ULTRAFAST DIAGNOSTICS

Technologies Delivering Results in Under 10 Minutes

A Technology Landscape for Clinical and Donor Audiences
India and Global Perspective · 2026

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Executive Summary

The ability to diagnose infectious disease rapidly, ideally within the time a patient waits in a clinic is one of the most transformative goals in global health. Delayed or absent diagnosis is a key driver of inappropriate antibiotic use, antimicrobial resistance (AMR), preventable mortality, and spiralling healthcare costs.

This document maps the current and emerging landscape of ultrafast diagnostic technologies as on April 2026, those capable of delivering clinically actionable results in under 10 minutes, or approaching that threshold. It covers **17 distinct technology classes**, from the broadly deployed (lateral flow assays) to the frontier (mid-infrared spectroscopy with AI), assessing each against the practical realities of clinical deployment, cost, supply chain, and suitability for India and low- and middle-income country (LMIC) settings.

A comparative matrix is included at the end of this document to enable side-by-side assessment of all technologies across thirteen parameters.

Why Speed Matters

When a patient presents with fever, the clinical decision whether to prescribe an antibiotic, which antibiotic, whether to admit, etc. is almost always made before any diagnostic result is available. The consequence is:

- Empirical antibiotic prescribing in ~80% of cases in PHC settings in India (Chalotra R et al, 2025)
- Over-prescription of broad-spectrum antibiotics, accelerating AMR
- Under-treatment of viral infections with unnecessary antibiotics
- Missed TB, dengue, and malaria diagnoses at first contact
- A growing AMR crisis estimated to cause 700,000 deaths per year globally (O'Neill Review, 2016)

A test that returns a result within the consultation window of under 10 minutes can fundamentally change the clinical decision. It enables precision prescribing at the point of care, transforms antibiotic stewardship from a retrospective audit into a real-time clinical tool, and has the potential to close the diagnostic gap that drives AMR.

Technology Profiles

01. Lateral Flow Assay (LFA) / Rapid Antigen Test

Category	Readiness	Time to Result
Immunoassay	**Commercially Available**	**5 to 15 minutes**

Lateral flow assays are the most widely deployed rapid diagnostic technology globally. They work by detecting a target protein (antigen) in a patient sample using antibodies conjugated to coloured nanoparticles (typically colloidal gold or latex). When the sample flows along a nitrocellulose membrane, a visible coloured line appears if the target is present.

Lateral flow tests require no equipment, no electricity, and minimal training. They are the backbone of COVID-19 home testing, malaria diagnosis, and pregnancy testing worldwide. In India, LFAs are deployed at district hospitals, sub-centres, and ASHAs under the ICMR RAT programme.

Their core limitation is sensitivity as they typically miss 20 to 40% of true positives at low pathogen loads, which is a significant problem for TB and early-stage infections.

Key Diagnostic Targets

- SARS-CoV-2
- Influenza A/B
- Malaria (P. falciparum / P. vivax)
- Dengue NS1
- HIV
- Strep A
- Hepatitis B surface antigen

India Context	Global Context
Widely deployed under ICMR RAT programmes; manufactured domestically (Mylab, Meril, J. Mitra). Cost: ₹50 to ₹400 per test.	Distributed by FIND, WHO prequalified products available. Dominant platform for LMIC diagnostics.

02. Rapid Molecular Testing (RT-PCR / NAAT - Cartridge-Based)

Category	Readiness	Time to Result
Molecular / Nucleic Acid Amplification	**Commercially Available**	**45 to 90 minutes (some platforms: 15 to 20 min)**

Cartridge-based molecular platforms bring the gold-standard sensitivity of PCR into a near-point-of-care format. The sample (swab, sputum, blood) is loaded into a sealed cartridge that contains all reagents pre-loaded. The instrument handles DNA/RNA extraction, amplification, and detection automatically.

Key platforms include Cepheid GeneXpert (widely used for TB/HIV/COVID), Abbott ID NOW (Influenza, 13 minutes), bioMérieux BIOFIRE (respiratory panels, 45 min), and Molbio Truenat (India-developed, solar-powered, WHO-prequalified for TB).

These systems offer high sensitivity and specificity (~95 to 99% for most targets), with multiplex capability on some platforms. Their limitation is cost per test and instrument dependency, making them suited to mid-level facilities rather than last-mile settings.

Key Diagnostic Targets

- TB / Rifampicin resistance (GeneXpert)
- SARS-CoV-2
- Influenza / RSV
- HIV viral load
- HPV
- Sepsis panels
- Antimicrobial resistance genes (mecA, blaKPC, NDM)

India Context	Global Context
GeneXpert deployed in >5,000 sites under NTEP. Truenat (Molbio, Goa) is made in India, WHO-prequalified for TB and COVID-19. High government procurement volume.	FIND-negotiated pricing for LMICs. GeneXpert cartridge ~$10 to $15 in public sector. Dominant molecular POC platform globally.

03. Loop-Mediated Isothermal Amplification (LAMP)

Category	Readiness	Time to Result
Molecular / Isothermal	**Commercially Available / Scaling**	**20 to 40 minutes**

LAMP is a nucleic acid amplification method that works at a single, constant temperature (60 to 65°C), eliminating the need for the expensive thermal cycling equipment required by conventional PCR. This makes LAMP instruments significantly simpler, cheaper, and more portable.

The reaction produces large amounts of DNA very rapidly, and results can be read visually (colour change, turbidity) or by a low-cost fluorescence reader. LAMP has strong sensitivity for high-burden diseases, including TB, malaria, and dengue. Eiken Chemical (Japan) pioneered commercial LAMP kits; several India-based manufacturers now produce LAMP reagents.

Key limitation: LAMP is inherently less multiplex-capable than PCR platforms, and primer design is complex. It is better suited to single-target or narrow-panel testing.

Key Diagnostic Targets

- TB (Eiken TB-LAMP)
- Malaria species differentiation
- SARS-CoV-2
- Dengue
- Filariasis
- Leishmania

India Context	Global Context
LAMP kits available from domestic manufacturers; TB-LAMP evaluated at PHC level in India. Suitable for district-level laboratories without PCR infrastructure.	WHO-prequalified TB-LAMP available. Used in high-burden African and Asian settings. Cost per test ~$3 to $8.

04. CRISPR-Based Diagnostics (SHERLOCK / DETECTR / Feluda)

Category	Readiness	Time to Result
Molecular / CRISPR	**Near-Market / Early Commercial**	**30 to 60 minutes (with sample prep)**

CRISPR diagnostics exploit the precision of CRISPR enzymes (Cas12, Cas13, Cas9) to detect specific nucleic acid sequences with very high accuracy. When the CRISPR complex finds its target, it 'activates' and cuts a fluorescent reporter molecule, producing a detectable signal. This can be read on a lateral flow strip or a simple fluorescence reader.

SHERLOCK (Broad Institute, MIT) uses Cas13 for RNA targets; DETECTR (UC Berkeley / Mammoth Biosciences) uses Cas12 for DNA. India developed FELUDA, a CRISPR-Cas9-based COVID-19 test from CSIR-IGIB / Tata Chemicals, which received ICMR approval in 2020 — the first CRISPR diagnostic to receive regulatory approval in India.

CRISPR diagnostics combine near-PCR sensitivity with LFA-level simplicity of result readout. The remaining barrier is sample preparation — most CRISPR diagnostics still require an upstream amplification step (RT-LAMP or RT-PCR) before CRISPR detection, adding complexity. Fully integrated CRISPR-in-a-cartridge systems are in active development.

Key Diagnostic Targets

- SARS-CoV-2 (FELUDA, SHERLOCK)
- Dengue / Zika differentiation
- TB
- HPV genotyping
- AMR gene detection (NDM-1, blaKPC)
- Influenza A/B strain differentiation

India Context	Global Context
FELUDA approved by DCGI in 2020. CSIR-IGIB continues CRISPR diagnostic development. Tata Medical and Diagnostics commercialised FELUDA strips.	Mammoth Biosciences and Sherlock Biosciences advancing commercial CRISPR platforms. WHO and FIND tracking closely for LMIC deployment.

05. Microfluidic / Lab-on-Chip Platforms

Category	Readiness	Time to Result
Platform Technology	Commercial (select applications) / Active R&D	10 to 45 minutes

Lab-on-chip technology miniaturises an entire laboratory workflow including sample preparation, reagent mixing, separation, detection, onto a chip typically the size of a credit card. Microfluidic channels, valves, and reaction chambers are etched into plastic, glass, or silicon substrates, enabling highly controlled fluidic processes at micro- or nanolitre volumes.

This miniaturisation drastically reduces reagent consumption, shortens reaction times, and enables multiplex detection of many analytes simultaneously from a single small sample. Commercial successes include the bioMérieux BIOFIRE FilmArray (respiratory syndromic panels), Abbott i-STAT (blood chemistry and cardiac biomarkers), and Fluidigm platforms.

For infectious disease in LMICs, microfluidic platforms are being developed by several Indian academic groups (IIT, IISER) as well as globally by imec (Belgium), Caltech, and numerous diagnostics companies. The challenge remains integrating sample lysis and nucleic acid extraction (the 'dirty' biological steps) cleanly into sealed chip architectures.

Key Diagnostic Targets

- Sepsis panels (blood)
- Respiratory syndromic panels
- Cardiac biomarkers
- CD4/HIV
- Haematology parameters
- AMR gene panels

India Context	Global Context
Active research at IIT Bombay, IIT Delhi, CCMB Hyderabad. Few commercial products at scale in India yet. BIRAC-funded startups (e.g., PathShodh) working on microfluidic chemistry panels.	bioMérieux BIOFIRE: $150 to $250 per panel (high-income settings). Significant cost reduction required for LMIC applicability. imec photonic chip platform in advanced R&D.

06. Surface-Enhanced Raman Spectroscopy (SERS)

Category	Readiness	Time to Result
Spectroscopic / Label-Based	Advanced R&D / Early Commercial	10 to 30 minutes

Raman spectroscopy detects the unique molecular 'fingerprint' of substances by measuring how light scatters off chemical bonds. Surface-Enhanced Raman Spectroscopy (SERS) amplifies this signal by orders of magnitude using metallic nanoparticles (gold, silver), making it sensitive enough to detect pathogens at clinically relevant concentrations.

SERS-based diagnostics can detect bacteria, viruses, and drug-resistance markers without labelling (label-free) or with nanoparticle tags. The technology is highly multiplexable (many analytes can be identified simultaneously) from a single spectrum. Portable Raman instruments (Metrohm, Wasatch Photonics, Agilent) are commercially available.

Current barriers to LMIC deployment include the cost of nanoparticle substrates, batch-to-batch reproducibility, and the need for spectral interpretation software. Several academic groups in India (IISc Bangalore, IIT Madras) are active in SERS diagnostics research.

Key Diagnostic Targets

- Bacteria (E. coli, S. aureus, K. pneumoniae)
- SARS-CoV-2
- Malaria
- TB
- Antimicrobial resistance phenotyping
- Viral load monitoring

India Context	Global Context
Research-stage in India; IISc, IISER, IIT groups publishing in this space. No major commercial SERS diagnostic product deployed in India at scale.	BioNano Genomics, Nanospec, and university spin-outs developing SERS platforms. Regulatory approvals for in-vitro diagnostics still pending for most.

07. Mid-Infrared (Mid-IR) Spectroscopy with AI (ARKAS Platform)

Category	Readiness	Time to Result
Spectroscopic / Label-Free / AI-Integrated	**R&D / Pre-Clinical Prototype**	**< 5 minutes (target)**

Mid-infrared spectroscopy identifies the molecular composition of a sample by measuring how it absorbs infrared light across the 'fingerprint region' (2.5–12.5 μm), where every organic molecule has a unique absorption signature. Unlike immunoassay tests that detect one specific antigen, mid-IR spectroscopy reads the entire biochemical composition of a sample simultaneously, thus providing a rich, label-free molecular portrait.

The ARKAS platform combines a laser source, providing greater photon flux than conventional globar sources, integrated systems for direct clinical sample manipulation without preparation steps, and a neural network architecture for spectral classification.

The platform is designed from first principles for last-mile deployment: zero reagents, zero consumables, zero waste, and a target handheld form (the size of a mobile phone) factor. Its clinical development will be supported by AIIMS and ICMR partnerships. ARKAS is being developed under CDPH (Centre for Digital and Public Health), with IP protection in progress.

Key Diagnostic Targets

- Bacterial pathogens (broad-spectrum, simultaneous multiplex)
- AMR phenotype detection (without culture)
- TB and drug-resistant TB
- Viral respiratory pathogens
- Sepsis markers (blood-based)
- Cancer liquid biopsy (longer-term)
- Environmental / One Health surveillance
- Biochemical molecules

India Context	Global Context
Being developed under CDPH with AIIMS and ICMR collaboration. DPIIT startup recognition in progress. R&D will be carried out in IIT incubator space. LMIC-first deployment strategy.	No comparable platform exists commercially in our initial patent review. Nearest comparators: Spore.bio (FT-IR + ML, France, Google-funded; pharma/industrial focus, not LMIC clinical); Pendar Technologies (QCL-based, USA-industrial/pharma); imec photonic chip (near-IR, Belgium, R&D stage).

08. Electrochemical / Biosensor Platforms

Category	Readiness	Time to Result
Biosensor	**Commercial (glucose/cardiac) / R&D (infectious disease)**	**5 to 20 minutes**

Electrochemical biosensors detect analytes by measuring changes in electrical current, voltage, or impedance when a target molecule binds to a recognition element (antibody, aptamer, or DNA probe) on an electrode surface. The Abbott i-STAT and glucose monitors are the most successful commercial examples.

For infectious disease, electrochemical biosensors are being developed to detect bacterial 16S rRNA, viral nucleic acids, and resistance determinants. Graphene and carbon nanotube electrodes significantly enhance sensitivity. These platforms can be miniaturised to a handheld device with a smartphone interface.

The challenge is that biological fluids (blood, sputum) contain many electrochemically active compounds that create background noise, requiring careful electrode engineering. Shelf-life of biosensor strips in tropical climates (heat, humidity) is also a significant challenge for India and LMIC deployment.

Key Diagnostic Targets

- Glucose / metabolic (established)
- Cardiac troponin (Abbott i-STAT)
- Procalcitonin (sepsis marker)
- HIV p24 antigen
- Hepatitis B/C
- E. coli / S. aureus (research-stage)

India Context	Global Context
Glucose biosensors ubiquitous (Accu-Chek, Dr. Morepen). Research-stage infectious disease biosensors from IIT groups, CSIR labs. PathShodh (IIT Bombay spin-out) developing multi-analyte platforms.	Abbott, Siemens, Roche dominate commercial cardiac biosensor space. Multiple startups (Biolinq, Halo Diagnostics) developing infectious disease biosensors for POC.

09. Whole Blood Flow Cytometry (Portable)

Category	Readiness	Time to Result
Cell-Based / Immunophenotyping	Commercial (select products)	15 to 30 minutes

Flow cytometry identifies and counts cells by passing them one at a time through a laser beam and measuring fluorescence and scatter signals. Traditional flow cytometers are large, expensive laboratory instruments. A new generation of miniaturised, cartridge-based flow cytometers brings this capability to near-POC settings.

The key clinical application in infectious disease is CD4 T-cell counting for HIV treatment monitoring, critical for deciding when to initiate antiretroviral therapy. Sight Diagnostics (Israel) developed the OLO analyser, a portable AI-powered blood analyser; Beckman Coulter's MicroDiff and Sysmex platforms offer compact haematology. CytoFLEX and BD FACSLyric are semi-portable.

For AMR and infectious disease phenotyping, flow cytometry can assess bacterial viability under antibiotic exposure and thus essentially a rapid phenotypic AST. Though this is still largely research-stage for POC applications.

Key Diagnostic Targets

- CD4 counting (HIV)
- Complete blood count
- Malaria parasite detection
- Rapid phenotypic AST (research)
- Leukocyte differential (sepsis)

India Context	Global Context
CD4 testing critical for NACO HIV programme. PointCare NOW and Alere PIMA CD4 deployed in government ART centres. Haematology analysers (Sysmex, Nihon Kohden) widely used in district hospitals.	Sight Diagnostics OLO: AI-integrated portable haematology. PIMA CD4 widely deployed in sub-Saharan Africa under PEPFAR. ~$8 to $15 per CD4 test in public sector.

10. Phage-Based / Bacteriophage Diagnostics

Category	Readiness	Time to Result
Biological / Novel	**Early Commercial / R&D**	**2 to 4 hours (improving)**

Bacteriophages (viruses that infect bacteria) are extraordinarily specific: a phage that infects Mycobacterium tuberculosis will not infect E. coli, and vice versa. Phage-based diagnostics exploit this specificity to detect and identify bacteria without conventional culture, often within 2 to 4 hours.

The FASTPlaque-TB test (Biosyntech) and the phage amplification technology developed at UCL (UK) detect TB by observing whether phages can replicate inside mycobacterial cells. Replication proves the bacteria are present and viable. More recent platforms use engineered reporter phages that express luciferase when they infect target bacteria, producing a bioluminescent signal detectable by a simple reader.

For AMR, phage-based rapid AST is an active area; the phage replication rate changes when bacteria are exposed to antibiotics, enabling susceptibility classification without overnight culture. The technology remains at early commercial / advanced R&D stage for most applications outside TB.

Key Diagnostic Targets

- TB / MDR-TB viability testing
- S. aureus / MRSA
- E. coli / ESBL
- Pseudomonas aeruginosa
- AMR phenotyping (research)

India Context	Global Context
FASTPlaque-TB evaluated at RNTCP sites. Research collaborations between Indian TB programmes and UK/US phage diagnostic groups. Not yet in routine deployment.	Phage diagnostics company Fastinov (Portugal), Ampliphi/C3J Therapeutics (USA) developing platforms. WHO considering phage-based AST for TB.

11. Oxford Nanopore Sequencing (ONT - MinION / Flongle)

Category	Readiness	Time to Result
Genomic Sequencing / Metagenomics	**Commercially Available**	**20 to 60 min (streaming); 2 to 4 hr full workflow**

Oxford Nanopore Technologies has done something previously considered impossible: it miniaturised a DNA sequencer to the size of a USB thumb drive. The MinION device is the flagship portable instrument which weighs 87 grams, runs off a laptop USB port, and begins streaming real-time sequencing data within minutes of sample loading.

The technology works by threading individual DNA or RNA strands through protein nanopores embedded in a synthetic membrane. As each nucleotide passes through the pore, it disrupts an electrical current in a characteristic way, and that pattern is decoded in real time into a DNA sequence. Unlike Illumina sequencing, which requires amplification, fluorescent labelling and optical detection, nanopore sequencing reads the native molecule directly.

Because ONT sequences everything in a sample rather than testing for pre-specified targets, it can identify any pathogen like bacterial, viral, fungal, or parasitic, without prior knowledge of what is present. This 'diagnose the unknown' capability is unique among all diagnostic platforms in this landscape. For TB, it does not just confirm presence; it identifies the exact strain, characterises every known drug resistance mutation simultaneously, and enables outbreak cluster analysis in a single run.

India's engagement with ONT is more advanced than most in the clinical community realise. CSIR-IGIB was one of the earliest adopters globally, establishing MinION-based COVID-19 sequencing workflows scaled nationally under INSACOG (Indian SARS-CoV-2 Genomics Consortium). The genomic surveillance infrastructure built during COVID-19 is now being repurposed for AMR surveillance under NAP-AMR.

Note: total sample-to-answer time is 2 to 4 hours for most clinical workflows, placing it outside the under-10-minutes threshold of this document. The Rapid Sequencing Kit reduces library prep to approximately 10 minutes, but extraction time remains. ONT is therefore positioned here as a critical near-POC and field-deployable sequencing platform rather than a sub-10-minute diagnostic.

Key Diagnostic Targets

- TB / MDR-TB — full resistance profiling and strain typing from direct sputum
- SARS-CoV-2 and respiratory virus variant surveillance (INSACOG)
- Sepsis of unknown origin — metagenomic blood/CSF sequencing
- AMR surveillance — full resistome characterisation
- Neglected tropical diseases — Leishmania, filarial, enteric pathogen typing
- Outbreak investigation and One Health genomic surveillance

India Context	Global Context
CSIR-IGIB (New Delhi) pioneered India's MinION deployment. INSACOG used ONT across 28 laboratories for COVID-19 variant surveillance. NCDC, NIMHANS, and several ICMR regional institutes now operate ONT platforms. Oxford Nanopore India office based in Bengaluru. DBT and ICMR in discussions on expanded national AMR surveillance deployment. Cost per run: Flongle flow cell ~$90 to 120; MinION flow cell ~$500 to 600.	Deployed in over 100 countries. Used by Africa CDC, WHO Ebola response, and the ARTIC network for LMIC genomic surveillance. PATH has supported ONT deployment in several African countries for respiratory pathogen surveillance. The Flongle adapter specifically designed to lower per-sample cost for LMIC settings. Cost per sample can be $20 to 40 for targeted amplicon AMR panels.

12. MALDI-TOF Mass Spectrometry

Category	Readiness	Time to Result
Mass Spectrometry / Proteomic Identification	**Commercially Available (reference labs)**	**6 to 15 minutes (from isolated colony)**

MALDI-TOF (Matrix-Assisted Laser Desorption/Ionisation - Time of Flight) mass spectrometry is the current global standard for rapid bacterial and fungal identification in clinical microbiology laboratories. It has quietly transformed hospital microbiology over the past fifteen years, replacing biochemical identification methods that took 24 to 48 hours with a process that takes under 15 minutes.

A small amount of bacterial or fungal material typically a single colony from a culture plate is mixed with a matrix compound and spotted onto a metal target. A laser pulse vaporises and ionises the mixture, and the resulting charged protein fragments travel through a vacuum tube to a detector. The time each fragment takes to reach the detector depends on its mass-to-charge ratio, producing a unique spectral fingerprint matched against a database of over 6,000 organism spectra. Identification accuracy for common clinical pathogens exceeds 97–99%.

The consumable cost per identification is extraordinarily low; approximately $0.50 to $2 per sample once the instrument is in place. The two dominant platforms are bioMérieux VITEK MS and Bruker Biotyper. MALDI-TOF does not replace culture; it still requires an isolated colony as input, meaning the culture step (16 to 24 hours) precedes identification. However, integrated blood culture workflows reduce total time from blood draw to organism ID to 18-24 hours; a clinically meaningful improvement over conventional 48 to 72-hour workflows.

MALDI-TOF has directly improved the quality of antibiogram data generated across India's AMR surveillance network. Accurate organism identification is a prerequisite for meaningful antibiogram generation; misidentified organisms produce misleading resistance data. The ICMR AMR surveillance network uses MALDI-TOF as the organism identification backbone at all sentinel surveillance sites.

Note: This requires culture as input; cannot meet the under-10-minutes from sample threshold. High capital cost ($80,000 to $150,000 per instrument) restricts deployment to tertiary and large secondary care facilities. Does not currently provide antimicrobial susceptibility results; a separate AST step is still required.

Key Diagnostic Targets

- Bacterial ID from culture; all major clinical pathogens to species level in under 15 minutes
- Fungal identification: Candida species (critical for C. auris differentiation), Aspergillus
- Blood culture identification - ID within minutes of positive flag
- Mycobacterial identification - NTM and M. tuberculosis complex members
- Carbapenemase detection - MBT STAR-BL module, ~90 minutes
- ESBL screening and vancomycin-resistant Enterococcus detection

India Context	Global Context
Deployed at AIIMS New Delhi, PGI Chandigarh, CMC Vellore, NIMHANS Bengaluru, ICMR National Reference Laboratories, and several state public health laboratories under NAP-AMR. Both major platforms (Bruker Biotyper, bioMérieux VITEK MS) are imported; no domestic manufacturing yet. DBT has expressed interest in supporting indigenous MALDI-TOF development.	Standard of care in clinical microbiology across North America, Europe, and Australia. WHO prequalification for MALDI-TOF IVD use under development. FIND has assessed MALDI-TOF for LMIC settings; primary barrier is capital cost, not performance. Lease and reagent-rental models emerging. Routine in national reference laboratories in Brazil, South Africa, and Thailand. Instrument costs have fallen ~40% over the past decade.

13. AI-Powered Digital Microscopy and Smartphone Diagnostics

Category	Readiness	Time to Result
AI / Computer Vision / Digital Diagnostics	**Commercial (select) / Rapidly Scaling**	**2 to 10 minutes (image to AI result)**

Microscopy has been the foundation of infectious disease diagnosis for 150 years. The challenge has never been the microscope; it has been the expert human required to interpret what the microscope shows. Trained microscopists are scarce at primary care level, performance is variable, and reading slides is time-consuming, fatiguing work.

Convolutional neural networks (CNNs) trained on hundreds of thousands of annotated microscopy images now identify malaria parasites, TB bacilli, helminth eggs, and leukocyte differentials with accuracy matching or exceeding expert microscopists and they do not fatigue, do not vary between shifts, and can operate on a $200 smartphone clipped to a basic microscope.

India is home to one of the world's leading AI diagnostics companies in this space. Qure.ai (Mumbai) has deployed AI chest X-ray analysis; reading X-rays for TB with sensitivity and specificity comparable to radiologists across 25+ countries, integrated into India's NTEP as an AI triage tool for active TB case finding. Qure.ai has received CDSCO approval and has been assessed for WHO prequalification. AI-assisted visual inspection with acetic acid (VIA) for cervical cancer screening has been evaluated at ASHA/ANM level in India, and the same smartphone-camera infrastructure applies directly to infectious disease LFA reading.

AI-powered lateral flow assay readers: Standard LFAs read by eye have high inter-reader variability. AI smartphone readers quantify test line intensity, converting a qualitative yes/no result into a semi-quantitative measurement, reducing reader variability, enabling automatic result recording, and allowing geospatial disease surveillance aggregation from community level upward.

Note: AI models trained in one setting often perform poorly when deployed on different microscopes, different slide preparation quality, or different lighting; a problem called distribution shift. Robust AI diagnostics require training data from the specific deployment context. Regulatory approval for AI-as-a-medical-device (AI/AMD) is evolving; CDSCO and the FDA are developing AI-specific frameworks. Data privacy considerations apply when patient images are uploaded to cloud-based AI servers.

Key Diagnostic Targets

- Malaria - species identification and parasite density from blood smears (EasyScan GO, Matibabu, Fio)
- TB - sputum smear AFB reading; AI chest X-ray triage (Qure.ai, CAD4TB)
- Complete blood count / differential - AI leukocyte differential for sepsis, dengue
- Urinalysis - AI reading of urine dipsticks (UTI, schistosomiasis, kidney disease)
- LFA interpretation - semi-quantitative HIV, malaria, dengue, COVID-19 rapid test reading
- Cervical cancer screening - AI-assisted VIA (directly relevant to JHPIEGO reproductive health programmes)
- Skin disease - leprosy, leishmaniasis skin lesion AI classification

India Context	Global Context
Qure.ai (Mumbai) deployed across 25+ countries; integrated into NTEP for TB active case finding; CDSCO-approved. NVBDCP has piloted AI-assisted malaria microscopy in Odisha and Jharkhand settings. ICMR has evaluated multiple AI microscopy platforms for malaria at district level. AI-assisted VIA evaluated at ASHA/ANM level under NHM collaborations.	WHO Global Observatory on Health R&D tracks AI diagnostics as a priority. FIND AI diagnostic evaluation framework assesses these platforms alongside conventional IVDs. EasyScan GO (Motic) and WHO-endorsed AI malaria platforms being scaled in Africa. Bill & Melinda Gates Foundation has made significant investments in AI malaria and TB microscopy.

14. Clinical Metagenomics (mNGS - Metagenomic Next-Generation Sequencing)

Category	Readiness	Time to Result
Genomic / Unbiased Sequencing	**Commercial (reference labs) / Emerging Clinical**	**6 to 24 hours (full workflow)**

Clinical metagenomics (mNGS) is the application of unbiased next-generation sequencing to clinical samples, sequencing everything present without prior assumption about what the pathogen might be. This is the most profound conceptual departure from all other platforms in this landscape: every other diagnostic technology requires you to know, or at least suspect, what you are looking for. Metagenomics does not.

A blood, cerebrospinal fluid, bronchoalveolar lavage, or stool sample is processed, all nucleic acids extracted and sequenced, and the resulting millions of DNA/RNA reads are computationally sorted against reference databases of all known organisms. Human reads are filtered out; the remaining non-human reads identify which bacteria, viruses, fungi, and parasites are present, and at what relative abundance. Simultaneously, resistance genes, virulence factors, and novel sequences are identified.

The clinical use case where metagenomics has proven transformative is unexplained infection particularly in immunocompromised patients (transplant recipients, oncology patients, HIV with AIDS), patients with culture-negative sepsis, and encephalitis of unknown origin. The landmark UCSF ICARE study (Benoit P et al., Nature Medicine 2024) demonstrated that mNGS identified causative organisms in CSF in cases where conventional testing had failed, directly changing clinical management.

For AMR, metagenomics provides the most comprehensive resistance profiling possible detecting not just known resistance genes but novel resistance mechanisms, plasmids carrying resistance determinants, and the full mobile genetic element landscape. This is directly relevant to WHO priority pathogen surveillance and India's NAP-AMR objectives. Oxford Nanopore (Technology 11) is the platform of choice for portable rapid clinical metagenomics; Illumina remains the standard for high-throughput reference laboratory work.

Note: Total workflow time is 6 to 24 hours which is well outside this document's 10-minute threshold. It is included because colleagues working on AMR surveillance and pandemic preparedness will encounter it regularly in programme discussions. Cost at $200 to $500 per sample restricts use to complex cases. Bioinformatics expertise is required. Sensitivity for low-abundance organisms in blood is limited by the high proportion of human DNA in clinical samples.

Key Diagnostic Targets

- Culture-negative sepsis and endocarditis - ID when blood cultures repeatedly negative
- Encephalitis of unknown origin - CSF metagenomics when standard panels negative
- Immunocompromised patient pneumonia - BAL metagenomics identifying PCP, CMV, Aspergillus simultaneously
- Novel pathogen discovery - primary platform for new pathogen identification during outbreaks (SARS-CoV-2 identified by metagenomics, Wuhan, 2019)
- AMR resistome surveillance - community and hospital AMR gene surveillance without culture
- One Health surveillance - environmental, animal, and human pathogen genomic integration

India Context	Global Context
Early adoption stage. AIIMS New Delhi, NIMHANS, and Manipal Hospitals have begun offering or evaluating clinical mNGS for complex infections. CSIR-IGIB has the strongest metagenomics capability in the public sector. Cost ($200 to $500/sample) limits use to complex/refractory cases. ICMR One Health programme investing in environmental and animal reservoir metagenomics for AMR surveillance under NAP-AMR.	UCSF offers a CLIA-certified metagenomic CSF test commercially. Karius (USA) offers blood mNGS clinically. IDbyDNA, Illumina DRAGEN bioinformatics pipeline, and Oxford Nanopore EPI2ME are the leading platforms. WHO and FIND are tracking clinical metagenomics for LMIC pandemic preparedness. Reference: Wilson MR et al. Actionable Diagnosis of Neuroleptospirosis by Next-Generation Sequencing. NEJM 2014; and Langelier C et al. Integrating host response and unbiased microbe detection for lower respiratory tract infection diagnosis in critically ill adults. PNAS 2018.

15. C-DAC Kolkata / MeitY — ColoSENS and SWASTHA (Indigenous Indian Diagnostic Platforms)

Category	Readiness	Time to Result
Colorimetric Biosensor / Nanoelectronics (MeitY / Government of India)	**R&D / Field Trial (India-developed)**	**10 to 30 minutes (target)**

C-DAC (Centre for Development of Advanced Computing) Kolkata, operating under the Ministry of Electronics and Information Technology (MeitY), has been developing two healthcare diagnostic platforms that represent India's indigenous government-funded effort to create affordable, deployable diagnostics for primary and community care, and which are distinct from the academic research platforms described elsewhere in this document.

ColoSENS is an affordable colorimetric diagnostic instrument developed under a MeitY R&D award to C-DAC Kolkata. Colorimetric diagnostics detect the presence of a target pathogen or biomarker by producing a visible colour change; the same principle as a pregnancy test, but applied to bacterial detection in clinical and environmental samples. ColoSENS has been specifically developed and field-trialled for the detection of bacterial diarrhea; a major cause of under-five mortality in India with clinical evaluation underway at the Regional Institute of Medical Sciences (RIMS), Imphal, and the Institute of Child Health (ICH), Kolkata. The system is designed for low-resource settings with minimal infrastructure requirements.

SWASTHA: Smart Wearable Advanced nanoSensing Technologies in Healthcare ASICs is a MeitY Centre of Excellence programme led by IIT Guwahati in partnership with C-DAC and multiple IITs (Bombay, Madras, Delhi, Kharagpur). Showcased at the MeitY Nano Electronics Road Show at IISc Bengaluru in March 2025, SWASTHA focuses on nanoelectronic sensor integration for healthcare applications including smart allergen sensing and point-of-care nano biosensors. The programme aims to deliver integrated circuit (ASIC) -level sensor platforms that can be embedded in wearable or handheld diagnostic devices.

Any large-scale government health programme deployment will increasingly preference domestically developed and manufactured diagnostic platforms, and C-DAC/MeitY products, developed with public funds, have a natural pathway into government procurement under NHM, NTEP, and Ayushman Bharat.

Note: both platforms are at R&D to early field-trial stage. Peer-reviewed clinical performance data is limited compared to the international commercial platforms described in this document. However, the institutional backing (MeitY, C-DAC, IIT network), the clinical partner network (RIMS, ICH, AIIMS), and the government procurement pathway give these platforms strategic importance.

Key Diagnostic Targets

- Bacterial diarrhea detection - ColoSENS, field-trialled at RIMS Imphal and ICH Kolkata
- Allergen detection - SWASTHA smart allergen sensing platform
- Wearable physiological monitoring - SWASTHA ASIC-integrated nano biosensors
- Point-of-care colorimetric pathogen detection - rural and remote settings
- Potential expansion to water quality and environmental pathogen surveillance

India Context	Global Context
C-DAC Kolkata (Salt Lake City, Sector V) is the primary development centre. Field trials ongoing at RIMS Imphal (Manipur) and Institute of Child Health, Kolkata. Funded by MeitY. SWASTHA Centre of Excellence at IIT Guwahati, in partnership with IIT Bombay, IIT Madras, IIT Delhi, IIT Kharagpur, and C-DAC. Showcased publicly at MeitY Nano Electronics Road Show, IISc Bengaluru, March 2025 in the presence of the Secretary, MeitY.	No direct international equivalent at the same government-funded, primary-care-targeted level. The closest international comparators are government-funded diagnostic R&D programmes in South Korea (KIST), China (NIMTE), and Germany (Fraunhofer institutes). MeitY's approach of combining C-DAC engineering capabilities with IIT academic partners and clinical trial sites mirrors successful models in these countries. India is the first LMIC to develop a government-ministry-funded nano-biosensor diagnostic programme at this scale.

16. Digital PCR (dPCR)

Category	Readiness	Time to Result
Molecular / Absolute Quantification	Commercial (reference / research labs)	2 to 4 hours

Digital PCR (dPCR) is a refinement of conventional quantitative PCR (qPCR) that partitions a sample into thousands or millions of individual micro-reactions either in droplets (ddPCR, droplet digital PCR, by Bio-Rad) or in nanowells etched onto a chip (Fluidigm, Stilla Technologies). Each partition either contains the target molecule or does not, producing a binary positive/negative result per partition. By counting positive and negative partitions and applying Poisson statistics, dPCR provides an absolute copy number of the target without the need for a standard calibration curve.

This is clinically significant in several ways. For HIV viral load monitoring, absolute quantification enables more precise management of treatment response and detection of low-level viraemia below the threshold of conventional qPCR. For TB minimal residual disease and treatment response monitoring, dPCR can detect viable mycobacterial DNA at concentrations that qPCR would classify as negative. For AMR gene detection, dPCR can quantify resistance gene copy numbers, relevant for understanding whether resistance is plasmid-borne (and therefore transmissible) or chromosomal.

dPCR is also the reference method for validating new diagnostic platforms. When clinical accuracy data for platforms like ARKAS (Technology 07) or CRISPR diagnostics are generated, dPCR will serve as the gold standard comparator for low-concentration samples.

Note: dPCR is not a point-of-care technology in its current commercial form. Instruments (Bio-Rad QX200 ddPCR, RainDance, Stilla Crystal Digital PCR) require laboratory infrastructure, trained operators, and cost $50,000 to $150,000. Workflow time is 2 to 4 hours. Per-test cost is $15 to $50. It is included here because it represents the technical ceiling of PCR-based quantitative accuracy, and dPCR would be a comparator platform in clinical validation studies.

Key Diagnostic Targets

- HIV viral load - absolute quantification at low copy numbers below conventional qPCR threshold
- TB treatment monitoring - detection of minimal residual mycobacterial DNA
- AMR gene copy number quantification - distinguishing plasmid-borne from chromosomal resistance
- Hepatitis B/C - ultra-low viral load monitoring during treatment
- Oncology / liquid biopsy - circulating tumour DNA quantification
- Platform validation - gold-standard comparator for novel diagnostic accuracy studies

India Context	Global Context
Available at select ICMR reference laboratories, AIIMS, and academic research centres. Not in routine clinical deployment. ICMR AMR surveillance research groups use ddPCR for resistance gene quantification studies. Bio-Rad India distributes QX200 ddPCR systems. BIRAC has funded dPCR research applications in oncology and infectious disease.	Bio-Rad Laboratories (USA) and Stilla Technologies (France) are leading commercial providers. FDA-cleared applications include HIV viral load and oncology ctDNA detection. WHO expert groups have evaluated dPCR for TB treatment monitoring. Cost reduction trajectory is slower than for isothermal platforms; miniaturised chip-based dPCR (Fluidigm, Formulatrix) may enable future POC applications.

17. Photoacoustic Spectroscopy (PAS)

Category	Readiness	Time to Result
Optical / Acoustic / Label-Free Sensing	**Advanced R&D / Pre-Commercial**	**5 to 20 minutes (target)**

Photoacoustic spectroscopy (PAS) is a label-free detection method that combines optical excitation with acoustic detection. When a pulsed or modulated laser beam is absorbed by a sample, the absorbed energy is converted to heat, causing rapid thermal expansion that generates a pressure wave, a sound wave detectable by a microphone or piezoelectric sensor. The intensity and frequency profile of this acoustic signal encodes the molecular composition of the sample, analogous in principle to conventional optical spectroscopy but with the practical advantage that acoustic detection is not affected by scattering or turbidity in biological matrices such as blood or sputum.

This is a significant practical advantage for clinical diagnostics. Conventional optical spectroscopy (including Raman and mid-IR) struggles with turbid or opaque samples because scattering and absorption of the probe light by the matrix (red blood cells, lipids, proteins) overwhelm the signal from the target pathogen. Photoacoustic detection, by contrast, works through the acoustic signal generated by absorbed energy; meaning it can detect targets in whole blood, thick sputum, and tissue without extensive sample preparation.

The most clinically advanced application of PAS in infectious disease is non-invasive malaria detection. Hemozoin: the crystalline byproduct of haemoglobin digestion by Plasmodium parasites has a distinctive photoacoustic signature. Research groups at MIT, the University of Michigan, and Intellectual Ventures Laboratory (Global Good programme, supported by Bill Gates) have developed photoacoustic malaria detection devices capable of detecting malaria parasites through the skin, entirely non-invasively, without a blood draw, without reagents, in under a minute. In India, IISc Bangalore and IISER groups are active in PAS diagnostics research.

For TB and respiratory infection, PAS of exhaled breath condensate (EBC) or sputum is being investigated as a reagent-free identification platform. Mycobacterial cell wall lipids (mycolic acids, cord factors) have characteristic mid-IR photoacoustic signatures that could enable non-culture TB identification. For AMR, photoacoustic whole-cell bacterial identification in blood is analogous in concept to ARKAS's mid-IR spectroscopy and is an active research direction. **ARKAS (Technology 7) has PAS technology partially native to its architecture and not a separate development track.**

Note: PAS is at TRL 3–4 for most infectious disease applications. The non-invasive malaria device is the most advanced, having undergone preliminary human studies. No PAS-based diagnostic has yet received regulatory clearance. The technology is highly promising but requires significant development work before clinical deployment.

Key Diagnostic Targets

- Malaria - non-invasive transdermal detection via hemozoin photoacoustic signature (MIT, Intellectual Ventures)
- TB - photoacoustic spectroscopy of sputum mycobacterial lipids
- Blood-based pathogen detection in whole blood without sample prep
- Exhaled breath analysis for respiratory infection biomarkers
- Non-invasive glucose monitoring (established application pathway)
- Environmental pathogen detection in water and food

India Context	Global Context
Research-stage in India. IISc Bangalore and multiple IISER campuses are active in PAS biosensor and spectroscopy research. BIRAC-funded exploratory projects in this space. No commercial Indian product yet. Close conceptual alignment with ARKAS platform goals; both pursue label-free, reagent-free, direct-sample spectroscopic identification.	Intellectual Ventures / Global Good (Bill Gates-backed) has invested substantially in non-invasive photoacoustic malaria detection. MIT Device Realization Lab has published on transdermal malaria detection. The Wellcome Trust and NIH have funded PAS diagnostic research. Regulatory pathway for non-invasive diagnostics is under development at FDA. Reference: Lukianova-Hleb E et al. Transient diagnosis of malaria using vapor nanobubbles. Emerg Infect Dis 2012.

Comparative Technology Matrix

*The matrix below compares all 17 technology platforms across thirteen parameters. Sensitivity and specificity figures marked * are indicative estimates from research literature and may vary by target organism and platform. ARKAS figures are design targets, not validated clinical performance data.*

Part A: Core Performance Parameters

Technology	Time to Result	Sensitivity	Specificity	Cost / Test (USD)	Multiplex	POC Possible	Reagents Required	Sample Prep	Supply Chain Risk	Power Required	LMIC Readiness	India Status
Lateral Flow Assay	5–15 min	60–80%	95–99%	$0.50–4	Limited (2–3 lines)	Yes	None (dry)	Minimal	Low	None	★★★★★	Deployed
Cartridge Molecular (GeneXpert, Truenat)	45–90 min	95–99%	97–99%	$10–15	Yes (panels)	Semi (facility)	Pre-loaded	Automated	Medium	Yes	★★★★☆	Deployed
LAMP (Isothermal PCR)	20–40 min	90–97%	95–99%	$3–8	Limited	Yes	Required	Moderate	Low	Minimal	★★★★☆	Scaling
CRISPR Diagnostics (FELUDA)	30–60 min	96–99%	98–99%	$5–12	Limited	Semi	Required	Moderate	Medium	Minimal	★★★☆☆	Early commercial
Microfluidic / Lab-on-Chip	10–45 min	95–99%	97–99%	$20–250	High (panels)	Semi	Pre-loaded	Automated	High	Yes	★★☆☆☆	R&D / select
SERS Spectroscopy	10–30 min	80–95%*	85–97%*	$5–20*	High	Potential	None (label-free)	Minimal	Medium	Low	★★☆☆☆	Research
ARKAS (Mid-IR + AI)	**< 5 min (target)**	**Target: >97%**	**Target: >97%**	**< $0.5 - $1 (target)**	**Very High**	**Yes (target)**	**None (zero reagent)**	**None (direct)**	**Low (target)**	**Low**	**★★★★★ (target)**	**R&D / Pre-clinical**
Electrochemical Biosensor	5–20 min	85–97%	90–98%	$3–15	Limited	Yes	Minimal	Minimal	Medium	Minimal	★★★☆☆	Research
Portable Flow Cytometry	15–30 min	95–99%	97–99%	$8–20	Moderate	Semi	Required	Minimal (blood)	Medium	Yes	★★★☆☆	Deployed (CD4)
Phage-Based Diagnostics	2–4 hr	88–95%*	95–99%*	$8–20*	Limited	Semi	Required	Moderate	High	Minimal	★★☆☆☆	Early

Technology	Time to Result	Sensitivity	Specificity	Cost / Test (USD)	Multiplex	POC Possible	Reagents Required	Sample Prep	Supply Chain Risk	Power Required	LMIC Readiness	India Status
Oxford Nanopore (MinION/Flongle)	20–60 min (streaming); 2–4 hr full	92–99%*	95–99%*	$20–120	Unlimited (metagenomics)	Yes (field-deployable)	Yes (library prep kit)	Moderate (extraction + library prep)	Medium (imported consumables)	Laptop USB (minimal)	★★★☆☆	Deployed (INSACOG, CSIR-IGIB, ICMR)
MALDI-TOF Mass Spectrometry	15 min (colony); 18–24 hr (sample)	97–99%	97–99%	$0.50–2 (consumable)	Yes (full ID in one run)	No (lab instrument)	Yes (matrix, minimal)	Requires prior culture	Medium (imported platforms)	Yes (laboratory)	★★★☆☆	Deployed (AIIMS, PGI, ICMR reference labs)
AI Digital Microscopy / Smartphone Dx	2–10 min	90–97%*	92–98%*	$0.10–2 (marginal)	Limited (one model per app)	Yes (smartphone-based)	Minimal (stains)	Standard microscopy prep	Low (software-driven)	Smartphone battery	★★★★☆	Deployed (Qure.ai NTEP; NVBDCP malaria AI)
Clinical Metagenomics (mNGS)	6–24 hours	70–95%*	95–99%*	$200–500	Unlimited (all organisms)	No (lab-based)	Yes (library prep, depletion)	Complex (extraction, depletion)	High (specialised reagents)	Yes (laboratory)	★★☆☆☆	Early adoption (AIIMS, NIMHANS, CSIR-IGIB)
C-DAC / MeitY ColoSENS + SWASTHA	10–30 min (target)	Research-stage	Research-stage	< $2 (target)	Limited (select targets)	Yes (POC target)	Minimal / colorimetric	Minimal	Low (domestic)	Battery / minimal	★★★☆☆ (India-specific)	R&D / field trial (RIMS Imphal, ICH Kolkata)
Digital PCR (dPCR)	2–4 hours	99%+ (absolute)	99%+	$15–50	Limited (2–4 targets)	Semi (portable platforms)	Yes (reagents)	Standard PCR prep	Medium	Yes	★★☆☆☆	Reference labs only
Photoacoustic Spectroscopy	5–20 min (target)	85–95%*	88–96%*	TBD	Moderate	Yes (handheld, target)	None (label-free)	Minimal	Low	Low (battery)	★★☆☆☆	Research-stage (IISc, IISER)

ARKAS: The Next-Generation Benchmark

ARKAS is included in this landscape as the only platform in active development that has been architecturally designed to simultaneously achieve all five parameters that define a truly transformative diagnostic platform for the 21st century:

- Under 10-minute result; within the clinical consultation window
- Zero reagents, zero consumables; eliminating cold chain and supply chain dependency
- Broad-spectrum multiplex; simultaneous bacterial, viral, and resistance profiling from a single sample
- Last-mile deployable; handheld, solar-powered, no laboratory infrastructure required
- AI-integrated; real-time spectral analysis with physics-informed neural networks

Competitive Differentiation

No existing commercial platform combines all five of the above attributes. The nearest comparators, assessed by the best of our reviews and knowledge are:

Competitor	Technology	Primary Market	Key Difference from ARKAS
Spore.bio (France)	FT-IR + ML	Pharma / industrial QC, high-income	Conventional globar IR source (10^6× less photon flux); no LMIC design intent; Google-funded, different market segment
Pendar Technologies (USA)	QCL array + AI	Industrial / pharmaceutical	Discrete wavelength QCL (no full fingerprint coverage); no clinical deployment; no LMIC design
GeneXpert / Cepheid	Cartridge RT-PCR	Clinical (hospital & POC)	Single-target per cartridge; reagent-dependent; $10 to 15/test; not zero-waste; 45 to 90 min
imec photonic chip (Belgium)	Near-IR integrated photonics	R&D / platform technology	Near-IR not mid-IR fingerprint region; R&D stage; no clinical system; different sensitivity profile
IRsweep (Switzerland)	Dual-comb spectroscopy	Research / industrial	No clinical deployment; no LMIC design; high instrument cost; no integrated sample handling

Technology Readiness and Development Roadmap

ARKAS is currently at TRL 2–3 (proof of concept / technology formulation). The development pathway has been designed as a dual-track:

- Desktop prototype (TRL 4–5): 18–24 months. Full spectral performance validation on clinical isolates. Clinical partnerships with AIIMS and ICMR for sample access.
- Handheld POC device (TRL 6–7): 36–48 months. Miniaturised version with chipset, regulatory submissions (CDSCO India, CE-IVD Europe), field validation in PHC settings.

The platform's IP position includes provisional patent claims across **6 distinct invention areas.**

India Policy and Funding Context

National Programmes Driving Demand

The following national programmes create direct demand for ultrafast diagnostics at primary and secondary care level:

Programme	Diagnostic Need	Technology Opportunity
NTEP (National TB Elimination Programme)	Rapid TB diagnosis, drug-resistance testing	GeneXpert, Truenat (deployed); LAMP scaling; ARKAS (future - direct sputum, no prep)
NACO (HIV/AIDS)	CD4 counting, viral load, early infant diagnosis	PIMA CD4 (deployed); electrochemical VL; microfluidic EID panels
NVBDCP (Vector-borne diseases)	Malaria, dengue, chikungunya rapid diagnosis	LFA (deployed); LAMP; CRISPR differentiation (Plasmodium species)
Ayushman Bharat / AB-HWC	Broad infectious disease diagnosis at HWC level	LFA, LAMP, ARKAS - all relevant to sub-district deployment
NAP-AMR (National AMR Action Plan)	Antibiotic resistance surveillance, rational prescribing	Molecular AST, ARKAS phenotypic resistance - central to NAP-AMR objectives
Pradhan Mantri Swasthya Suraksha Yojana	Strengthening tertiary care diagnostics	Microfluidic panels, syndromic testing, molecular platforms

Funding and Innovation Bodies

- BIRAC (Biotechnology Industry Research Assistance Council): Primary grant body for diagnostics startups; BIPP, BIG, and SIIP schemes relevant
- DBT (Department of Biotechnology): Funds diagnostic R&D, international collaborations, and clinical validation studies
- ICMR: Provides regulatory evaluation support, reference lab access, and co-development partnerships for novel diagnostics
- DPIIT Startup India: Tax benefits, IP fast-tracking, and procurement advantages for recognised startups
- National Health Authority: Procurement pathways under Ayushman Bharat for WHO-prequalified and CDSCO-approved diagnostics
- Wellcome Trust / GCGH: International funding for diagnostics addressing AMR, TB, and neglected tropical diseases; relevant for ARKAS development pathway

Conclusion

The ultrafast diagnostics landscape in 2026 is characterised by a clear stratification. At one end, lateral flow assays and cartridge molecular platforms are deployed at scale, delivering meaningful clinical value but constrained by sensitivity, cost, or time-to-result limitations. In the middle, LAMP, CRISPR, electrochemical biosensors, and microfluidic platforms are scaling commercially, offering improved performance in defined settings.

At the frontier, mid-infrared spectroscopy with AI exemplified by the ARKAS platform represents a qualitative leap in what diagnostics can deliver: label-free, reagent-free, sub-10-minute, multiplex identification of pathogens and resistance patterns directly from clinical samples, deployable at last-mile settings in India and globally.

The case for investing in this frontier is not speculative. The clinical need is established, the policy framework (NAP-AMR, NTEP, Ayushman Bharat) creates procurement demand, the convergence of photonics, microfluidics, and AI has reached the point where integration is feasible, and the Indian clinical ecosystem through AIIMS, ICMR, and national disease programmes provides the validation infrastructure needed to take a platform from prototype to regulatory clearance.

"The question for funders and health system leaders is not whether ultrafast, reagent-free, multiplex diagnostics will exist; they will. The question is whether India will develop them domestically, deploy them at scale first, and export the platform globally, or import that capability from elsewhere at a later date and a higher cost." – Dr. Giridara Gopal Parameswaran.

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