Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	03D0700237	05/15/2019
Name of Provider or Supplier	**Street Address, City, State**	
Desert West Obgyn	6678 W Thunderbird Rd, Glendale, AZ	

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
D5293	GENERAL LABORATORY SYSTEMS QUALITY ASSESSMENT CFR(s): 493.1239(b)(c) (b) The general laboratory systems quality assessment must include a review of the effectiveness of corrective actions taken to resolve problems, revision of policies and procedures necessary to prevent recurrence of problems, and discussion of general laboratory systems quality assessment reviews with appropriate staff. (c) The laboratory must document all general laboratory systems quality assessment activities. This STANDARD is not met as evidenced by: Based on review of the laboratory's Quality Assessment (QA) records and interview with the facility personnel, it was determined that the laboratory failed to document corrective actions taken to resolve problems associated with Proficiency Testing (PT). Findings include: 1. The laboratory performs patient testing on the BD Affirm analyzer in the specialty of Microbiology, with an approximate annual test volume of 2,207. 2. The laboratory participates in PT for the regulated analyte, Gardnerella vaginalis, and failed to receive a score for the 3rd event of 2017. 3. The laboratory participates in PT for the analytes, Candida sp. and Parasitology, as a means to verify accuracy for these two tests which are not included in Subpart I and failed to receive a score for the 3rd testing event of 2017. 4. The laboratory presented documentation of a remedial PT event that was performed in December 2017 for the analytes listed above. 5. No corrective action documentation was presented for review during the survey to indicate the laboratory identified and documented the fact that the PT agency failed to provide a score for the 3rd event of 2017. 6. The facility personnel confirmed that the laboratory failed to document corrective action for the missing PT scores indicated above.
D5775	COMPARISON OF TEST RESULTS CFR(s): 493.1281(a)(c)

	(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites. (c) The laboratory must document all test result comparison activities. This STANDARD is not met as evidenced by: Based on lack of test comparison results from 2018 and interview with the facility personnel, the laboratory failed to have a system in place that twice a year evaluates and defines the relationship between test results using two separate BD Affirm instruments. Findings include: 1. The laboratory utilizes two separate BD Affirm analyzers (instrument 1 and instrument 2) to perform Microbiology testing on patient specimens. The laboratory's approximate annual test volume in the specialty of Microbiology is 2,207. 2. No documentation was presented for review to indicate the laboratory had a system in place that twice a year evaluates and defines the relationship between the test results from each BD Affirm instrument. 3. The facility personnel confirmed that the laboratory did not have a system in place at the time of the survey to evaluate and document a comparison of test results between the two BD Affirm instruments.