

## **LyoDx announces MHRA registration of TB-SIX for the GB market**

**LONDON, UNITED KINGDOM - MONDAY 18<sup>TH</sup> MAY 2026** - LyoDx announced that TB-SIX, its host-response molecular assay for tuberculosis, has been successfully registered with the Medicines and Healthcare products Regulatory Agency (MHRA) for placement on the Great Britain (GB) market.

This registration marks a significant regulatory milestone, reflecting LyoDx's self-declaration of conformity with the applicable safety and performance requirements under the UK medical device regulatory framework and is eligible for use within the GB market.

TB-SIX is intended for use as:

- an aid in the diagnosis of active tuberculosis (TB) disease; and
- an aid in monitoring the effectiveness of anti-tuberculosis treatment in individuals with confirmed active TB.

Tuberculosis (TB) remains a persistent global public health challenge, with an ongoing need for diagnostic tools that can support timely clinical decision-making and treatment management. TB-SIX helps clinicians identify active TB and track how well treatment is working, in a single, streamlined test and without the need for sputum sampling or cold-chain transport. It works by measuring the relative expression of six mRNA transcripts in whole blood using a multiplexed qPCR approach. Based on the validated RISK6 signature, TB-SIX offers a faster, higher-throughput workflow to support both diagnostic and treatment-monitoring pathways.

“MHRA registration represents an important regulatory milestone for TB-SIX and for LyoDx,” said Jennie Orton, Chief Commercialisation Officer at LyoDx. “This achievement demonstrates our commitment to address the gaps that exist in current TB diagnostics, launching new, robust assays to assist those working hard to eliminate TB by providing additional diagnostic information not currently available without the use of sputum samples.”

The MHRA registration follows the completion of comprehensive technical documentation, including analytical and clinical evaluation activities, risk management and quality system alignment in accordance with UK requirements.

LyoDx plans to progress TB-SIX into evaluation settings in the UK and internationally, while continuing to work towards global regulatory submissions to address tuberculosis and broader global health priorities.

**FOR IMMEDIATE RELEASE**



LyoDx welcomes enquiries from clinicians, researchers and partners interested in TB-SIX.

**About LyoDx**

LyoDx is a UK-based diagnostics company developing lyophilised molecular assays designed to simplify workflows and support clinical and research decision-making, with a focus on tuberculosis.

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