

## **IGRA Product Profile**



## RIDASCREEN® TB

Manufacturer:	R-Biopharm AG, Darmstadt, Germany
Type of IGRA:	ELISA-based utilizing IP-10 detection
Approval status:	EU IVDR (Class C) Note: Authorization for use by one of the Regulatory Authorities of the Founding Members of the Global Harmonization Task Force, i.e., the regulatory authorities of the USA, the European Union, Japan, Canada and Australia, when stringently assessed (as Class C or D), meets the eligibility criteria for procurement using Global Fund resources
Global access pricing:	Cost of reagents per patient tested: \$12.99 Available through PFSCM (prices as of August 2025 and subject to change)
Type of laboratory required:	Centralized laboratory
Required equipment:	<ul> <li>37°C ± 1°C incubator</li> <li>Centrifuge for harvesting plasma</li> <li>Calibrated pipettes</li> <li>Microplate shaker</li> <li>Microplate washer (automated washer recommended)</li> <li>Microplate reader fitted with 450 nm filter</li> </ul>
Blood collection tubes:	Proprietary: Negative control, TB-specific (ESAT-6 and CFP-10 antigens), Positive control
Stimulating antigens:	ESAT-6, CFP-10 The biomarker detected is interferon-gamma induced protein 10 (IP-10), which is secreted in concentrations up to 100 times higher than interferon-gamma
Total processing time:	Antigen stimulation: 16-24 hours ELISA processing: 2 hours Total turnaround time: ~18-26 hours from blood collection to results
Manufacturer website and contact information:	https://clinical.r-biopharm.com/diagnostics/tuberculosis/ tb-diagnostics@r-biopharm.de

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## **Product images:**



RIDASCREEN® TB ELISA plate



RIDA® TB Tubes

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