

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D1076583	(X3) Date Survey Completed 11/27/2019
Name of Provider or Supplier Gardens Medical Center Inc	Street Address, City, State 7218 Garfield Ave, Bell Gardens, 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 review of the laboratory proficiency testing (PT) result reports by American Association of Bioanalysts (AAB) PT provider, and interview with the laboratory testing personnel, it was determined that the laboratory failed to attain an overall testing even score of at least 80 percent was unsatisfactory performance. the findings include: a. The laboratory performed CT/GC (Chlamydia/Gonorrhoeae) using BD Probetec ET procedures. b. The laboratory enrolled the proficiency testing with AAB to ensure and verify the accuracy of the testing system annually to meet the CLIA requirements. c. The laboratory attained a score of 0 % in the 3rd 2018 AAB PT event, which was unsatisfactory performance. d. The laboratory performed CT/GC in approximately 80 patient samples monthly. e. The laboratory affirmed (11/27/2019 @ 11:45 am) that the laboratory attained a score of 0 % in the 3rd 2018 AAB PT event, which was unsatisfactory performance.</p>
D6016	<p>LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1407(e)(4)(i)</p> <p>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;</p>

This STANDARD is not met as evidenced by:
Based on review of the laboratory AAB PT test result reports, and interview with the laboratory testing personnel, it was determined that the laboratory director failed to ensure the proficiency testing samples were tested as required in the rules and regulations and to be compliance with CLIA. The findings included: a. The laboratory performed CT/GC using BD Probetek ET and enrolled its PT with AAB PT provider.
b. The laboratory attained a score of 0 % in the 3rd 2018 AAB PT event, see D-2020.