, or external PT samples. The findings were: 1. Review

	of the laboratory's submitted Form CMS-209 signed by the laboratory director on July 18, 2019 revealed the laboratory identified four testing persons who perform moderate complexity testing. 2. Review of Microbiology PT records for 2017 (events 2 and 3), 2018 (events 1, 2, and 3), and 2019 (event 1) revealed testing personnel three did not participate in any of the past six events. 3. Review of personnel records for testing personnel three revealed there was no documentation evaluating the testing person's competency through use of previously tested samples, blinded test samples, or external proficiency testing samples. 4. Interview with testing personnel one (as listed on Form CMS-209) on July 18, 2019 at 10:15 hours in the break room confirmed the findings. She revealed that the other two testing persons were not in the lab as much as herself and testing person two.