Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	05D0958017	06/19/2018
Name of Provider or Supplier	**Street Address, City, State**	
Gail Mallard Warren Md Inc	6107 N 1st St Ste 103, Fresno, 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
D5217	EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1) At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part. This STANDARD is not met as evidenced by: Based on review of the laboratory proficiency testing (PT) test result reports, and interview with the laboratory staff, it was determined that the laboratory failed to ensure the accuracy of the testing procedures it performed that are not included in the subpart I of 42 CFR part 493. The findings included as follows: a. The laboratory performed BD Affirm III to test for Candida sp. and Trichomonas vaginalis, which are listed in the subpart I of 42 CFR part 493. b. In order to verify the accuracy of the testing system, the laboratory elected to enroll its proficiency testing program with API (American Proficiency Institute) approved by CMS. c. The laboratory attained a score of 40% for Trichomonas vaginalis in the 1st 2017 PT event, which was unsatisfactory performance. d. The laboratory attained a score of 60% for Candida species in the 1st 2017 PT event, which was unsatisfactory performance. e. The laboratory performed Candida sp. and Trichomonas vaginalis each in approximately 80 patient samples monthly. f. The laboratory staff affirmed (6/19/18 @ 11:45 am) that the laboratory attained an overall testing event score of 60 and 40% % for Candida sp. and Trichomonas vaginalis, respectively, in the 1st 2017 PT event was unsatisfactory performance. g. The laboratory failed to ensure and verify the accuracy of the testing procedures at least twice annually.
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 the laboratory records, and interview with the laboratory staff, it was determined that the laboratory failed to monitor and document temperatures for proper storage of reagents and specimens and to provide accurate and reliable test system operation. The findings included as follows: a. Review of the laboratory temperature records, June 2018, under the columns for "Room Temp" and "Heater temp". b. The laboratory did not provide acceptable temperature range for "Room Temp" readings. c. The laboratory used analog (not digital) thermometers to monitor their temperature conditions. d. The temperature recorded were written with a decimal. One can not record accurate reading from a traditional thermometer (non digital). d. An analog (traditional) thermometer can not provide exact readings of temperatures with decimals. e. The laboratory staff affirmed (6/19/2018 @ 11:35 am) that traditional thermometers were used.
D5415	TEST SYSTEMS, EQUIPMENT, INSTRUMENTS, REAGENT CFR(s): 493.1252(c) Reagents, solutions, culture media, control materials, calibration materials, and other supplies, as appropriate, must be labeled to indicate the following: (1) Identity and when significant, titer, strength or concentration. (2) Storage requirements. (3) Preparation and expiration dates. (4) Other pertinent information required for proper use. This STANDARD is not met as evidenced by: Based on observation of the laboratory facility, and interview with the laboratory staff, it was determined that the laboratory failed to label and indicate the preparation and expiration dates for the reagents, solutions or supplies for proper use, which required to provide accurate patient testing results. The findings included as follows: a. The laboratory used BD Affirm III analyzer to test for Candida species, Gardnerella vaginalis, and Trichomonas vaginalis. b. The laboratory used Probetec ET CT/GC to test Chlamydia trachomatis and Neiseria gonorrhoeae. c. Observation of bottles of reagents, solutions used for these two testing mentioned above were noted laying around on the work bench. d. Most of the bottles were found without caps closed or lay down on the table around the instrument areas. e. The laboratory personnel affirmed (6/19/18 @ 11 45 am) that the laboratory did not label the containers to indicate when open or when to expire.
D6016	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(4)(i) Ensure that the proficiency testing samples are tested as

	required under Subpart H of this part; This STANDARD is not met as evidenced by: Based on review of the laboratory's proficiency testing (PT) test result reports, and interview with the laboratory staff, it was determined that the laboratory director failed to be for the overall operation, and proficiently and for assuring compliance with the applicable regulations and to ensure that the proficiency testing samples were tested as required. The findings included as follows; See D- 5217
D6021	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(5) The laboratory director is responsible for the overall operation and administration of the laboratory, including the employment of personnel who are competent to perform test procedures, and record and report test results promptly, accurate, and proficiently and for assuring compliance with the applicable regulations. (e) The laboratory director must-- (e)(5) Ensure that quality assessment programs are established and maintained to assure the quality of laboratory services provided. This STANDARD is not met as evidenced by: Based on review of the laboratory records, and observation of the laboratory facility, and interview with the laboratory staff, it was determined that the laboratory director failed to ensure that quality assessment programs were established and maintained to assure the quality of laboratory services provided. the findings included as follows: See D-5413 and D-5415