

IGRA Product Profile



IGRA-TB

Manufacturer:	Boditech Med Inc., Chuncheon, Republic of Korea
Type of IGRA:	Lateral flow fluorescence immunoassay (FIA) utilizing proprietary instrument
Approval status:	EU IVDR (Class C) <i>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</i>
Global access pricing:	Not yet established
Type of laboratory required:	Decentralized or centralized laboratory, depending on instrument model selected
Required equipment:	• 37°C ± 1°C incubator • Centrifuge for harvesting plasma • Basic pipetting equipment • Proprietary instrument for readout and result interpretation: - ichroma™ II: portable, battery-powered - ichroma™ III: semi-automated with panel testing - ichroma™ 50 PLUS: high throughput - AFIAS-3, AFIAS-6, AFIAS-10 for panel testing
Blood collection tubes:	Proprietary: Negative control, TB-specific (ESAT-6 and CFP-10 antigens), Positive control
Stimulating antigens:	ESAT-6, CFP-10
Total processing time:	Antigen stimulation: 16-24 hours Lateral flow test: 15 minutes for results
Manufacturer website and contact information:	www.boditech.co.kr/en/product/reagents/id/342 khs3@boditech.co.kr

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Product images:



ichroma™ II analyzer



ichroma™ III analyzer



ichroma™-50 PLUS analyzer

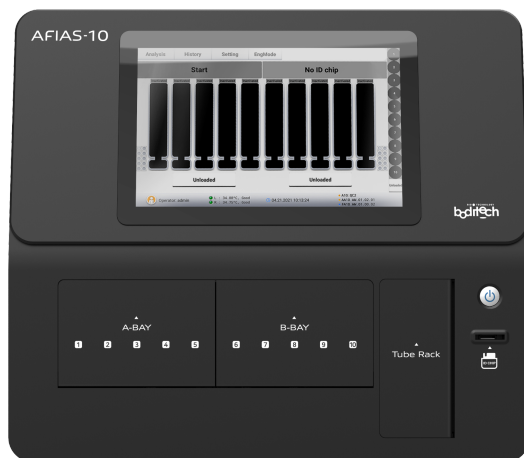
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AFIAS-3 analyzer



AFIAS-6 analyzer



AFIAS-10 analyzer

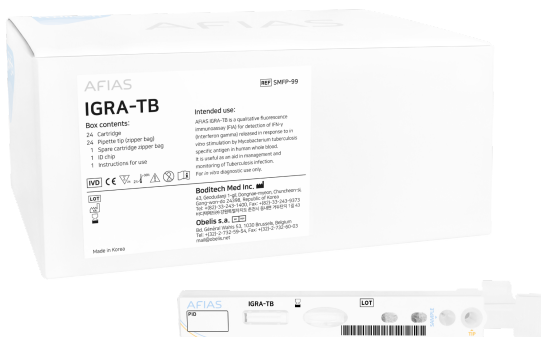
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ichroma™ IGRA-TB Tubes (compatible with both ichroma™ and AFIAS cartridges)



ichroma™ IGRA-TB 25



AFIAS IGRA-TB