

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0911622	(X3) Date Survey Completed 11/02/2021
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
D2020	<p>BACTERIOLOGY CFR(s): 493.823(a)</p> <p>Failure to attain an overall testing event score of at least 80 percent is unsatisfactory performance.</p> <p>This STANDARD is not met as evidenced by: Based on the surveyor's review of the laboratory's records for evaluation of proficiency testing performance from CMS, laboratory proficiency reporting from API, and an interview with the laboratory personnel (LP) on 11/2/2021 between 8:30 a.m. and 10:30 a.m., it was determined that there was one cycle of unacceptable proficiency testing (PT) results for Microbiology for cycle 3 in 2019. Findings include: 1. On 11/2/2021, an inspection was conducted between 8:30 a.m. and 10:30 am. 2 During a review of the laboratory documentation from API (agency providing the proficiency specimens), it was noted at approximately 9 a.m. that there were three unacceptable PT results for cycle 3 in 2019. The LP recognized these atypical results. 3. The findings were as follows: Microbiology Bacteriology: Garderella Vaginalis Result: 0 % Microbiology Mycology (Candida sp.) Result: 0 % Microbiology Parasitology (Trichomonas vag.) Result: 0 % 4. The LP affirmed the unacceptable results listed above.</p>
D6046	<p>TECHNICAL CONSULTANT RESPONSIBILITIES CFR(s): 493.1413(b)(8)</p> <p>(b) The technical consultant is responsible for-- (b)(8) Evaluating the competency of all testing personnel and assuring that the staff maintain their competency to perform test procedures and report test results promptly, accurately and proficiently.</p> <p>This STANDARD is not met as evidenced by:</p>

Based on the surveyor's review of the laboratory's records for evaluation of competency reporting and an interview with laboratory personnel (LP) on 11/2/2021 between 8:30 a.m and 10:30 a.m. , it was determined that the staff competency reports for one medical assistant (MA) were missing for 2020. Findings include: 1. On 11/2//2021, an inspection was conducted between 8:30 a.m. and 10:30 a.m. 2. During a review of the laboratory documentation for staff competency, the reports for one of the four medical assistants was missing. 3. The findings were discussed with the LP, and verified that the 2020 records were absent for one staff member