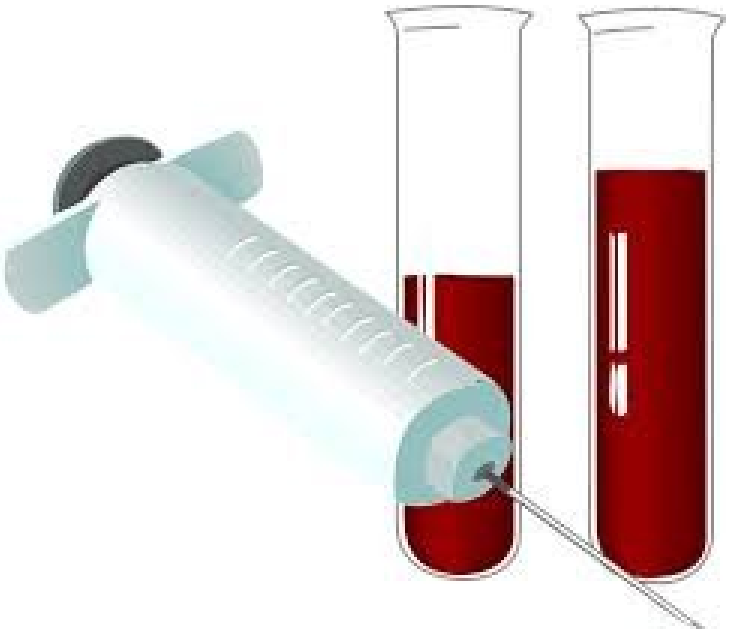
BioSpectrum
the business of Bio & Health Sciences
ASIA EDITION

QIAGEN's QuantiFERON-TB Gold Plus gains U.S. FDA approval

June 14, 2017 | News

Fourth generation Latent TB blood test combines breakthrough CD4/CD8 design for comprehensive immune response detection with the most flexible blood collection workflow



Singapore - QIAGEN N.V., Netherlands-based holding company announced the U.S. regulatory approval of QuantiFERON-TB Gold Plus, the fourth generation of the market leading blood test for detecting latent tuberculosis (TB) infection.

The approval by the U.S. Food and Drug Administration (FDA) comes after QIAGEN submitted the test in a pre-market approval (PMA) supplement in late 2016, and the U.S. commercialization of the fourth-generation test is planned to begin later this year.

"We are pleased by the timely FDA approval for QuantiFERON-TB Gold Plus and that we can now bring a range of very attractive clinical and workflow benefits to customers who have helped us to create the market-leading latent TB testing franchise. Tuberculosis is a global disease that is having an impact in the United States as well, where up to 13 million people are infected and nearly 10,000 people are currently suffering with active disease," said Thierry Bernard, Senior Vice President and head of QIAGEN's Molecular Diagnostics Business Area.

The U.S. approval follows the 2016 launch and successful uptake of QFT-Plus in more than 75 countries across Europe, the Middle East, Africa, Asia and Latin America, where nearly two million of the new tests have already been used.