G A D Humanity Tested

What does COVIOS Ag offer?

Introducing a new, high quality COVID-19 antigen test from Global Access Diagnostics

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Global Access Diagnostics

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Company Introduction

GAD Humanity Tested

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COVID-19 has exposed the difficulties lower- and middle-income countries (LMICs) face in obtaining rapid diagnostic tests (RDTs). With global demand outstripping supply, poorer countries often find themselves at the back of the queue. GAD was founded to address this issue.

We are…

- a **social enterprise**, spun out of Mologic in 2020 with the goal of **building access to reliable, affordable RDTs in LMICs**.
- funded through the **Bill and Melinda Gates Foundation**, **Foundation for Innovative New Diagnostics** and **Soros Economic Development Fund**. Longer term, GAD will be wholly owned by the charity 'Global Access Health'.
- **Re-invested profits** generated back into the service of our mission
- granted **perpetual, royalty-free access to IP** generated by Mologic to develop improved RDT platforms and tests for neglected endemic and epidemic infections for LMICs.
- expanding **manufacturing capacity** to make >**200 million RDTs** by the end of **2021.**
- working to **support the development of diagnostic manufacturing capacity directly within LMICs** and build financially sustainable entities that are not profit driven and responsive to local needs.
- **a developer-agnostic manufacturing platform.** We aim to become an active partner to the donor, philanthropic and LMIC community to help address RDT innovation and supply gaps.

See Financial Times coverage here

*To find out more, contact us on **info@globalaccessdiagnostics.com***

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The world’s largest social enterprise for diagnostics

BILL & MELINDA GATES foundation

OPEN SOCIETY FOUNDATIONS

History of Global Access Diagnostics

1988 Clearblue pregnancy test developed as first commercial lateral flow device (LFD). Prof. Paul Davis named one of three inventors.

2003 Paul Davis his son Mark established Mologic, an R&D company focused on LFD technology.

2016 Investment from BMGF establishes CARD laboratory at Mologic, dedicated to innovation for epidemic and neglected diseases.

2020 Global Access Diagnostics (GAD) spun out of Mologic as a social enterprise LFD manufacutring platform focused on the needs of low and middle-income countries. GAD is funded by BMGF, FIND, Soros Economic Development Fund (SEDF) at the Open Society Foundations, and UK government.

2021 Mologic was bought by Global Access Health (GAH). The deal was funded by a group of impact investors led by SEDF. GAH is a not-for-profit holding company that also owns GAD.

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Our North Star:

The best tests to the most people at the lowest cost

What differentiates Global Access Diagnostics?

1. We are developer agnostic & LMIC focused

We have a strong internal product pipeline, but we are also happy to manufacture tests for other developers, when these meet our objectives of quality, relevance and affordability for low and middle-income countries (LMICs).

2. We are committed to transparent pricing

For LMICs, we operate on a COGS+ basis, meaning that our objective is to only cover costs and a small margin for sustainability, rather than maximizing profit.

3. We support distributed manufacture

We are working with partners in several LMICs to move the center of gravity for diagnostic test manufacturing to those regions.

4. We believe in innovation

We have projects ongoing not only to innovate in the science, but also in areas such as LFD manufacturing technology, eco-appropriate materials and data enablement.

COVIOS Rapid Antigen Test product overview

Product Features of GAD COVIOS Ag

COVID 19 RAPID ANTIGEN TEST

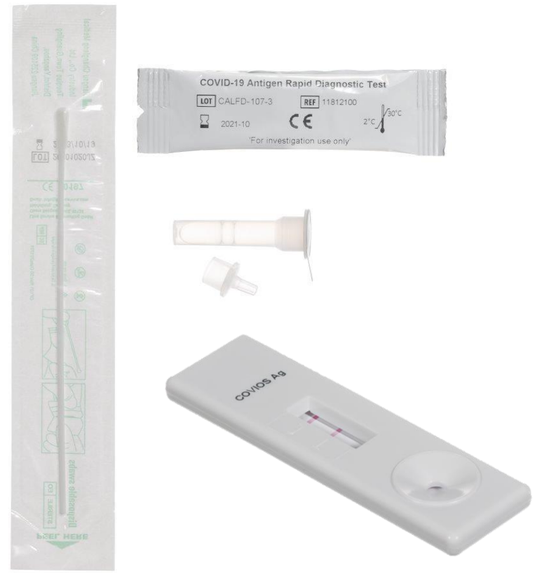
Global Access Diagnostics

Feature	Details
Brand name	• COVIOS

Intended use	• Point of care LFA for qualitative detection of SARS-CoV-2 Ag
	• Individuals with symptoms during:
	  • Acute phase of infection (no cap on days included)
	  • Pre-symptomatic or asymptomatic but suspected of COVID-19 by provider

Clinical data	• Sensitivity: 90.6% (85.6% to 94.0%) • Specificity: 100.0% (99.2% to 100.0%)
Detection of variants	• Reliable detection of the following variants: • B1.1.7 in UK, B1.351 in South Africa, and P1 in Brazil
Limit of detection	• 2.5 x 10^2 pfu/ml
Sample type	• Nasal swabs
Conditions	• Stable storage at room temperature (2-30˚C)
Shelf-life	• 18 months (24 months expected by September 2021)
Time to results	• 10 minutes
Pack size	• 25 tests per pack (individually wrapped)

Pack contents	• Test kit:
	  • Lateral flow device
	  • Swab extraction buffer tube and nozzle
	  • Sterile swab
	• Instructions for use
	• Positive control



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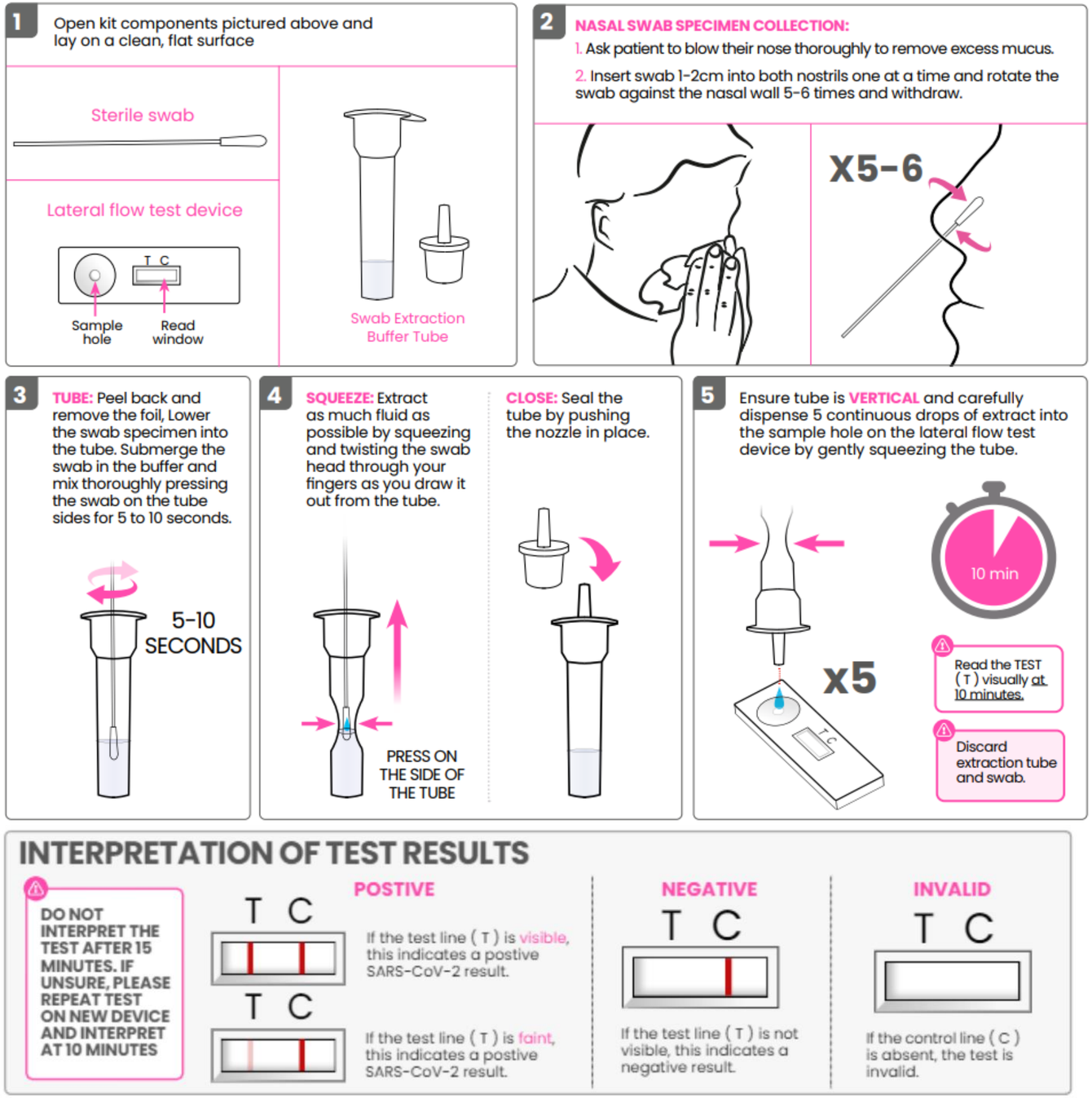
User guide:
Specimen Collection and Handling



Clinical studies & performance

Global clinical sites for the validation of Mologic/GAD COVID-19 Rapid Antigen Test POC Cassette

FIND/WHO
Dr Claudia Denkinger (Germany)
UHCP (Peru)

Institut Pasteur de Dakar, Senegal
Dr Amadou Sall
Dr Cheikh Tidiane Diagne

Zankli Research Centre, Nigeria
Dr John Bimba
Prof Luis Cuevas

University of Witwaterstand, South Africa
Prof Wendy Stevens
Prof Lesley Scott

Instituto Nacional de Saude (INS), Mozambique
Dr Ilesh Jani

Federal University of Sergipe, Brazil
Prof. Ricardo Gurgel

UK
Dr Emily Adams, LSTM Dr Nicholas Easom, HUTH Dr David Tate, NHNFT
Dr Rahul Batra, GSTT
Dr Tim Planche, SGUL
Prof. Sanjeev Krishna, SGUL

USA
Dr Paul Drain, UW
Dr Tyler Miller, MGH

University of Indonesia
Dr Erni Elwan
Dr Rukhsana Ahmed

University of Malaysia
Prof. Jamal I-Ching Sam
Dr Yolanda Augustin

Funders
FIND Diagnosis for all
UKRI UK Research and Innovation
wellcome
UKaid from the British people
Bill & Melinda Gates foundation

GAD COVIOS Ag Rapid Test: Clinical results of FIND independent evaluation

- GAD COVIOS Ag rapid diagnostic test (developed at Mologic) has demonstrated comparable performance to lateral flow with WHO emergency use listing in independent evaluations by FIND
- GAD cassette format have been submitted to the WHO for EUL and USFDA for EUA

Lateral flow tests with WHO EUL

	Location	Setting	% of patients symptomatic	Total N	Positivity	Specificity	Sensitivity by cycle threshold value					
							N	All	N	≤33	N	≤25
Abbott PanBio	Germany	Drive-in	46.2%	281	16% (44/281)	99.2%	44	86.4% (73.3-93.9%)	42	90.5% (77.9-96.2%)	31	96.8% (83.8%-99.4%)
SD BIOSENSOR Standard Q	Germany	Ambulatory	96.6%	179	23% (41/179)	99.3%	41	80.5% (66-89.8%)	32	87.5% (71.9-95%)	21	100% (84.5-100%)
	Brazil	Community	100%	214	36% (78/214)	99.3%	78	84.6% (75-91%)	72	91.7% (83-96.1%)	46	100% (92.3-100%)
PREMIER Sure Status	Germany	Drive-in + Ambulatory	63.1%	529	19% (100/529)	97%	100	91% (83.8-95.2%)	96	93.8% (87-97.1%)	80	97.5% (91.3-99.3%)
	India	Hospital	20.8%	600	18% (105-600)	99.6%	105	74.3% (65.2-81.7%)	103	74.8% (65.6 - 82.2%)	81	87.7% (78.7-93.2%)
Global Access Diagnostics COVID-19 RDT	Germany	Ambulatory and drive-in	66.5%	665	29% (194/665)	100%	191	90.6% (85.6-94%)	186	92.5% (87.8-95.5%)	166	96.4% (92.3-98.3%)

Source: FIND Evaluation External Reports

Top performance in FIND Germany trial for WHO EUL

FIND independent evaluation of 665 participants in Germany found a 91% sensitivity and 100% specificity

Information from IFU
(Source: Germany FIND study)

Prospective Recruitment		RT-qPCR		
		Pos	Neg	Total
GAD Rapid Antigen Test	Pos	173	0	173
	Neg	18	458	476
	Total	191	458	649

Performance	Sensitivity	Specificity
	90.6% (85.6% to 94.0%)	**100.0%** (99.2% to 100.0%)

- GAD COVID-19 Rapid Antigen Test uses a nose only (anterior nares) swab
- RT-qPCR platforms: TibMolbiol and Roche
- Range Ct: 11.7 to 34.7
- FINDDX Ref: https://bit.ly/3nEeoi2

Sensitivity stratified by RT-PCR cycle threshold value

Ct	Sensitivity
<20	100.0% (92/92)
<25	96.4% (160/166)
<33	92.5% (172/186)

Information directly from FIND report

	Lowest dilution detected	Verified LOD concentration	Viral Copy equivalent	Supplier-reported LOD
Analytical Sensitivity	**2.5 x10^2 pfu/ml ~** 3.52 x 10^2 $TCID_{50}$/ml	**2.5 x10^2** pfu/ml	**5.9 x10^5 copies/ml** applied to test	<350 $TCID_{50}$/ml ~ 245 **pfu/ml**

Note: viral dilution was applied directly to the test cassette, not to the provided swab

Reference PCR method	• LightMix® Modular SARS-CoV (COVID19) E-gene (Tib Molbiol)
	  ○ N = 323
	• Cobas SARS-CoV-2 (Roche Diagnostics Inc)
	  ○ N = 342

Sample type, PCR test	1. HD: Nasopharyngeal swabs (oropharyngeal if NP contraindicated) 2. Berlin: Combined nasopharyngeal/oropharyngeal swabs

Source: FIND Evaluation External Reports

Regulatory status

Regulatory Strategy for GAD COVID-19 Rapid Antigen Test

Aggregate regulatory pathways

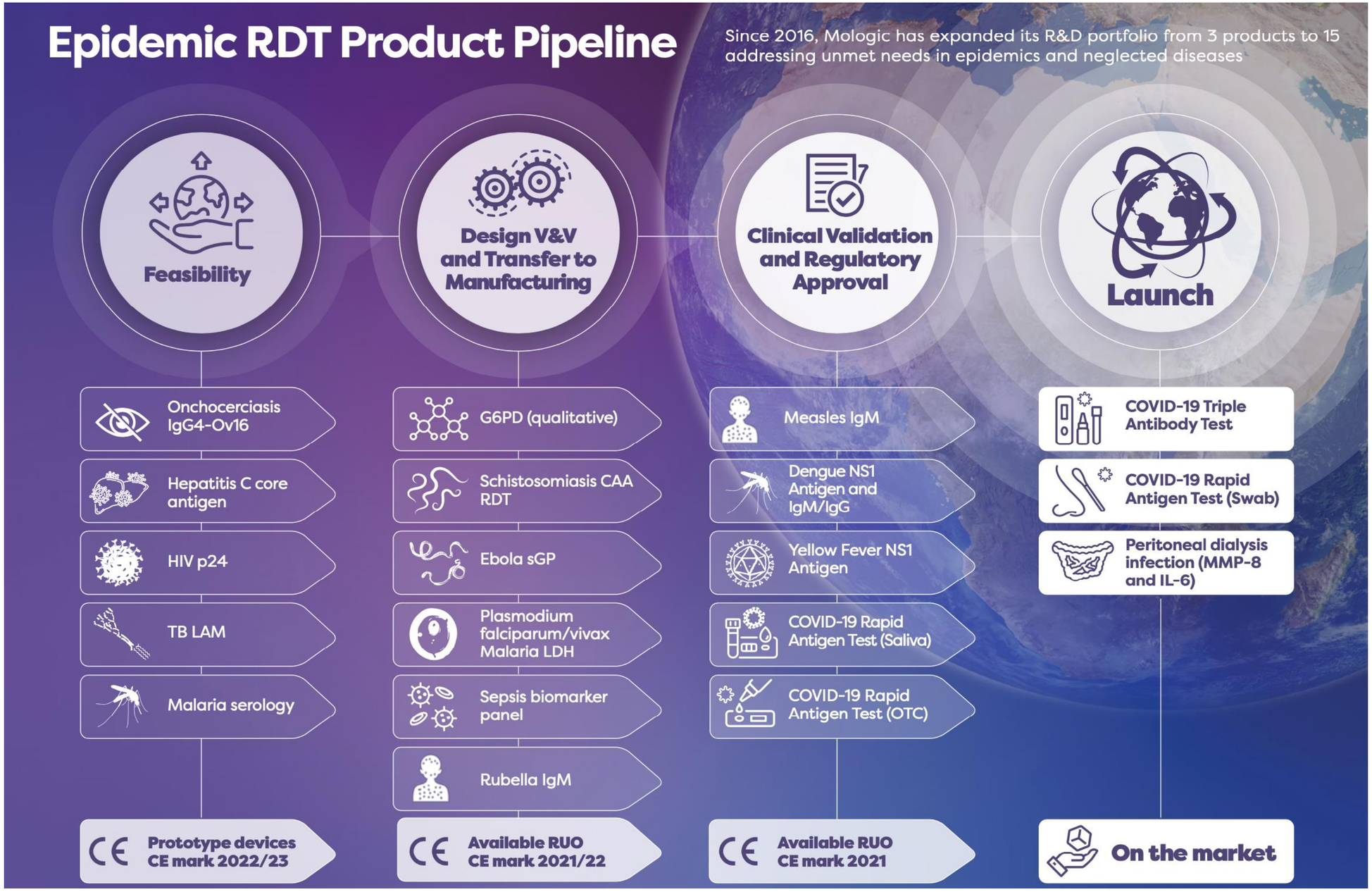
- **CE Mark**
  - ✓ Achieved in December 2020
- **MHRA (UK)**
  - ✓ Achieved in December 2020
- **WHO EUL**
  - ✓ Submitted in May 2021: link
  - ❑ Responding to first round of WHO questions
- **FDA EUA**
  - ✓ Received RADx funding in April 2021
  - ✓ Submitted application in June 2021
  - ❑ Awaiting approval

In-country validation & verification

Region	Country	V&V organizations
Africa	Botswana	Ministry of Tertiary Education, Research, Science and Technology (contact from President's Office)
	Burkina Faso	Institut de Rechersche En Sciences de la Sante (IRSS)
	Cameroon	National Research Lab (NRL) or Centre International de Référence Chantal Biya (CIRCB) or Centre Pasteur du Cameroun (CPC)
	DRC	Institut National pour la Recherche Biomedicale (INRB)
	Ethiopia	Ethiopian Public Health Institute (EPHI)
	Ghana	Noguchi Labs/ Public Reference lab
	Kenya	Kenya Medical Research Institute (KEMRI)
	Lesotho	National Research Lab (NRL)
	Malawi	Department of HIV and AIDS, Ministry of Health (CHSU) - (National Research Lab)
	Mali	Institut National de Santé Publique (INSP)
	Mozambique	Instituto Nacional de Saúde (INS) / Liverpool School of Medicine
	Nigeria	Medical Laboratory Science Council of Nigeria (MLSCN); Zankli Research Centre with funding from Wellcome Trust *(V&V not needed)*
	Rwanda	Rwanda Biomedical Centre (National Research Lab - NRL)
	Senegal	Institut Pasteur de Dakar
	South Africa	University of Witwatersrand
	South Sudan	
	Uganda	Uganda Virus Research Institute (UVRI)
	Zambia	University Teaching Hospital or any designated lab by Ministry of Health
	Zimbabwe	National Microbiology Reference Lab (NMRL)
LATAM	Brazil	Sergipe institution with Ricardo Gurgel
	Colombia	Instituto Nacional de Salud
	Peru	FIND
Rest of World	Bangladesh	Barisal Biotech
	India	Indian Council of Medical Research (ICMR)
	Indonesia	University of Indonesia
	Pakistan	Aga Khan University
	Philippines	Biological Life Science
	Timor-Leste	*V&V not needed*

Product pipeline

GAD maintains access to Mologic's clinical pipeline for global health



Contact details

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