Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number** 05D0911622	**(X3) Date Survey Completed** 10/07/2019
Name of Provider or Supplier Women's Health Center	**Street Address, City, State** 9940 Talbert Ave Ste 303, Fountain Valley, CA	
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**
D5203	SPECIMEN IDENTIFICATION AND INTEGRITY CFR(s): 493.1232 The laboratory must establish and follow written policies and procedures that ensure positive identification and optimum integrity of a patient's specimen from the time of collection or receipt of the specimen through completion of testing and reporting of results. This STANDARD is not met as evidenced by: Based on review of the laboratory's policies and procedures manual under, Individual Quality Control Plan IQCP "Risk Management", patients test reports (EMR) and interview with the laboratory personnel, it was determined that from 12/18/2017 to 06 /04/2019 for 1 out of 10 patients' test reports records reviewed, the laboratory failed to establish and follow written policies and procedures for proper recording of patient specimen information. The Findings included: a. Review of the "Affirm Patient Test Log" for Trichomonas vaginalis (T), Gardnerella vaginalis (G) and Candida vaginalis (C) testing performed on 04/03/2018 for patient MRN 11601421 showed that the patient's Trichomonas vaginalis result on the Afform patient test log did not match the patient's result found in the patient's electronic final report (EMR). Date PT ID Results* T G C 04/03/2018 116021421 (+) (-) (-) * (+) = Pos, (-) - Neg The laboratory's IQCP under "Rick Management line item 6." state: Patient results not documented in Epic a. Identification in Epic in Provider notes that testing done, but results not documented. b. Test results accurate. c. Results could be communicated verbally to Provider and treatment followed. Results could be looked up in Affirm log and added to Epic record. b. On 10/07/2019 11:30 AM (survey date), the laboratory personnel confirmed showed that the patient's Trichomonas vaginalis result on the Afform patient test log did not match the patient's result found in the patient's electronic final report (EMR). c. Based on the laboratory's annual test volume declaration (07/19/2019) the laboratory performed 131 (Parasitology) tests annually.