Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D1000973	11/15/2018
Name of Provider or Supplier	**Street Address, City, State**	
Family Medicine Clinic Pa	704 E Wonsley Drive, Suite 100, Austin, 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
D5411	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(a) Test systems must be selected by the laboratory. The testing must be performed following the manufacturer's instructions and in a manner that provides test results within the laboratory's stated performance specifications for each test system as determined under 493.1253. This STANDARD is not met as evidenced by: Based on review of the Beckman Coulter Access 25(OH) Vitamin D Total assay instructions for use and interview with facility personnel, the laboratory failed to follow manufacturer instructions for preparing the reagent for patient testing for 10 of 10 months between January 2018 and October 2018. The findings included: 1. Based on review of the Beckman Coulter Access 25(OH) Vitamin D Total assay instructions for use (REF B24838), the document states the following: "To ensure that the paramagnetic particles in the regent pack are fully suspended, mix the pack using a vortex mixer immediately before loading the reagent pack on the instrument for the first time. To mix: * Use a vortex mixer with a continuous 'On' mode (i.e. not 'Auto' or 'Touch' mode) and a maximum speed between 2500 and 3200 rpm. *Start the vortex mixer in the continuous mode and set it to its maximum speed. *Hold the pack upright by the clip end and place the base of the particle well (R1a) on the vortex pad at a slight downward angle (See instruction for Use for addition detail). *Mix the reagent pack continuously (do not pulse) for 20 to 30 seconds. *It is not necessary to remix packs after loading. Do not mix a puncture pack. The requirement to mix the reagent pack by vortex mixer is unique to the Vitamin D assay. Do not mix other Access reagent packs using a vortex mixer:" 2. In an interview at 11:41 hours on 11/15/2018 in the patient room, Testing Person 3 (as listed on the CMS-209 laboratory personnel report) stated the laboratory had not been using a vortex to mix Beckman Coulter Access 25(OH) Vitamin D Total reagent packs prior to loading them on the Access II analyzer.

D5431	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(a)(2) For unmodified manufacturer's equipment, instruments, or test systems, the laboratory must perform and document function checks as defined by the manufacturer and with at least the frequency specified by the manufacturer. Function checks must be within the manufacturer's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on review of Beckman Coulter Access II chemistry analyzer function check records, manufacturer instructions, and interview with facility personnel, the laboratory failed to performance function checks at the interval required by the manufacturer and ensure that 2 of 2 function checks were within the manufacturer's established limits before patient testing was performed between September 13, 2018 and November 5, 2018. The findings included: 1. Based on review of Beckman Coulter Access II chemistry analyzer function check records from September 24, 2018 and November 5, 2018, the following function checks failed to meet manufacturer's established limits before patient testing was performed: 9/13/2018 Substrate percent CV - 23.62 (High) Acceptable defined 0.00 - 5.00 percent 09/24/2018 Substrate percent CV - 22.32 (High) - Acceptable defined 0.00 - 5.00 percent Based on the "Substrate Check Troubleshooting Table": High percent CV from high values in 1 or 2 replicates may be due to the System Check solution diluted incorrectly or Sample Containers out of order in the maintenance rack. High percent CV throughout the run may be due to insufficient supply of substrate, air in the substrate line, leak in the substrate system tubing, bent substrate probe tip, substrate pump or valve failure, or a luminometer problem. 2. On the Beckman Coulter Access II Maintenance log, "Run System check" is listed as a weekly procedure. Based on review of maintenance logs from September 2018, October, 2018, and November 2018, the laboratory performed the "Run System Check" on the following dates: 9/13/2018 9/20/2018 9/24/2018 9/27 /2018 10/04/2018 10/08/2018 10/15/2018 10/22/2018 10/24/2018 11/05/2018 Based on the System check record printed on 9/16/2018, the previous system check was performed on 9/13/2018 and had failed the Substrate percent CV. For the record printed on 9/24/2018 at 10:00 a.m., the System Check had been performed on 9/24 /2018 at 09:29 a.m. and had failed the Substrate percent CV. For the record printed on 10/01/2018, the System Check had been performed on 9/24/2018 at 09:29 a.m. For the record printed out 10/15/2018, the System Check had been performed on 9/24/2018 at 09:29 a.m. For the record printed out 10/22/2018, the System Check had been performed on 9/24/2018 at 09:29 a.m. For the record printed out 10/29/2018, the System Check had been performed on 9/24/2018 at 09:29 a.m. 3. On the Beckman Coulter Access II Maintenance log, "Replace/Clean Aspirate Probes" is listed as a weekly procedure. Based on review of maintenance logs from September 2018, October, 2018, and November 2018, the laboratory performed the "Replace/Clean Aspirate Probes" on the following dates: 9/20/2018 9/24/2018 9/27/2018 10/04/2018 10/08/2018 10/15/2018 10/22/2018 10/24/2018 11/05/2018 4. In an interview at 11:46 hours on 11/15/2018, Testing Person 3 confirmed the laboratory had not been removing the aspirate probes and cleaning them per the manufacturer's instructions and the laboratory had not ensured function checks were within manufacturer established limits prior to reporting patients for the two function checks that could be verified on 9/13/2018 and 9/24/2018.
D5435	MAINTENANCE AND FUNCTION CHECKS CFR(s): 493.1254(b)(2)

	For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must: (i) Define a function check protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. (ii) Perform and document the function checks, including background or baseline checks, specified in paragraph (b)(2)(i) of this section. Function checks must be within the laboratory's established limits before patient testing is conducted. This STANDARD is not met as evidenced by: Based on surveyor observations and interview with facility personnel, the laboratory failed to establish and follow a function check protocol for 2 of 2 VanGuard V6500 centrifuges used to process patient specimens between 2015 and November 15, 2018. The findings included: 1. At 12:32 hours on 11/15/2018 in the laboratory, the surveyor observed two VanGuard V6500 centrifuges used to process patient specimens. The centrifuge on the left had a sticker on the right side with the following information: Date: 3/20/2015 RPM: 3340 RPM The VanGuard V6500 centrifuge on the right had a sticker on the right side with the following information: Date: 8/20 /2015 RPM: 3415 RPM 2. In an interview at 12:32 hours on 11/15/2018 in the laboratory, the surveyor requested documentation that the laboratory had established and followed function check protocols to verify the speed and time setting of the VanGuard V6500 centrifuges. The Technical Consultant stated the laboratory had not yet defined a protocol for verifying the function of the two centrifuges and the last verification of the performance had been performed on 3/20/2015 and 8/202/2015, respectively.