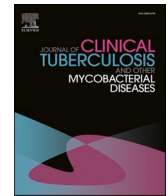Contents lists available at ScienceDirect

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Asia emerges as a hotbed of diagnostic innovations for tuberculosis

The diagnostic technology landscape for tuberculosis (TB) has never been more varied. Eight products or classes of technologies are recommended by the World Health Organization (WHO) [1], a further eighteen products are under evaluation by the WHO [2] and dozens more are on the market—a recent landscape analysis found 20 tests for TB infection alone [3].

However, actual use and procurement remains concentrated to a handful of tests. Further, the list of WHO-endorsed products is dominated by companies from Europe and North America. Many of these technologies remain expensive, despite advocacy campaigns for price reductions [4], or not ideal for low-resource settings, meaning there have been problems scaling up their use in low- and middle-income countries (LMICs) where the TB burden is highest [5–8].

In general, the field of global health has a problem—an excessive reliance on product and innovations being developed in the Global North that then slowly trickle down to the Global South, where the biggest needs are, and where technologies often have the greatest impact [9]. However, there is capacity in other parts of the world to develop and commercialize diagnostics technologies that should be part of the solution to address global health challenges. This issue has received a lot of attention during the ongoing Covid-19 pandemic, with calls to expand vaccine manufacturing to Africa and other regions, along with TRIPS waiver and technology transfer.

In 2019, Indian company Molbio Diagnostics became the first company from an LMIC to receive WHO approval for its TB diagnostic technology [10]. Along with Eiken and Nipro from Japan, it is the only Asian company with a WHO-recommended molecular TB diagnostic. All these products are available for countries to procure via the Global Drug Facility (GDF) [11], housed at the Stop TB Partnership. By contrast, the WHO's emergency use listing for SARS-CoV-2 in-vitro diagnostics (IVDs) includes several companies from Asia, particularly China, showing that the capacity for diagnostic innovation and manufacturing on the continent is strong [12].

In fact, Asia is also a hotbed of innovation for TB diagnostics, with products on the market which span the complete spectrum of TB diagnosis, from laboratory-based molecular diagnostics to artificial intelligence (AI) for chest x-ray (CXR) interpretation. In 2021, analysis of the results of studies of Qure.ai from India and Lunit from South Korea contributed to the WHO's recommendation for computer-aided detection (CAD) of CXRs [13]. As seen in the current pandemic, having a broad global manufacturing base for diagnostic technologies is highly advantageous.

We recently conducted a landscape analysis of the diagnostic technologies for TB produced by companies in four Asian countries—China, India, South Korea, and Japan. Diagnostic technologies were identified

through a review of the literature, internet searches and contacts in Asian countries. Where possible, specific contacts within each company were identified, with help from contacts who spoke Chinese and Korean, and emailed questions in English concerning product technical details and national and international regulatory approval. Where specific contacts were unavailable, companies were contacted using generic email addresses or through contact forms on their websites. Data on companies which could not be contacted were compiled using information in the public domain. Data were collected on company and product names, diagnostic method, use case and regulatory approval. Product variants which identify different combinations of drug resistance and are marketed separately were classified as distinct products. Product use cases are as described by the companies.

In total, 82 TB diagnostic products were identified from 39 companies [Appendix]. Twelve companies are based in China, seven in India, five in Japan and fifteen in South Korea. Fig. 1 displays company names and diagnostic categories. Most identified products were molecular diagnostics, with a wide range of diagnostic methods and drug resistance detection options available. Diagnostics currently endorsed by the WHO include three chip-based real-time PCR assays by Molbio (Truenat MTB, MTB Plus and MTB-RIF Dx), two line-probe assays (LPAs) by Nipro for detection of resistance to rifampicin and isoniazid (Genoscholar NTM + MDRTB II) and pyrazinamide (Genoscholar PZA-TB II), a loop-mediated isothermal amplification (LAMP) assay by Eiken (Loop-amp MTBC Detection Kit), a rapid species identification test from culture by Tauns Laboratories (Capilia TB-Neo) and CAD technologies such as Qure.ai (qXR v2) and Lunit (Lunit Insight CXR).

A number of Asian companies make diagnostics for multidrug-resistant (MDR) and extensively drug-resistant (XDR) TB. Xiamen Zeesan Biotech makes the MeltPro real-time PCR assays which are approved by the Chinese regulator and can detect resistance to rifampicin, streptomycin, isoniazid, ethambutol, fluroquinolones and second-line injectables. Bioneer makes the Accupower real-time PCR assays, including for MDR and XDR TB; both Optipharm (OPTIMYGENE) and YD diagnostics (MolecuTech) make reverse blot hybridization assays for MDR and XDR TB; and Seegene makes the AllPlex and Anyplex II PCR-based assays for MDR and XDR TB. Other diagnostic methods include isothermal target and probe amplification (RapiDx MTB test by Raplegene), transcription-reverse transcription concerted reaction (TRCRapid-160 M.TB by Tosoh Bioscience), isothermal amplification lateral flow (EasyNAT Diagnostic Kit by Ustar Technologies), simultaneous amplification and testing (SAT-TB by Rendu Biotechnology) and DNA microarray assays (CapitalBio *M. Tuberculosis* Drug Resistance Detection Array Kit).

Interferon-gamma release assays (IGRAs) are made by seven
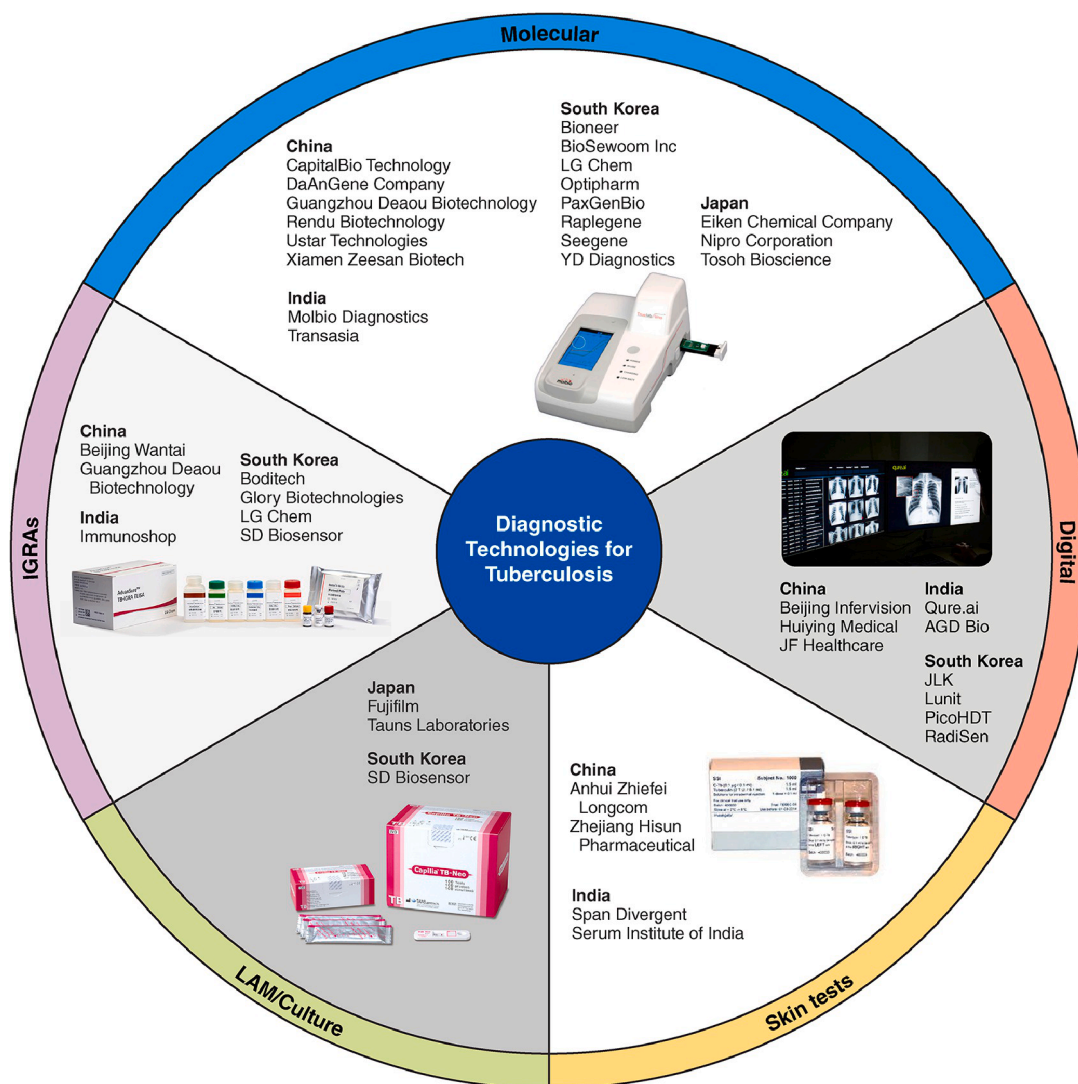
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Fig. 1. TB diagnostic products were identified from 39 companies in Asia.

companies (Beijing Wantai, Guangzhou Deauou, Immunoshop, Boditech, Glory Biotechnologies, LG Chem and SD Biosensor). The Beijing Wantai and SD Biosensor IGRAs are approved for procurement by the Global Fund's Expert Review Panel for Diagnostics [14]. Four companies manufacture skin tests (Anhui Zhifei Longcom, Zhejiang Hisum Pharmaceutical, Span Divergent and Serum Institute of India). Two make culture-based diagnostics for rapid species identification (Tauns Laboratories and SD Biosensor), with the Tauns Laboratories test recommended by the WHO. Fujifilm makes a urine lipoarabinomannan assay identifying *M. tb* in people who are HIV positive.

Seven companies make AI-based technologies for reading CXRs (Beijing Infervision Technology, Huiying Medical Technology, JF Healthcare, Qure.ai, JLK, Lunit and Radisen) and PicoHDT makes both wireless and wired versions of the Mine-2 portable x-ray machine, which incorporates diagnostic AI technology. AGD Bio makes the Mycovision smart microscope which uses AI to detect acid-fast bacilli under Ziehl-Neelsen stained slides.

Given the wide array of promising products identified, it is surprising that only a few Asian technologies are included in the WHO-recommended product list. To enter the global health market, technologies have needed to undergo independent, international evaluation studies for policy review and WHO endorsement. Such policy review has not happened with most Asian TB technologies. CE-IVD marking is currently not sufficient to meet these quality assurance criteria. Also, to

be internationally competitive, companies must have the ability to provide service and maintenance at the global level.

The process for WHO endorsement of TB IVDs is currently changing. The WHO Global Tuberculosis Programme will now focus on the evaluation of classes of TB diagnostic technologies for WHO recommendation, while WHO prequalification will evaluate specific product brands for quality, safety and performance [15]. Companies may also need to meet quality assurance criteria of major donors and procurers such as the Global Fund [16]. An additional recent opportunity for manufacturers of TB diagnostics to get their products into the global marketplace is via the Global Fund's Expert Review Panel for Diagnostics, the approval of which allows for countries to use Global Fund support (the largest international funding source for TB) to procure products that are on the pathway to becoming WHO-approved.

We hope more Asian companies can learn from the experience of innovators such as Eiken, Nipro, Molbio, Tauns, Qure.ai and Lunit, and find ways to validate promising technologies further and have them considered for international policy guidance [17]. For WHO endorsement, the current requirements are clearly defined [18] and involve demonstrating analytical and clinical validity, clinical and epidemiologic utility, economic outcomes and operational and qualitative aspects. The expectations for validation data and study design considerations for evaluating different types of TB tests are also published [18–22], along with target product profiles [23,24]. Partnerships

with international organizations such as the Foundation for Innovative New Diagnostics (FIND), and initiatives such as the Stop TB Partnership's Accelerator for Impact (a4i) [25] and the recently launched NIH-funded FEND-TB [26] and R2D2 TB Network [27] initiatives, might help Asian innovators better navigate the global policy process.

Beyond validation and inclusion in global policy, there is a need to also address other barriers to product uptake and scale, including pricing that is suitable for LMICs, capacity for service and maintenance, donor support for scale-up, and better guidance on when or how to switch from one product to another.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix

Molecular diagnostics

Company	Product	Diagnostic method	Use	Regulatory approval
China				
CapitalBio	CapitalBio *Mycobacteria* Species Identification Array Kit	DNA microarray assay	Identifies *M. tb* complex and 16 other Mycobacterial species in sputum	CE marking
	CapitalBio *M. Tuberculosis* Drug Resistance Detection Array Kit		Identifies *M. tb* complex Detects resistance to rifampicin and isoniazid	CE marking
DaAN GeneCompany	Mycobacterium Tuberculosis (TB) PCR Kit	PCR	Identifies *M. tb* complex in sputum and bronchoalveolar lavage fluid specimens	No information
Rendu Biotechnology	SAT-TB	Simultaneous amplification and testing	Identifies *M. tb*	No information
Guangzhou Deaou Biotechnology	DeFast.TB Mycobacterium Tuberculosis Complex (MTC) Nucleic Acid Detection Solution	No information	Identifies *M. tb* in bronchoalveolar lavage fluid, pleural effusion, abdominal effusion, cerebrospinal fluid, joint effusion, urine and other specimen types.	NMDA (China) approved
	DeFine.TB Mycobacterium Tuberculosis Specific Cellular Immunoreaction Detection Kit	Double-antibody sandwich ELISA	No information	No information
Ustar Technologies	EasyNAT Diagnostic Kit for Mycobacterium Tuberculosis (TB) DNA	Isothermal Amplification Lateral Flow	Identifies *M. tb* complex	CE marked
	EasyNAT Diagnostic Kit for Mycobacterium Tuberculosis Complex DNA	Isothermal Amplification Real Time Florescence Assay	Identifies *M. tb* complex in sputum	CE marked
Xiamen Zeesan Biotech	MeltPro *Mycobacterium Tuberculosis* test kit	Real-time PCR	Identifies *M. tb* complex	NMDA (China) approved
	MeltPro *Mycobacteria* identification kit		Identifies 19 common *Mycobacterial* species	CE marked
	MeltPro MTB/RIF; MTB/STR; MTB/INH; MTB/EMB; MTB/FQ; MTB/SL		Detects resistance to rifampicin; streptomycin; isoniazid; ethambutol; fluoroquinolones; second-line injectables	All NMDA (China) approved, except MTB/SL. All CE marked
India				
Molbio	Truenat MTB	Chip-based Real-time PCR	Quantitative detection of *M.tb* in human pulmonary and EPTB specimens	WHO endorsed CDSCO (India) approved CE marked
	Truenat MTB Plus		Semiquantitative detection of M.tb in human pulmonary and EPTB specimens	WHO endorsed CDSCO (India) approved CE marked
	Truenat MTB-RIF Dx		Detects resistance to rifampicin. "Follow on test, to be performed only on the extracted DNA from Truenat MTB/MTB Plus positive sample"	WHO endorsed CDSCO (India) approved CE marked
Transasia/Erba Molecular	MX16	No information	No information	No information
Japan				
Eiken Chemical Company	Loopamp MTBC Detection Kit	Loop-mediated isothermal amplification (LAMP)	Identifies *M. tb* extracted from sputum	WHO endorsed CE marked
Nipro Corporation	Genoscholar PZA TB II	Line probe assay	Identifies *M. tb* complex in sputum Detects resistance to pyrazinamide	CE marked
	Genoscholar NTM + MDRTB II		Identifies *M. tb complex, M. avium, M. intracellulare and M. kansasii* Detects resistance to rifampicin and isoniazid in *M. tb*	WHO endorsed CE marked
	Genoscholar FQ + KM-TB II		Detects resistance to fluoroquinolones and kanamycin in *M. tb* **For research use only**	CE marked
Tosoh Bioscience	TRCRapid-160 M.TB	Transcription-reverse transcription concerted reaction	Detection of *M.tb* complex in a clinical specimen or suspension of cultured cells	No information
	TRCReady-80 M.TB		Detection of *M.tb* complex in a clinical specimen or suspension of cultured cells	No information
South Korea				
Bioneer	Accupower MTB	Real-time PCR	Identifies *M. tb* in sputum, bronchoalveolar lavage and urine	No information
	Accupower MTB & NTM		Identifies *M. tb* and non-tuberculous mycobacteria	No information

(*continued*)

Company	Product	Diagnostic method	Use	Regulatory approval
	Accupower TB & MDR		Identifies *M. tb*; detects resistance to rifampicin and isoniazid	No information
	Accupower XDR-TB		Identifies *M. tb*; detects resistance to fluoroquinolones, aminoglycosides, ethambutol and streptomycin	No information
Biosewoom	Real-Q M. tuberculosis kit	Line probe assay	Identifies *M. tb* and non-tuberculous mycobacteria	No information
LG Chem	AdvanSure TB/NTM assay	Real-time PCR	Identifies *M. tb* and non-tuberculous mycobacteria in sputum, bronchial washing fluid, cerebrospinal fluid, urine, body fluid, EDTA-whole blood and tissues	No information
	AdvanSure MDR-TB GenoBlot assay	Reverse blot hybridization assay	Detects resistance to rifampicin and isoniazid in *M. tb*	No information
Optipharm	OPTIMYGENE Real TB – Tag Kit	Real-time quantitative PCR	Identifies *M. tb*	No information
	OPTIMYGENE Real MTB – ID Kit		Identifies *M. tb* and non-tuberculous mycobacteria	No information
	OPTIMYGENE Inf – TB Kit	No information	Differentiation of active TB and latent TB infection by measuring interferon-gamma expression by RT-qPCR	No information
	OPTIMYGENE REBA MTB – MDR Kit	Reverse blot hybridization assay	Detects rifampin and isoniazid resistance	No information
	OPTIMYGENE REBA MTB – XDR Kit		Detects fluoroquinolone, kanamycin and streptomycin resistance	No information
	QMAP Dual-ID (Disk-based PCR)	Disk-based PCR	Identifies *M. tb* and NTM; detects rifampin resistance	No information
PaxGenBio	PaxView TB/NTM MPCR-UFLA kit	Multiplex PCR and universal lateral flow assay	Identifies *M. tb* and NTM in sputum or brochoalveolar lavage	CE marked South Korean FDA approved
Raplegene	RapiDx MTB test	Isothermal target and probe amplification	Identifies *M. tb*	No information
Seegene	AllPlex MTB/MDRe; MTB/MDR/XDRe; MTB/XDRe	PCR	Identifies *M. tb* and detects resistance to rifampicin and isoniazid; rifampicin and isoniazid, fluoroquinolones and injectable drugs; fluoroquinolones and injectable drugs	All CE marked
	Anyplex II MTB/MDR; MTB/MDR/XDR; MTB/XDR; MTB/NTM		Identifies *M. tb* and detects resistance to rifampicin and isoniazid; rifampicin and isoniazid, fluoroquinolones and injectable drugs; fluoroquinolones and injectable drugs; Identifies *M. tb* and NTB and detects resistance to rifampicin and isoniazid	All CE marked
YD (Youngdong) Diagnostics	MolecuTech TB-Tag Two	PCR	Identification of *M. tb*	No information
	MolecuTech MTB-ID V3		Identification of *M. tb* and non-tuberculous mycobacteria	No information
	MolecuTech Real TB-Tag	Real-time PCR	Identification of *M. tb*	No information
	MolecuTech Real MTB-ID		Identification of *M. tb* and non-tuberculous mycobacteria	No information
	MolecuTech REBA Myco-ID	Reverse blot hybridization assay	Identification of *M. tb* and non-tuberculous mycobacteria	No information
	MolecuTech REBA MTB-MDR		Detection of resistance to rifampin and isoniazid	No information
	MolecuTech REBA MTB-XDR		Detection of resistance to fluoroquinolones, kanamycin and streptomycin	No information

Lipoarabinomannan (LAM) assays

Company	Product	Diagnostic method	Use	Regulatory approval
Japan				
Fujifilm	SILVAMP TB LAM (FujiLAM)	Urine lipoarabinomannan assay	Identifies *M.tb* in urine of people who are HIV positive	No information

Rapid species identification of *M. tuberculosis* from culture

Company	Product	Diagnostic method	Use	Regulatory approval
Japan				
Tauns Laboratories	Capilia TB-Neo	Immuno-chromatographic assay detecting MPB64 antigen	Identifies *M. tb* complex isolates from solid and liquid cultures	WHO endorsed CE marked
South Korea				
SD Biosensor	STANDARD Q TB MPT64 Ag	Immuno-chromatographic assay detecting MPT64 antigen	Identifies *M. tb* in solid or liquid culture	No information

Interferon-gamma release assays (IGRAs)

Company	Product	Diagnostic method	Use	Regulatory approval
China				
Beijing Wantai	TB-IGRA	IGRA ELISA	Identifies *M. tb* infection in whole blood	GF ERPD recommended CE marked
Guangzhou Deaou Biotechnology	SPOTestTM Mycobacterium Tuberculosis Specific Cellular Immunoreaction Detection Kit	IGRA ELISPOT	Identifies *M. tb* infection	No information
India				
Immunoshop	TB Platinum	IGRA	Identifies *M. tb* infection in whole blood	No information
South Korea				
Boditech Inc	Ichroma IGRA-TB	ESAT-6 and CFP-10 IGRA lateral flow assay	Diagnosis of infection with *M. tb* in whole blood	CE marked
Glory Biotechnologies Group	GBTsol Latent TB Test Kit	ESAT-6 and CFP-10 IGRA	Identifies *M. tb* infection	No information
LG Chem	Advansure I3 TB-IGRA	ESAT-6 and CFP-10 chemo-luminescence IGRA	Diagnosis of *M.tb* infection in whole blood	No information
	Advansure TB IGRA	ESAT-6 and CFP-10 IGRA ELISA	Diagnosis of *M.tb* infection in whole blood	CE marked
SD Biosensor	STANDARD E TB-Feron ELISA	ESAT-6, CFP-10 and TB7.7 IGRA ELISA	Diagnosis of infection with *M. tb* in whole blood	GF ERPD recommended CE marked
	STANDARD F TB-Feron FIA (IFN-gamma)	ESAT-6, CFP-10 and TB7.7 IGRA lateral flow assay	Diagnosis of infection with *M. tb*	CE marked

Further details on tests for tuberculosis infection are available in Hamada Y, Cirillo DM, Matteelli A, et al. Tests for tuberculosis infection: landscape analysis. Eur Respir J 2021; *in press* (https://doi.org/10.1183/13993003.00167–2021).

Skin tests

Company	Product	Diagnostic method	Use	Regulatory approval
China				
Anhui Zhifei Longcom Biopharmaceutical Co., Ltd	EC-Test	ESAT6 and CFP10 skin test	Identifies *M. tb* infection	NMPA (China) approved
Zhejiang Hisun Pharmaceutical Co., Ltd	Identification Allergen	ESAT6 and CFP10 skin test	Identifies *M. tb* infection	No information
India				
Span Divergent/Arkray Japan	Tuberculin PPD	Skin test	Identifies *M. tb* infection	No information
Serum Institute of India/Statens Serum Institute	C-Tb	ESAT6 and CFP10 skin test	Identifies *M. tb* infection	No information

Further details on tests for tuberculosis infection are available in Hamada Y, Cirillo DM, Matteelli A, et al. Tests for tuberculosis infection: landscape analysis. Eur Respir J 2021; in press (https://doi.org/10.1183/13993003.00167–2021).

Digital CXR and CAD technologies

Company	Product	Diagnostic method	Use	Regulatory approval
China				
Beijing Infervision Technology Company	InferRead DR Chest	Artificial intelligence	AI-aided screening of CXR, including for TBAI-aided detection of TB on CXR	CE marked
Huiying Medical Technology	DR Chest	Artificial intelligence	AI-aided preliminary screening of CXR, including for TB	No information
JF Healthcare	JF CXR-1	Artificial intelligence	AI-aided detection of TB on CXR	NMPA (China) Tier 2 approved
	JF CXR-2	Artificial intelligence	AI-aided multi-thorax disease model	No information
India				
Qure.ai	qXR TB	Automated chest x-ray interpretation	Detects signs of pulmonary, hilar, and pleural tuberculosis on CXR	CE marked
South Korea				
JLK	JLD-02 K (JVIEWER-X)	Automated chest x-ray interpretation	Detects several pulmonary abnormalities, including signs of pulmonary tuberculosis	CE marked South Korean FDA approved

(continued)

Company	Product	Diagnostic method	Use	Regulatory approval
Lunit	Lunit INSIGHT CXR	Artificial intelligence-assisted x-ray reading	Acts as second reader for physicians reading CXRs	Australian FDA approved CE marked
PicoHDT	Mine-2 system (wired type)	Portable x-ray machine with diagnostic AI technology	Produces x-ray images; interprets x-rays	CE marked
	Mine-2 system (wireless type)		Produces x-ray images; interprets x-rays	CE marked
RadiSen	AXIR TB	Artificial intelligence	Detects signs of pulmonary tuberculosis on CXR	CE marked

Further details on digital technologies are available:

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Smart microscope

Company	Product	Diagnostic method	Use	Regulatory approval
India				
AGD Bio	Mycovision	Smart microscope	Artificial intelligence-based automated microscope for detection of acid fast bacilli under Ziehl-Neelsen stained slides	No information

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