

Frost & Sullivan Insights : Point of Care Testing (POCT) Landscape

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FOREWORD

In the wake of the COVID-19 pandemic, which has starkly illuminated the vulnerabilities of healthcare systems worldwide, the imperative for innovation in healthcare delivery has never been more pressing. In this era of rapid technological advancement, where efficiency, accuracy, and accessibility are paramount, the concept of point-of-care testing (POCT) emerges as a beacon of hope, fundamentally reshaping the landscape of disease diagnosis and management.

POCT represents a transformative approach wherein diagnostic testing is conducted in close proximity to the patient, enabling timely interventions that can significantly alter patient outcomes. By circumventing traditional pathways and facilitating immediate testing, POCT facilitates early diagnosis and treatment initiation, thereby mitigating the devastating consequences of delayed intervention.

Moreover, POCT has emerged as a potent tool in addressing the pervasive challenges of inadequate health infrastructure, particularly in resource-constrained settings such as rural India. By leveraging technology to improve the efficiency of disease testing and diagnosis, POCT transcends geographical barriers and enhances the accessibility of healthcare services to underserved populations. Its cost-effectiveness further underscores its potential to democratize healthcare, ensuring that every individual, regardless of socioeconomic status, can avail themselves of timely and accurate diagnostic solutions.

As we embark on this journey through the dynamic landscape of POCT, let us embrace the spirit of innovation, collaboration, and continuous learning. Together, let us harness the transformative power of point-of-care testing to revolutionize healthcare delivery, improve health outcomes, and ultimately, enrich lives.



Dr. Naveen Nishchal
Founder and Chairman,
Voice of Healthcare

The Indian Healthcare Industry is going through massive reforms and diagnostics is also seeing profound changes. The consumer is now playing a bigger role in the care ecosystem and Point of Care Testing (POCT) will see huge growth in coming years. With the expected expansion in decentralized testing, the direct-to-consumer test-focused business model will gain prominence. Companies will focus more on home POCTs to create new market segments.

As the market moves toward more complex at-home tests like cancer screening and organ function tests, patients will need support for interpreting the results and determining the next steps.

To address these needs, companies will need to shift from a product-focused mindset toward a service-driven culture.

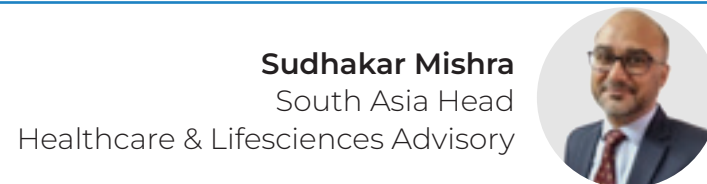
In the years to come POCT will play a bigger role in care continuum moving beyond risk assessment & preventive measures. It will add significant value into risk monitoring, diagnosis, and therapy monitoring.

It will extend further to antimicrobial resistance (AMR), routine testing, oncology, newborn screening, and neurology.

There are huge technological uptakes driving innovation within POCT industry. Innovations in RT-PCR, droplet digital PCR, micro-mass spectrometry, AI integrations, 3D printing, wearable POCT and many other new age technologies are driving POCT industry northwards.

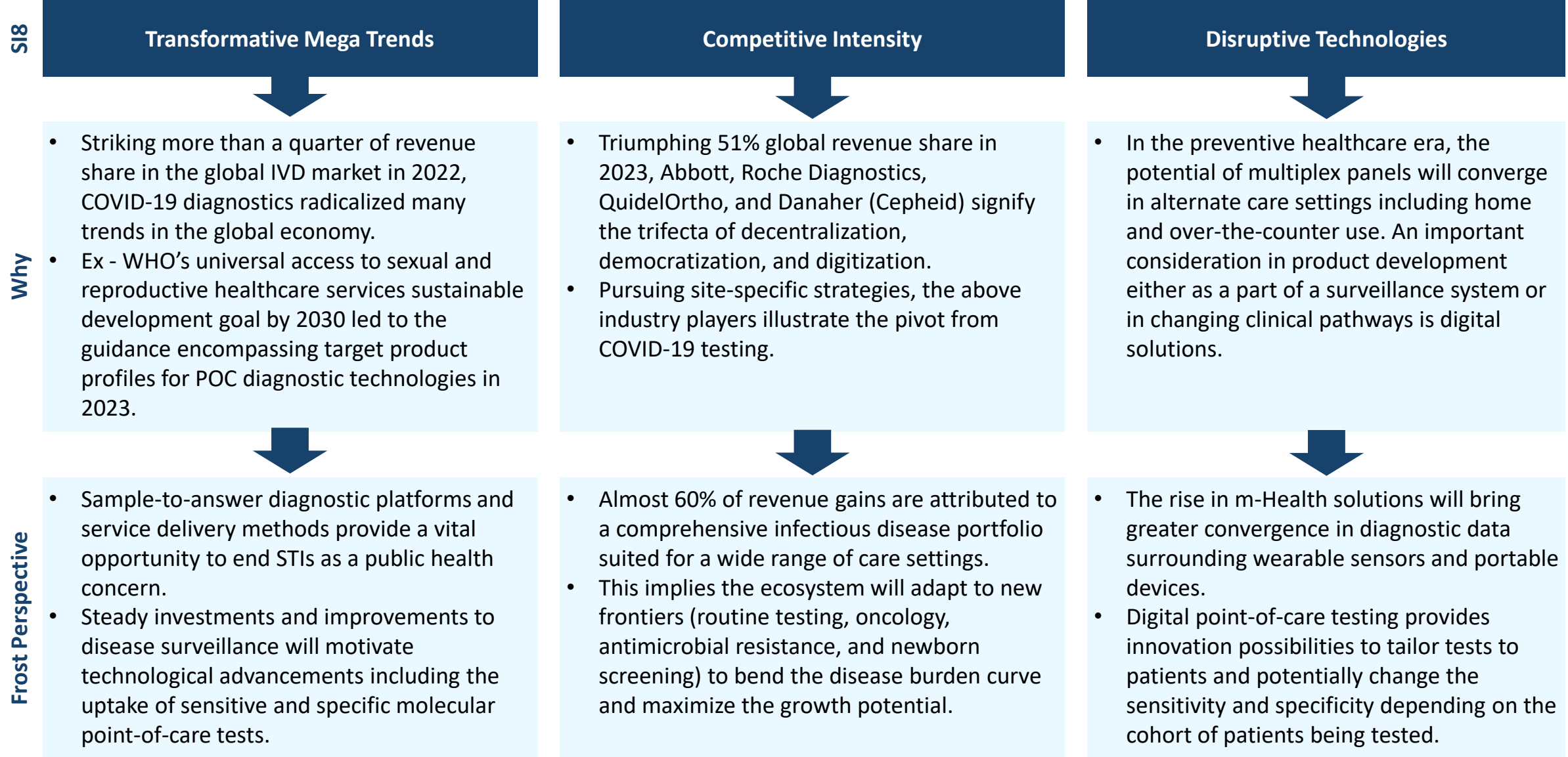
In India, POCT is helping to increase the access to care in remote areas with limited infrastructure and trained healthcare resources. The POCT solutions are turning out to be a cost-effective alternative and accelerate test turn-around time. There are many innovative POCT solutions from multi-nationals and domestic companies in the areas of diabetes, cardiology, oncology, infectious diseases and beyond.

We believe that POCT will be a game changer in making diagnosis faster, better, and more accurate in the years to come. POCT has a bright future and will make Indian and global healthcare eco-system smarter by 2030.



Sudhakar Mishra
South Asia Head
Healthcare & Lifesciences Advisory

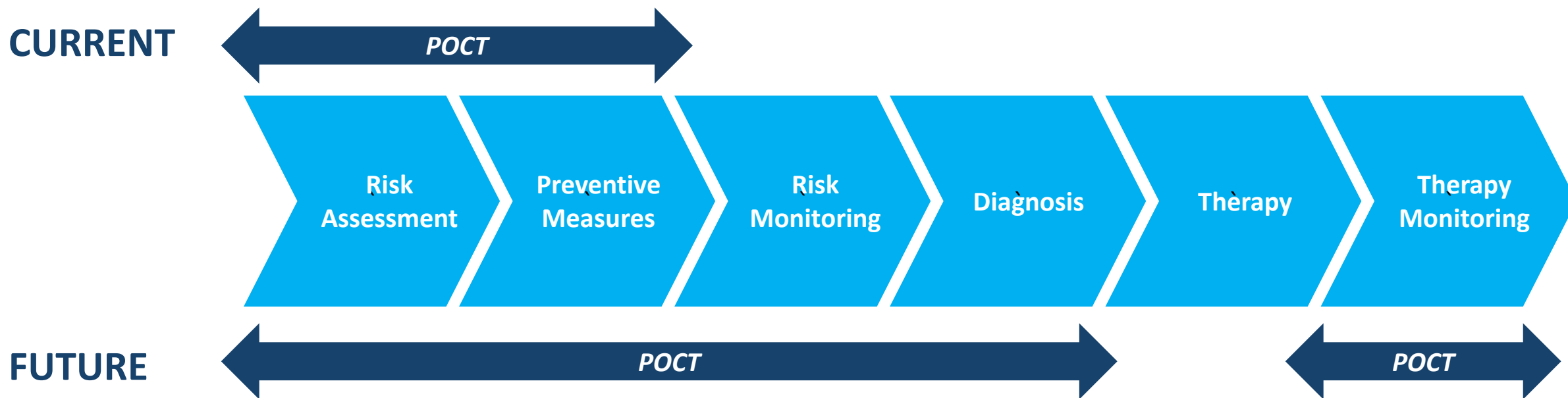
FROST & SULLIVAN ANALYSIS : THE IMPACT OF THE TOP 3 STRATEGIC IMPERATIVES ON THE POINT-OF-CARE TESTING INDUSTRY



Note: STi – Sexually Transmitted Infections, WHO – World Health Organization IVD - In vitro diagnostics, POC –Point-of-Care, POCT – Point-of-Care Testing

Source: Frost & Sullivan

FUTURE OF POCT IN CARE CONTINUUM – GLOBAL LANDSCAPE



- Extension to antimicrobial resistance (AMR), routine testing, oncology, newborn screening, and neurology.
- Adaptability to multiplexing harmonizing and aggregating lab and non-lab diagnostic data streams for analogous tests.
- AI/ML-enabled device software functions growing digital diagnostics revenue by protecting and promoting public health, preventing diseases, and improving outcomes.

*This list is not exhaustive.

EHR - Electronic Health Records, CDSS: Clinical decision support systems


Source: Frost & Sullivan


POCT TESTS ACROSS DIFFERENT THERAPY AREAS

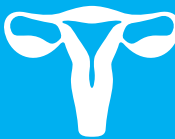
Tests in Common Use


Available but variable use


Emerging and future potential


Cardiovascular 	Brain natriuretic peptide (BNP) test (heart failure)
	PT/INR test (clotting disorder/VTE)
	Troponin test (heart attack)
	D-dimer test (clotting disorder/DVT)
	Stroke Markers


Infectious Disease 	RSV
	Influenza
	Streptococcus/Step-throat
	COVID-19 test (ART)
	C-reactive protein (CRP) test
	Procalcitonin (PCT) test
	Microbiology
	Sepsis Markers

STIS/GYN-OB 	HIV
	Hepatitis B
	Hepatitis C
	Pregnancy
	Streptococcus B

Routine Testing 	Blood gas analysis
	Hemoglobin
	Lipid profile
	Traumatic brain injury (TBI) test
	Magnesium
	Oncology Testing
	Newborn Screening

Routine Testing (Others) 	Coagulation for hemostasis (TEG)
	Platelet function testing
	Coagulation for transfusion
	Complete Blood Count

Gastrointestinal/Colorectal 	Clostridium difficile
	Faecal occult blood test







Endocrine (Diabetes) 	Rapid blood glucose test
	HbA1c test
	Ketone test

Source: Frost & Sullivan

COMPETITOR MATRIX - THERAPY AREAS

■ Clear Technology Leader
 ■ Developed/Developing Portfolio and offerings
 ■ Limited Portfolio and offerings
 ■ Absent or Lagging

Abbott and Roche Diagnostics demonstrate a comprehensive portfolio across therapy areas. Siemens Healthineers and QuidelOrtho demonstrate strength in immunochemistry. Cepheid’s portfolio incorporates molecular diagnostics and Sysmex illustrates a first-mover advantage in POC antimicrobial susceptibility testing.

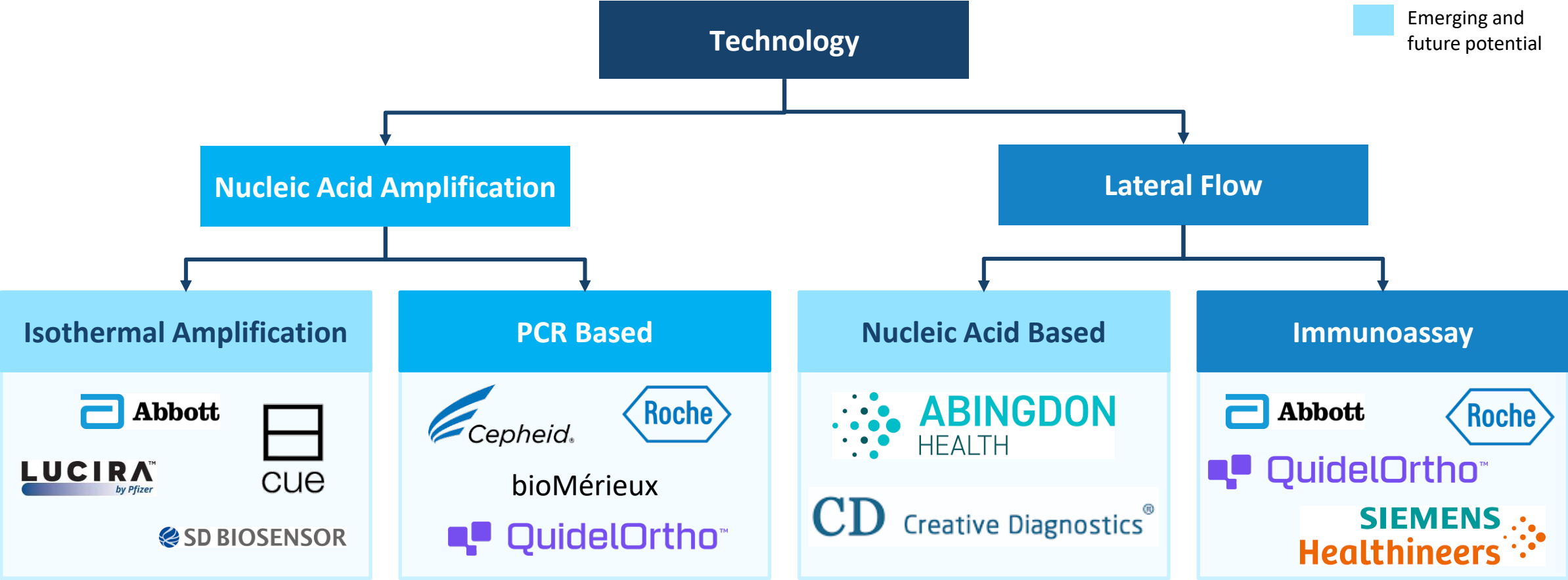
POCT Industry: Competitor Matrix for Therapy Area Portfolio Assessment, Global, 2023						
Selected Competitor	 Infectious	 Cardiovascular	 Diabetes	 Oncology	 Routine testing	 AMR/AST
Abbott	Clear Technology Leader	Clear Technology Leader	Clear Technology Leader	Absent or Lagging	Limited Portfolio and offerings	Absent or Lagging
Roche Diagnostics	Clear Technology Leader	Clear Technology Leader	Limited Portfolio and offerings	Absent or Lagging	Clear Technology Leader	Absent or Lagging
QuidelOrtho	Clear Technology Leader	Clear Technology Leader	Absent or Lagging	Limited Portfolio and offerings	Absent or Lagging	Absent or Lagging
Danaher (Cepheid)	Clear Technology Leader	Absent or Lagging	Absent or Lagging	Developed/Developing Portfolio and offerings	Absent or Lagging	Limited Portfolio and offerings
Siemens Healthineers	Limited Portfolio and offerings	Clear Technology Leader	Clear Technology Leader	Absent or Lagging	Clear Technology Leader	Absent or Lagging
bioMérieux	Clear Technology Leader	Limited Portfolio and offerings	Absent or Lagging	Absent or Lagging	Absent or Lagging	Absent or Lagging
Qiagen	Clear Technology Leader	Developed/Developing Portfolio and offerings	Absent or Lagging	Limited Portfolio and offerings	Absent or Lagging	Absent or Lagging
Sysmex	Limited Portfolio and offerings	Absent or Lagging	Limited Portfolio and offerings	Absent or Lagging	Limited Portfolio and offerings	Limited Portfolio and offerings
SD Biosensor	Clear Technology Leader	Absent or Lagging	Absent or Lagging	Absent or Lagging	Absent or Lagging	Absent or Lagging
Cue health	Limited Portfolio and offerings	Limited Portfolio and offerings	Limited Portfolio and offerings	Limited Portfolio and offerings	Clear Technology Leader	Absent or Lagging
BD	Limited Portfolio and offerings	Absent or Lagging	Absent or Lagging	Absent or Lagging	Absent or Lagging	Absent or Lagging
LumiraDx	Limited Portfolio and offerings	Limited Portfolio and offerings	Limited Portfolio and offerings	Absent or Lagging	Absent or Lagging	Absent or Lagging
Thermo Fisher Scientific (Mesa Biotech)	Limited Portfolio and offerings	Absent or Lagging	Absent or Lagging	Absent or Lagging	Absent or Lagging	Absent or Lagging

Note: Infectious disease include GI pathogens

Source: Frost & Sullivan

COMPETITOR MATRIX (CONTINUED) – TECHNOLOGY MAPPING

- Matured Industry
- Growing Industry
- Emerging and future potential



Key Opportunity Areas

-  AMR
-  STI
-  Oncology
-  Neonatal management

Key Opportunity Areas

-  AMR
-  Routine Testing
-  Newborn screening

Note: The competitor list is not exhaustive

Source: Frost & Sullivan

CURRENT TECHNOLOGICAL TRENDS IN POCT

- Traditional Technology: PCR – Extraction, amplification, detection
- Innovative Technologies: RT-PCR, droplet digital PCR, thermostatic amplification, and CRISPR/Cas, multiplexing multiple tests
- Types: Benchtop (wall plug) / Handheld (battery operated)

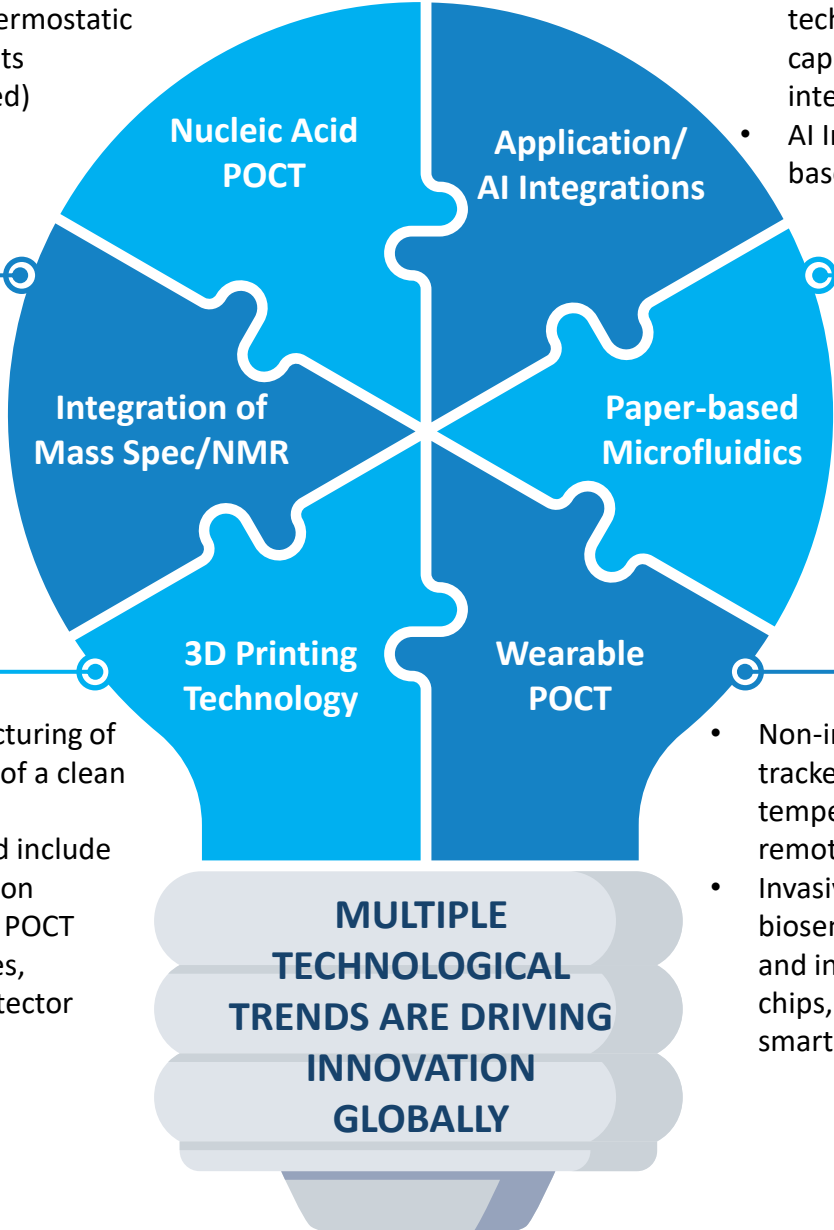
- Application Integrations: Application integrations with POCT technology will enable improved storage and communication capabilities, built-in flash and camera for optical sensing, integration with telemedicine and cloud-based services
- AI Integrations: AI integrations with POCTs will enable guidance based on clinical symptoms, examination, and medical history

- There is a significant momentum towards integration of analytical techniques with POCT analysis. Recent advancements in ionization and micro-mass spectrometry have enabled the practical implementation of Point-of-Care Mass Spectrometry (POC-MS) analysis

- Traditional Technologies: Paper-based microfluidic analysis device (μ PAD)
- Innovative Technologies: SHERLOCK technology for the detection of target DNA or RNA

- 3D printing is a rapid and cost-effective tool for manufacturing of various analytical instruments without the requirement of a clean room
- Commonly used 3D printing technologies in the IVD field include stereolithography, digital light projection, fused deposition modelling, and inkjet printing. Examples of 3D printable POCT device components include sample pretreatment devices, microfluidic reagents, blood mixers, fluid drive units, detector adapters, housing units, or entire microfluidic devices.

- Non-invasive: Includes devices like smartwatches and exercise trackers for monitoring parameters like heart rate, body temperature, and blood pressure, enabling sports healthcare and remote patient monitoring
- Invasive and Hybrid: Application in medical settings and utilizes biosensors, electronics, and microchips for real-time monitoring and intervention. Examples include blood glucose monitoring chips, healing chips, implantable contraceptive devices, and 3D smart organs.



POC TESTING IN INDIA

Increased Accessibility with decentralized testing

POCT offers huge potential in India particularly in remote locations and villages where the healthcare infrastructure penetration is low. Since, POCT can be used in simple setting, where medical infrastructure is lacking, it can aid in increasing accessibility to healthcare in remote locations

Enables testing with limited resources for HCPs

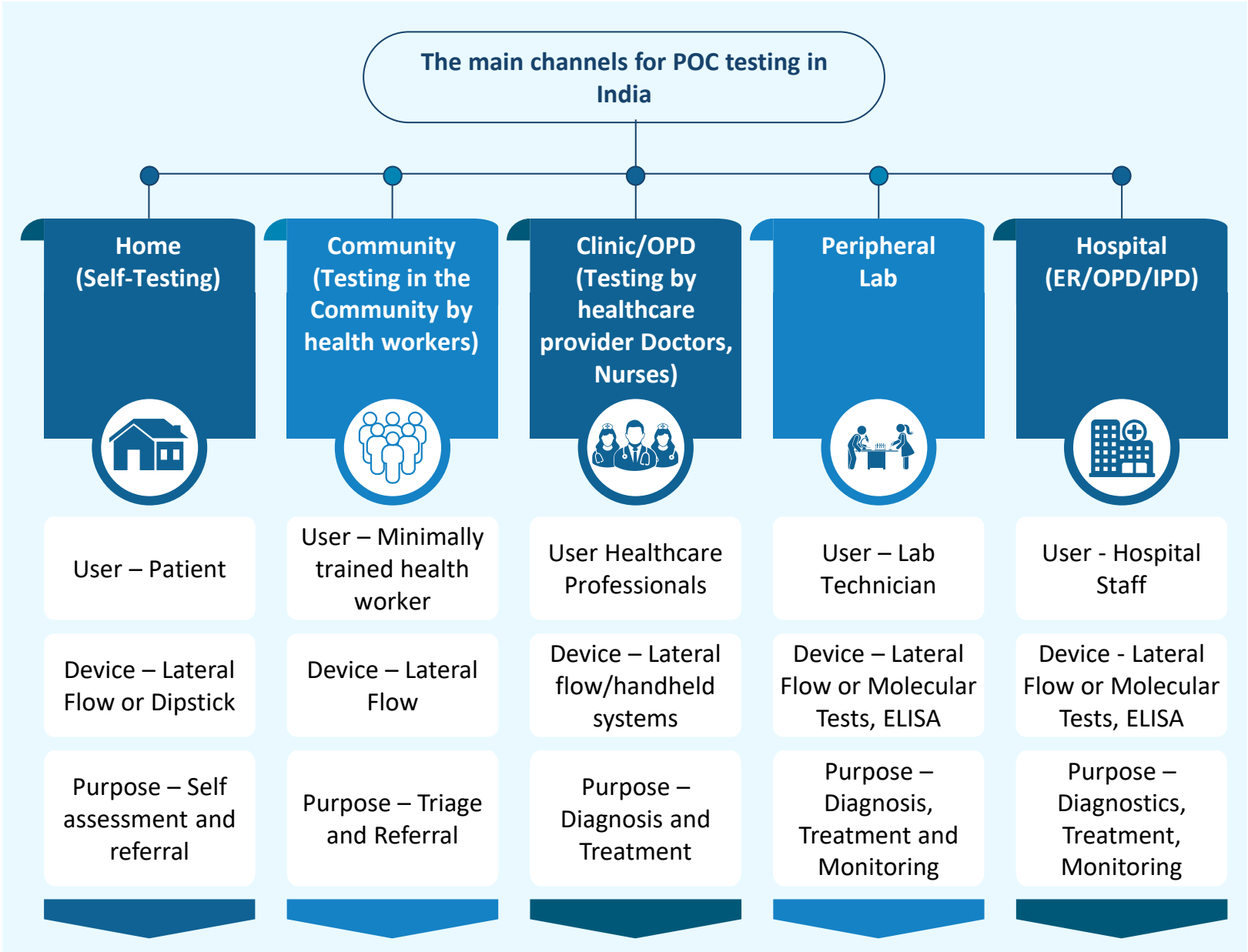
India faces a substantial resource deficit of more than 4 million healthcare workers. Approximately 60% of the current workforce is concentrated in urban regions, while 70% of the Indian population resides in rural areas. Since POCT does not require highly trained HCP to conduct the tests, it can still enable testing in places where medical talent is limited

Cost-effective solutions

It provides an economically viable in comparison to high end expensive clinical diagnostics technologies and equipment




Reduced TAT

It enables rapid testing with faster TAT, and rapid initiation of therapy in comparison regular testing








POPULAR POCT DEVICES IN THE INDIAN HEALTHCARE SYSTEM (1/2)

POCT devices are in the nascent stage in India and offer huge potential for growth, with a large patient population residing in remote areas

Application	Type of analysis	POC device used	Principle or mechanism applied in the device	Portability	Manufacturer
Diabetes 	Glycated haemoglobin analysis (HbA1c)	DCA Vantage analyzer	HbA1c: monoclonal antibody agglutination reaction	Benchtop POC	Siemens Healthcare
	Glycated haemoglobin analysis (HbA1c)	Afinion HbA1c	HbA1c: monoclonal antibody agglutination reaction	Benchtop POC	Abbot India Limited
	Total glucose	Cholestech LDX analyzer	Enzymatic method using glucose oxidase	Portable, lightweight	Abbot India Limited
	Glucose	i-STAT Handheld using CG8+ cartridge	Sensitive biosensors on a silicon chip	Handheld	Abbot India Limited
	Glucose	Cobas b 221 system	Electrochemical detection of glucose	Benchtop POC	Roche Diagnostics India Pvt. Ltd.
	Glucose	HemoCue Glucose 201+ system	Micro-cuvette technology	Handheld	HemoCue India
	Glycated haemoglobin analysis (HbA1c)	HemoCue HbA1c 501	–	Benchtop POC	HemoCue India
Cardiac 	Troponin analysis	Startus CS 200 Acute Care Troponin analyzer	–	Benchtop POC	Siemens Healthcare
	Several analytes: Troponin T, proBNP, D-Dimer, CK-MB, M Myoglobin	Cobas h 232 POC System	Quantitative detection of analytes	Handheld	Roche Diagnostics India Pvt. Ltd.
	Troponin T	Roche cardiac troponin T sensitive test (visual)	Qualitative detection through lateral flow immunoassay	Handheld strip	Roche Diagnostics India Pvt. Ltd.
	Total cholesterol, triglycerides,	Cholestech LDX analyzer	Enzymatic method and solid phase technology	Portable, lightweight	Abbot India Limited
	Cardiac markers such as CK-MB, BNP	i-STAT Handheld using CG8+ cartridge	Sensitive biosensors on a silicon chip	Handheld	Abbot India Limited
Coagulation 	Prothrombin time/international normalized ratio (PT/INR)	Xprecia stride coagulation analyzer	electrochemical detection using reagent test strips	Handheld	Siemens Healthcare
	PT/INR, activated clotting time (ACT) kaolin, ACT celite	i-STAT Handheld using CG8+ cartridge	Sensitive biosensors on a silicon chip	Handheld	Abbot India Limited
	PT and activated partial prothrombin time (aPTT)	CoaguCheck Pro II	Amperometric (electrochemical) determination	Handheld	Roche Diagnostics India Pvt. Ltd.
	PT/INR	CoaguCheck XS system	Amperometric (electrochemical) determination	Handheld	Roche Diagnostics India Pvt. Ltd.

Note: The above list is not comprehensive

POPULAR POCT DEVICES IN THE INDIAN HEALTHCARE SYSTEM (2/2)

Application	Type of analysis	POC device used	Principle or mechanism applied in the device	Portability	Manufacturer
Haematology 	Hemoglobin and whole blood CBS	HemoCue Hb 201+ system	–	Handheld	HemoCue India
	Low levels of haemoglobin	HemoCue Plasma/Low Hb system	Micro-cuvette technology	Handheld	HemoCue India
	Hemoglobin	I-STAT Handheld using CG8+ cartridge	Sensitive biosensors on a silicon chip	Handheld	Abbot India Limited
Oncology 	Nuclear matrix protein (NMP22) in urine	Alere NMP22 Bladdercheck	Lateral flow immunochromatographic strip (colloidal gold nanoparticles)	Handheld	Abbot India Limited
	Head domain of nuclear mitotic apparatus protein (NuMA)	Alere NMP22 test	Enzyme immunoassay using 96 well plate	Portable (test kit)	Abbot India Limited
Urinalysis 	Albumin, bilirubin, creatinine, glucose, ketone, leukocytes, nitrite, pH, protein, specific gravity, and urobilinogen	Clinitek status+ analyzer	–	Benchtop	Siemens Healthcare
	Leukocyte, Nitrite, Protein, Blood, Glucose, Ketone, Bilirubin, Urobilinogen, pH, Specific Gravity, Creatinine, and Protein-to-Creatinine Ratio	Clinitek Advantus Urine Chemistry Analyzer	–	Benchtop	Siemens Healthcare
	Urea nitrogen/Urea, Creatinine	I-STAT Handheld using CHEM8+ cartridge	Sensitive biosensors on a silicon chip	Handheld	Abbot India Limited
Infectious diseases 	Antibodies (IgG and IgM) to dengue virus in human blood	Panbio Dengue duo cassette	Immunochromatographic assay	Portable	Abbot India Limited
	Dengue virus Ns1 antigen and antibodies to dengue virus	SD Biotec Dengue duo	Immunochromatographic assay	Portable	Abbot India Limited
	E. coli- Shiga toxin from fecal samples	Shiga Toxin Quik Chek	Immunochromatographic assay	Portable	Abbot India Limited
	HIV- All the groups of HIV-1/2	Alere determine HIV-1/2	Lateral flow immunoassay (colloidal gold nanoparticles)	Portable	Abbot India Limited
Rapid drug screening 	Drug screening and detection in the oral fluid at workplace and vehicles	SoToxa – Mobile test system	–	Portable	Abbot India Limited

Note: The above list is not comprehensive

SOURCES & REFERENCES

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3. Source: Point-of-Care Testing for Infectious Diseases: Diversity, Complexity, and Barriers in Low- And Middle-Income Countries
4. Current status of point-of-care diagnostic devices in the Indian healthcare system with an update on COVID-19 pandemic
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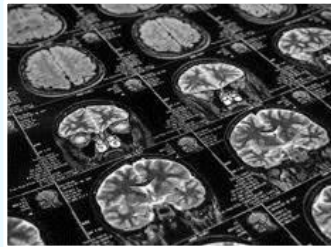
FROST & SULLIVAN HAS DEEP UNDERSTANDING OF MULTIPLE HEALTHCARE SECTORS & SUPPORTED THOUSANDS OF COMPANY IN THEIR GROWTH JOURNEY

Next Generation Diagnostics



- Clinical Chemistry
- Molecular Diagnostics
- Genomics
- POCT
- Pathology
- Analytical Tools
- Research Tools
- Consumables
- Digital Pathology

Medical Imaging



- PACS
- MRI
- Cardiac Imaging
- CT
- Ultrasound
- PET
- Nuclear Imaging
- Radiology
- Imaging Agents
- Imaging Software
- Digital Imaging

Pharmaceuticals And Biotechnology



- Clinical Trials
- CROs
- CDMOs
- Drugs
- Biologics
- Biosimilar
- Drug Delivery
- Emerging Therapies
- Pipeline Analysis
- Vaccines
- Antibiotics

Medical Devices & Patient Monitoring



- Cardiovascular Devices
- Orthopedic Devices
- Home Care
- Infection Control Products
- Neurosurgery
- Renal Care
- Endoscopy
- Oncology
- Diabetes
- Wound Management
- Patient Monitoring

Healthcare Delivery



- Hospital Services
- Primary care
- Diagnostic centers
- Medical education
- Ambulatory Services
- Home Care
- Pharmacies

Digital Health



- EMR
- HIS, Clinical Information Systems
- Telemedicine
- Life sciences IT
- Virtual Care
- Population Health Management
- CDSS
- MHealth



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HOW CAN FROST & SULLIVAN SUPPORT YOU?



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