FIND

ROUNDTABLE ON ACCESS TO MULTI-DISEASE MOLECULAR DIAGNOSTICS – June 2nd, 2022

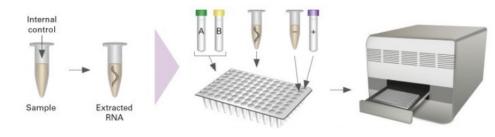
Landscape and pipeline for multidisease molecular diagnostic platforms

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MOLECULAR DX: EXISTING LANDSCAPE

LABORATORY BASED TESTS:



COGS

required

0.5 to 3 USD

Extraction unit and thermocycler (mostly) Instruments Integrated large system existing

Intended use & Confirmatory test for large centralized settings testing units and hospitals

> 550

Total tests in FIND landscape

80%

Open source platforms

POC MOLECULAR DIAGNOSTICS (MDx)







COGS	2 US
Instruments required	Singl Instru
Intended use &	Scree

SD to ~ 50 USD

le instruments and cartridge (mostly) uments free solutions exists

settings

ening test or fast confirmatory test for decentralized units down to primary centers

145 Total POC MDx platforms in FIND landscape

75

New POC MDx Launched in total post covid

3

Instruments free platform in the market

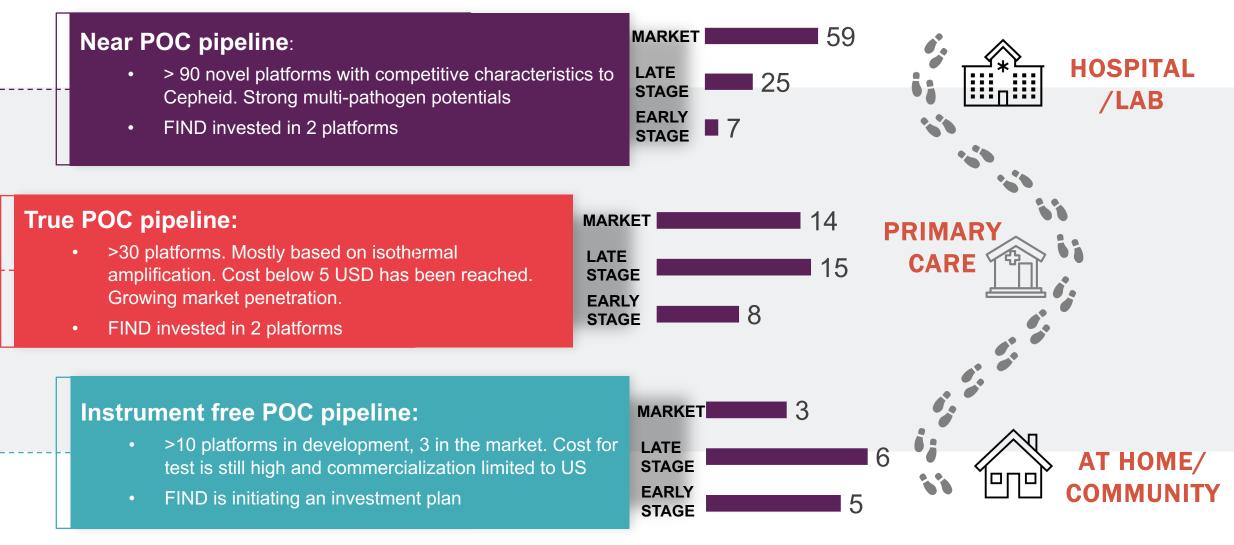


USER SETTINGS AND HEALTHCARE LEVEL

		Level 0 (L0) - Con	nmunity	Level 1 (L1) - Prima	ary Care	Level 2 (L	2) – District Hospital Lab	
	User setting· Community outreach · Home testingLab infrastructure· No mains power · No water · No lab equipment · No temperature control		ach	Primary care facility		Near-patient laboratoryReferral hospital laboratory		
			 No mains power (unreliable) Minimal lab equipment (may not support cold chain) BSL-1 containment 		 Mains power (may be intermittent) Basic lab equipment (biosafety cabinet, centrifuge, calibrated pipets, fridge) BSL-2/1 containment 			
Model 1: Samples to L2	2		J			->(Confirmatory NAT	>2 weeks dela sample spoila loss-to-follow-
Model 2: Patients to L2			1			->-(Confirmatory NAT	no-shows, los to-follow-up
Model 3: Screen & Conf	firm	RDT Scr	eening	RDT S	creening		Confirmatory NAT	Inaccurate screening, los to-follow-up
Model 4: MDX POC-bas	sed	High perfo Scree		<u> </u>	rformance confirmatory		Confirmatory NAT	
		free POC MDx		blex / low-plex othermal to high sensitivity	True POC MDx		Multiplex PCR High sensitivity	3



POINT OF CARE MOLECULAR DIAGNOSTICS: A STRONG PIPELINE



POINT OF CARE MOLECULAR DIAGNOSTICS: OPTIONS ARE AVAILABLE FOR LMICS

STANDARD M10

Near POC pipeline:

SDB M10







VISBY-COVID19

SENSE-VEROS





LUCIRA-COVID19





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BIONEER IRON Q PCR

QLIFE - EGOO THERMO - ACCULA

 \rightarrow FIND



Courses.

CEPHEID GENEXPERT



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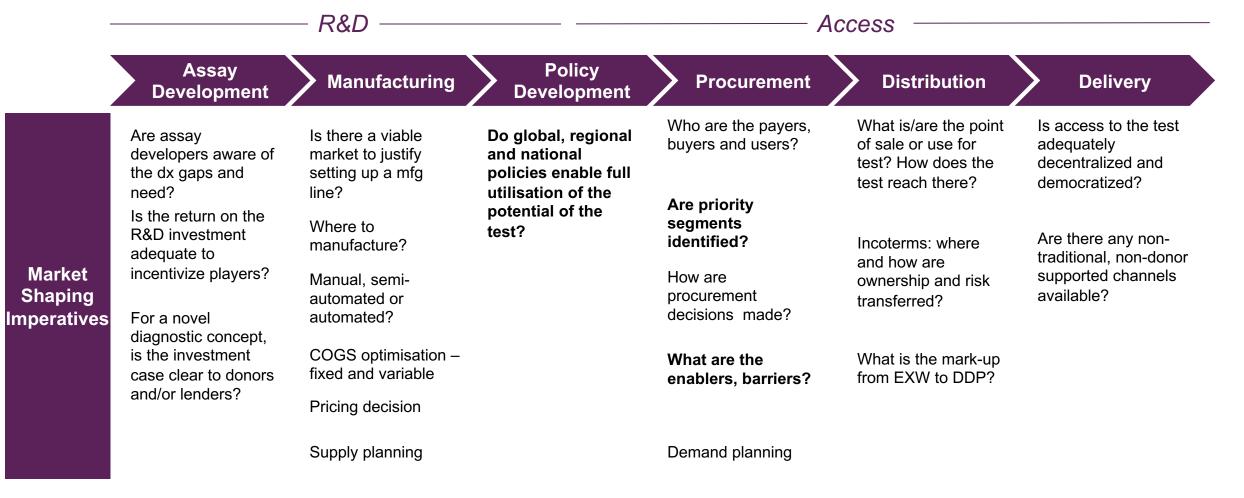




PLUSLIFE-DOCK



What are the key questions to answer that support product market entry? Diagnostic Product Lifecycle



Ensure availability of easy to use, quality and affordable diagnostics for patients in all healthcare settings through successful and sustainable commercialization

What are the main barriers that may impact the adoption of the platform? What can FIND and other partners do to overcome these barriers?



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Where and how should the product be rolled out?

L2 setting is the most accessible entry point. In some countries, it FIND >>> may make more sense to start with the private sector

Healthcare level setting

Private vs. Public

			Public Private	
			L2 network ¹	Conclusion
L3	Limited need for POC PCR. Already have advanced MDx platforms, with higher throughput	📀 Brazil	15% 85% 70K	L2, private, potentially incl. pharmacies
		🚩 DRC	NA 390	L2, public, urban areas
L2	Ideal shorter-term setting as there is the	Ethiopia	NA 390	L2, private, urban areas
	infrastructure needed to conduct the tests, and enough capacity to cover most of the areas by working with a hub and spoke model	岸 Kenya	NA 266	L2, public
		Nigeria	75% 25% 4K	L2, public, potentially in mobile surveillance too
	High impact setting, but low feasibility setting. However, infrastructure (incl. capacity) is poor, and most countries already	India	50% 50% 83K	L2, public, partner up with ICMR and potentially with a local manufacturer
	work with rapid tests in L1 settings (serology), as they are cheaper, faster, and easier to conduct. If there is a severe case, they refer to	Indonesia	NA	L2 and possibly L1, public. 1-day approval for COVID-19 equipment
Others	L2s, where a more sensitive test can be used) South Africa	a 90% 10% 5K	L2, public, with potential expansion to pharmacies
	Settings as pharmacies can be highly effective in UMICs (e.g., Brazil, South Africa)	Thailand	80% 20% 1K	L2, private (little donor funding)
	Mobile surveillance units can also be an opportunity specially during the COVID-19 pandemic	★ Vietnam	95% 5% 1K	L2, public
			100%	



