

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 05D0962012	(X3) Date Survey Completed 02/22/2018
Name of Provider or Supplier Eurofins Donor & Product Testing Llc	Street Address, City, State 1303 W Optical Dr Ste 380, Azusa, 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
D2066	<p>SYPHILIS SEROLOGY CFR(s): 493.835(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's proficiency testing (PT) result reports, and interview with the laboratory staff, five (5) randomly selected patients from 06/03 /2016 to 01/30/2018, test requisitions, control quality and final test reports, it was determined that the laboratory failed to attain an overall testing event scores of at least 80% (unsatisfactory performance). The findings included: a. The laboratory performs rapid plasma reagin (RPR) and fluorescent treponemal antibody absorption (FTA-ABS) testing and enrollment in the College of American Pathologists (CAP) proficiency testing (PT) program to ensure the accuracy of the analyte or testing procedure the laboratory performed with College of American Pathologists (CAP) PT provider. b. The laboratory attained a score of 80% for RPR serology using ASI and a score of 60% for FTA-ABS using SCIMEDX methodology in the 1st event 2016 PT event, which were unsatisfactory performances. c. The laboratory annual testing declaration (02/19/2018) estimated the patient RPR and FTA-ABS serology testing as approximately 6174. d. The laboratory staff affirmed the unsatisfactory performances on 02/22/2018 (survey date) and that the laboratory attained an overall PT testing event score of 80 % for RPR serology and 60% for FTA-ABS in the 1st PT event of 2016.</p>