G A D Humanity Tested

COVID-19 Rapid Antigen Test

August 2021

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Global Access Diagnostics

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Company Introduction

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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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We want to get the best diagnostics, to the most people, for the least cost.

Our north star. Diagnostics for Impact not for Profit

Our Purpose
Beating disease everywhere

Our Vision
A global health system where quality testing is available for all to guide the containment, management and treatment of disease. There is no weakest link.

Our Mission
Partnering with RDT developers, governments, donor organizations, regional experts and the private sector to innovate the technology and delivery of testing.

Using our infrastructure and social enterprise approach to make testing available, accessible and affordable.

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Core values:

Impact-focused, Mission-oriented

We are at heart a mission-driven organization. Our core purpose is to serve LMICs to increase access to low-cost diagnostics. Our profits generated goes back in service of our mission.

- Geographies: Intentional focus on **underserved markets** not well-served by current suppliers
- Cost: Committed to providing **cost transparency** and a **COGS+ pricing model**
- Regional investments: **Support capability building in LMICs**, starting with building of regional manufacturing hubs in Senegal, Pakistan and Malaysia

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Core values:

Adherence to high performance standards

Low-cost does not mean compromising standards. We hold ourselves to the high bar of excellence in product and service performance as leading commercial entities:

- Quality Product: Our **CE-marked COVID-19 test** performs as well as other **WHO-EUL approved RDT tests** by independent evaluation
- Operational Excellence: We uphold **strong quality manufacturing standards** with ISO 13485 certification.
- Continuous Innovation: We continue to **develop new technologies for LMICs** (e.g., digital, innovative extreme volume manufacturing)

Core values:

Reliable long-term partner

We are not a “fly-by-night” entity. Vetted by reputable funders, we are accountable to become your trusted partner for the long run.

- Supported by established philanthropic funders: Soros Economic Development Fund, Bill and Melinda Gates Foundation, Children’s Investment Fund Foundation, ELMA, Wellcome Trust, etc.
- Public government support: Received **funding from UK government,** part of **US’s RADx program** for accelerated pathway through FDA
- Global partners network: close collaboration multi-lateral partners - CHAI, FIND, Akesis

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COVID-19 Rapid Antigen Test product overview

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Product Features of GAD COVID-19 Rapid Antigen Test

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

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

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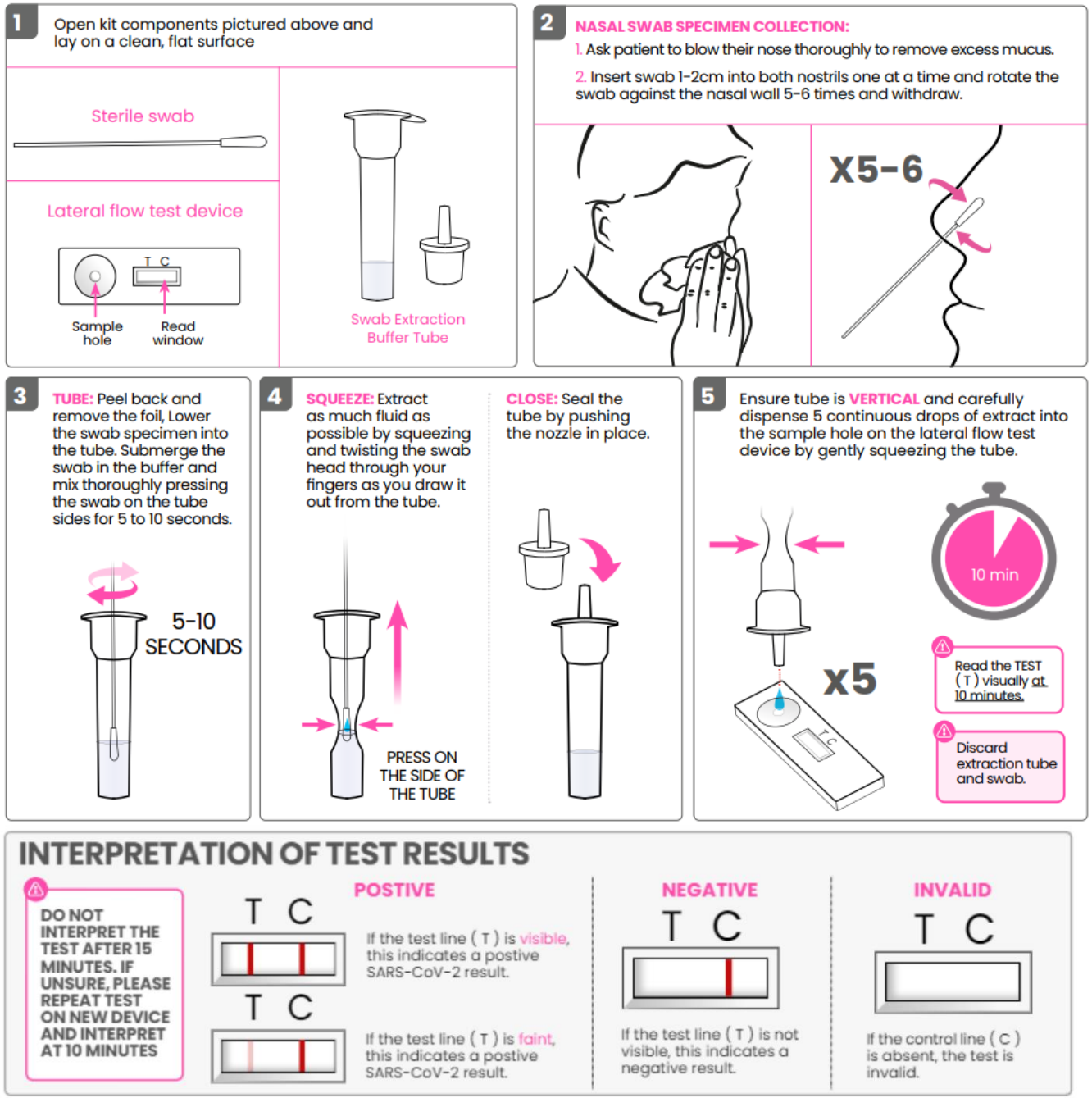
User guide:
Specimen Collection and Handling



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Clinical performance

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GAD COVID-19 Rapid Antigen Test: Clinical results of FIND independent evaluation

- GAD COVID-19 rapid diagnostic test 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 FDA for EUA
- GAD COVID-19 rapid diagnostic test is a test developed by Mologic and manufactured on GAD's platform. Clinical data generated is branded under Mologic

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%)

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Source: FIND Evaluation External Reports

Regulatory update

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Regulatory Strategy for GAD COVID-19 Rapid Antigen Test

Aggregate regulatory pathways

- **CE Mark**
  - ✓ 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	Distribution Partners	V&V organizations	Registration initiated
Africa	Botswana	Botswana Institute for Technology Research and Innovation (BITRI) President's Office	President's office will provide contact	Not required
	Burkina Faso	K-Yalley - Global Ventures	Institut de Rechersche En Sciences de la Sante (IRSS)	Not required
	Cameroon		National Research Lab (NRL) or Centre International de Référence Chantal Biya (CIRCB) or Centre Pasteur du Cameroun (CPC)	
	DRC	Essor Equipment	Institut National pour la Recherche Biomedicale (INRB)	
	Ethiopia		Ethiopian Public Health Institute (EPHI)	
	Ghana	Livful K-Yalley - Global Ventures	Noguchi Labs/ Public Reference lab	
	Kenya	PharmaAccess Foundation Governorship of Kisumu	Kenya Medical Research Institute (KEMRI)	
	Lesotho		National Research Lab (NRL)	Not required
	Malawi	Last Mile Health	Department of HIV and AIDS, Ministry of Health (CHSU) - (National Research Lab)	Not required
	Mali	MTECH	Institut National de Santé Publique (INSP)	Not required
	Mozambique	GAD has a partner – *confirming name and info*	Instituto Nacional de Saúde (INS) / Liverpool School of Medicine	Not required
	Nigeria	Akesis (previously Axios Foundation)	Medical Laboratory Science Council of Nigeria (MLSCN); Zankli Research Centre with funding from Wellcome Trust *(V&V not needed)*	
	Rwanda	GAD has a partner – *confirming name and info*	Rwanda Biomedical Centre (National Research Lab - NRL)	Not required
	South Africa	Smart Biotech (previously iVac Bio)	University of Witwatersrand	
	South Sudan	Biotech PVT Ltd.		Not required
	Uganda	Akron Diagnostics And Laboratory Supplies Limited	Uganda Virus Research Institute (UVRI)	Not required
	Zambia	Yash Pharmaceuticals Partnership for Improving supply Chain Management in Africa (PICMA)	University Teaching Hospital or any designated lab by Ministry of Health	
	Zimbabwe	Fima Enterprises LTD	National Microbiology Reference Lab (NMRL)	Not required
LATAM	Brazil	Brazilian Chamber of Laboratory Diagnosis (CBDL)	Sergipe institution with Ricardo Gurgel	Not required *(ANVISA is key)*
	Colombia	Brazilian Chamber of Laboratory Diagnosis (CBDL)	Instituto Nacional de Salud	Not required
	Peru	Brazilian Chamber of Laboratory Diagnosis (CBDL)	FIND	Not required
Rest of World	Bangladesh	Barisal Biotech	Barisal Biotech	
	India		Indian Council of Medical Research (ICMR)	
	Indonesia	Livful	University of Indonesia	
	Pakistan	BIOLOGICA	Aga Khan University	✓
	Philippines	Biological Life Science (BLS)	Biological Life Science	✓
	Timor-Leste	PPC Global Trading Company Lda Dili, Timor Leste	*V&V not needed*	

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