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QIAGEN K.K.

# QuantiFERON®-TB Gold Plus ELISA gains approval of the MHLW, Japan

QIAGEN's QuantiFERON®-TB Gold Plus (QFT®-Plus) ELISA gains approval as an In Vitro Diagnostic of the Ministry of Health Labor and Welfare (the MHLW) of Japanese Government on February 5. 2018 and its approval No is 23000EZX00004000.

The QFT-Plus ELISA is used with QFT-Plus Blood Collection Tubes (Certification No. 229AFBZX004000).

QFT-Plus is the fourth generation of QuantiFERON TB kit to detect TB infection, and combines CD4/CD8 design for comprehensive immune response detection with the most flexible blood collection workflow.

The Japan approval follows the 2017 approval in the US 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.

Workflow flexibility that allows for even more efficient implementation, especially in large-scale TB screening programs. These include a standard single-tube blood collection option which allows blood samples to be processed up to 48 hours after venipuncture without affecting the accuracy of the test.

In 2016, WHO estimates, there were 10.4 million new cases of active TB worldwide and 1.8 million deaths from TB. In latent tuberculosis infection (LTBI), the bacterium infects a person but produces no symptoms unless it progresses to the active disease. Screening of high-risk individuals and treatment for LTBI play an important role in tuberculosis control efforts in the Japan , U.S. and many European countries, as well as in other developed and emerging markets around the world. In 2015 Japanese government set the goal that TB incidents rate should be reduced to 10.0 per 100,000 by 2020 in Japan. QFT-Plus is expected to contribute to achievement of the goal as well as TB control in Japan.

For further details of new product launch will be informed later.

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