Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	45D2080114	09/13/2019
Name of Provider or Supplier	**Street Address, City, State**	
Women's Center Of Excellence Md Pa	4324 N Mccoll, Mcallen, 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.
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 surveyor's observation, review of manufacturer's instructions, and interview of facility personnel, it was revealed the laboratory failed to follow manufacturer instructions to monitor revised expiration dates for: A. Bio-Rad qUAntify Control B. Stanbio Uri-Chek 10SG Urinalysis Reagent Strips. The findings were: A) Bio-Rad qUAntify Control 1. Surveyor observation in the laboratory on 9/13/19 at 9:45 hours revealed one package with open vials Bio-Rad qUAntify Control Levels 1 and 2 (Lot#787890). Level 1 Lot #78791 exp 2020-01-25 Level 2 Lot #7892 exp 2020-01-25 Vials in use marked with open dates 06/06/19 2. A review of manufacturer's instructions stated " once opened, this product will be stable for 31 days when stored

	tightly capped at 2 to 25 C (Celsius) with the following exceptions: Ketones will be stable for 31 days at 2 to 8 C or 10 days at room temperature (18 to 25 C)". 3. The laboratory failed to follow the manufacturer's instructions to monitor revised expiration dates. 4. An interview with the technnical consultant on 09/13/2019 at 10: 05 hours in the conference room confirmed the findings. B) Stanbio Uri-Check Urinalysis Reagent Strips 1. Surveyor observation in the laboratory on 9/13/19 at 09: 45 hours revealed a bottle dated opened 9/12/19. 2. A review of manufacturer's instructions stated under [Storage and Stability] "Note: Once the bottle has been opened, the remaining strips are stable for up to 3 months. Stability may be reduced by high humidity conditions." 3. The laboratory failed to follow the manufacturer's instructions to monitor revised expiration dates. 4. An interview with the technnical consultant on 09/13/2019 at 10:05 hours in the conference room confirmed the findings. Key: C - Celsius
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 surveyor observations, review of manufacturer's instructions, and confirmed in interview of facility personnel, it was revealed the laboratory failed to follow the manufacturer's instructions for performing BD Affirm patient tests. The findings were: 1. Surveyor observation on 09/13/19 at 10:05 hours in the laboratory, revealed testing person #6 (as listed on Form CMS-209) perform two BD Affirm patient tests. While performing the tests, she held the dropper bottle vertically. 2. Review of the manufacturer's instructions for BD Affirm (670160JAA(03), 2017-08) under the section titled "Procedure" stated, "2. Uncap the sample collection tub (SCT), making sure the swab shaft is firmly seated in the cap. Add 12 drops or pipette 0.4ml of Lysis solution to the tube. Hold the dropper bottle vertically when adding drops." 3. Review of patient final reports revealed the results for the two tests performed were as follows: Patient 1 Date of Birth: 04/27/1985 collected 09:42 am Result: Candida species - not detected Gardnerella vaginalis - detected Trichomonas vaginalis - not detected Patient 2 Date of Birth: 01/12/1997 collected 09:49 am Result: Candida species - not detected Gardnerella vaginalis - detected Trichomonas - not detected 4. An interview with testing person #6 on 09/13/19 10:15 hours in the laboratory confirmed the findings. Key: BD- Becton Dickinson CMS- Centers for Medicare and Medicaid Services DOB - Date of Birth