



bioMérieux announces the CE marking of TB IGRA[®] test on VIDAS[®]

Marcy l'Etoile, France – March 24th, 2021 – Today marks *World Tuberculosis (TB) Day* and bioMérieux, a world leader in the field of *in vitro* diagnostics, announces the CE marking of its innovative and fully-automated test VIDAS[®] TB IGRA (Interferon-Gamma Release Assay) to diagnose latent TB infection.

Tuberculosis continues to be a major global health problem. With 10 million new active cases and 1.4 million related deaths worldwide in 2019¹, TB remains an important cause of mortality from a single infectious disease.

It is estimated that a fourth of the global population is infected with *Mycobacterium tuberculosis*, the bacteria responsible for TB disease. In most cases (90-95%), people with healthy immune systems can control the infection without developing the active disease: this is called “Latent Tuberculosis Infection” (LTBI). The remaining infected people (5-10%), will develop active TB disease (aTB), making them sick as well as infectious to others.

“Despite all efforts, tuberculosis has not been eradicated and remains a significant health problem for a large proportion of the world’s population, especially in low- and middle-income countries. Diagnosing people who have latent TB infection is an important tool for global TB control. Detecting and then following or treating people with latent TB infection can help in preventing their progression to active disease, which would make them sick and also infectious to others.” said Mark Miller, Executive Vice President and Chief Medical Officer, bioMérieux.

There is no single gold standard for diagnosing LTBI. Current diagnostic tools for LTBI include a detailed clinical history of exposure to TB, the tuberculin skin test (TST) or an IGRA test, which are indirect diagnostic methods based on the host immune response to the pathogen².

Despite their improved performances over TST, current IGRA tests are cumbersome, consist of many manual steps, and can negatively impact the lab workflow. There is a need for improved TB-IGRA tests having complete automation, standardization of each step, faster time to results, more accurate and reliable clinical performances and increased ease-of-use for any lab without specialized expertise.

VIDAS[®] TB-IGRA is the new fully automated assay intended as an aid in the diagnosis of infection with *Mycobacterium tuberculosis*.

Performed on the VIDAS[®] 3 platform, VIDAS[®] TB-IGRA provides reliable test results and improves current workflow compared to existing TB-IGRA solutions.

The complete test process is fully automated from sample to result interpretation, including the stimulation step. Only one whole blood sample tube is needed with no manual sample preparation. Thanks to this simplified “load & start” process, laboratories will now be able to easily manage TB-IGRA testing in-house and deliver faster results to clinicians without additional cost.

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In addition to full automation, VIDAS® TB-IGRA demonstrated strong clinical performances³. Clinical trials conducted on populations coming from different areas around the world demonstrated a better sensitivity in an active TB population compared to an existing test (97% vs 80,6%*), a high specificity of 97.5% in populations at very low risk of being TB infected ** and a strong agreement with the comparative assay* on populations at mixed risk levels of TB infection. Furthermore, significantly fewer indeterminate results (0,1% vs 1,3%*) were observed.

“For more than 55 years, bioMérieux has been driven by a pioneering spirit and unrelenting commitment to improve public health worldwide. It is a great achievement for us to provide laboratories with a fully automated assay with high performances to detect latent tuberculosis. As we commemorate World Tuberculosis Day today, the launch of VIDAS® TB-IGRA reaffirms our commitment to help end tuberculosis by detecting infected individuals” declared Alexandre Mérieux, Chief Executive Officer, bioMérieux.

VIDAS® TB-IGRA will be gradually deployed in countries that recognize CE marking. Hospitals and private laboratories will be able to run the test on bioMérieux’s VIDAS® 3 system, which allows for higher automation and traceability. bioMérieux is planning a submission for FDA clearance in the near future.

*Comparative assay used during clinical trials is a CE-marked and FDA-cleared TB-IGRA test

** Specificity assessed in healthy blood donors from a country with low TB prevalence

ABOUT VIDAS®

Launched 30 years ago, VIDAS® has transformed the field of immunoassays offering laboratories universal access to a simple, automated and robust technology providing fast and reliable results. Today, VIDAS® is still the most widely used immunoassay system in clinical laboratories worldwide.

The VIDAS® menu covers a wide range of pathologies, including infectious diseases and a range of tests dedicated to emergency and critical care. A number of these parameters are part of the bioMérieux full solution to address the global challenges of antimicrobial resistance (AMR) and sepsis. As it enters into its fourth decade, VIDAS® remains a major focus of the bioMérieux immunoassay strategy with ongoing research into new parameters and frequent launches that create value for labs and clinicians, for the benefits of the patients.

ABOUT BIOMÉRIEUX

Pioneering Diagnostics

A world leader in the field of *in vitro* diagnostics for over 55 years, bioMérieux is present in 44 countries and serves more than 160 countries with the support of a large network of distributors. In 2020, revenues reached €3.1 billion, with over 90% of international sales.

bioMérieux provides diagnostic solutions (systems, reagents, software and services) which determine the source of disease and contamination to improve patient health and ensure consumer safety. Its products are mainly used for diagnosing infectious diseases. They are also used for detecting microorganisms in agri-food, pharmaceutical and cosmetic products.



bioMérieux is listed on the Euronext Paris stock market.
Symbol: BIM – ISIN Code: FR0013280286
Reuters: BIOX.PA/Bloomberg: BIM.FP



Corporate website: www.biomerieux.com.

REFERENCES

1. World Health Organization. Tuberculosis [fact sheet]. Published on October 14, 2020. <https://www.who.int/news-room/fact-sheets/detail/tuberculosis>.
2. World Health Organization. Latent tuberculosis infection (LTBI) - FAQs. Published in 2015. <https://www.who.int/tb/areas-of-work/preventive-care/ltbi/faqs/en/>
3. VIDAS® TB-IGRA Package insert 053331

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