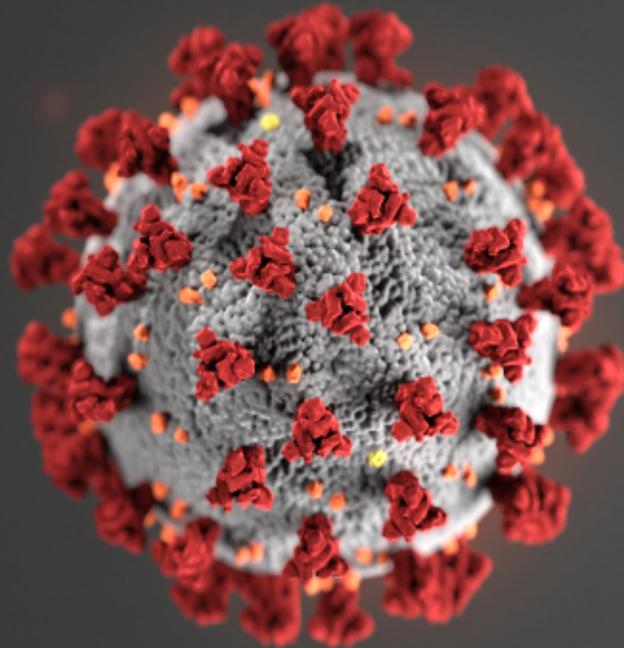




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# Slowing the Spread of Covid-19: How to Scale Up Antigen Rapid Diagnostic Testing in Africa

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As more contagious strains of Covid-19 emerge, testing is critical to slow transmission. Rapid testing can be scaled to the size of outbreak and enable safer economic activity.

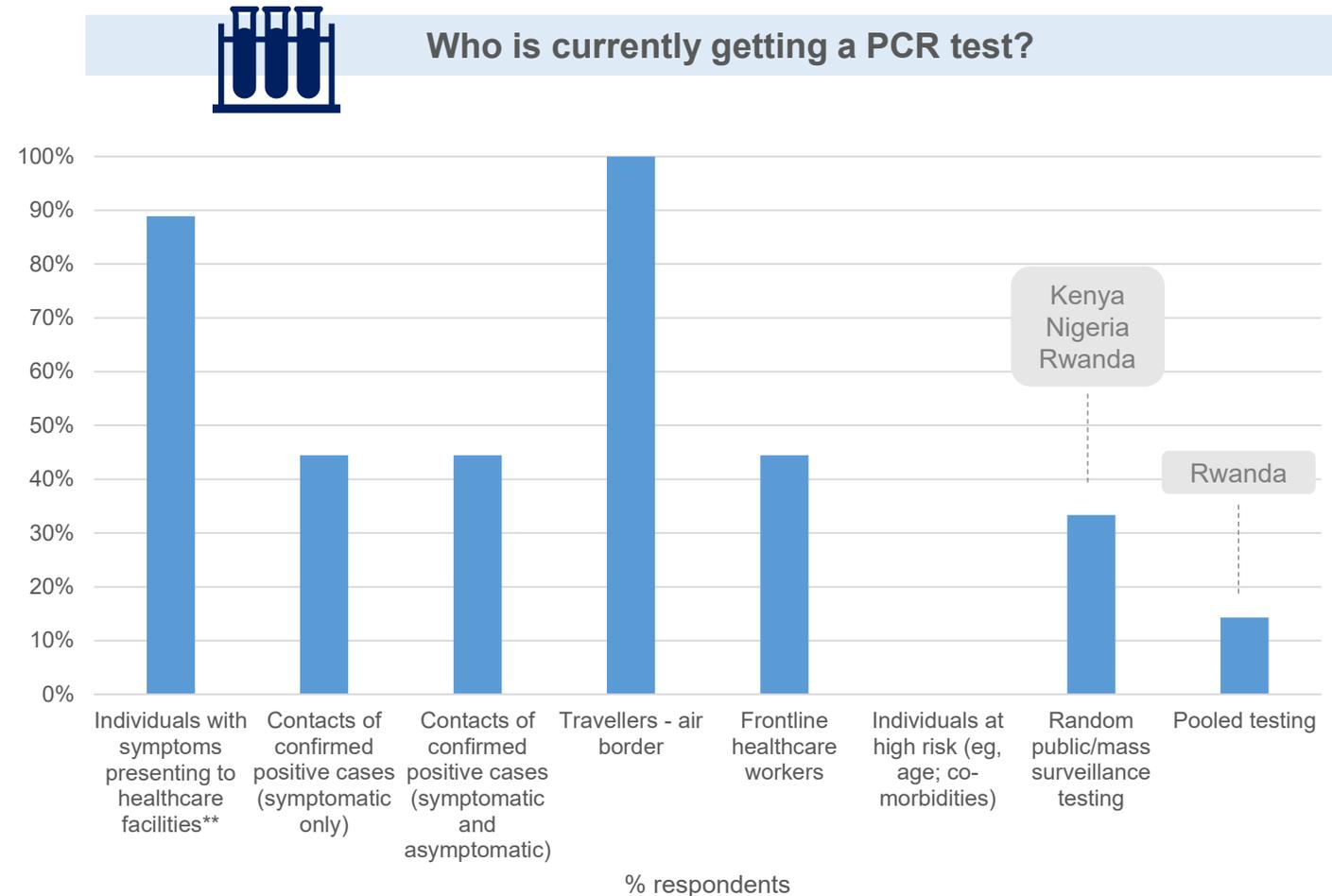


- Covid-19 will continue to negatively impact public health and economies worldwide in the coming years. **Until population immunity is achieved globally**, through vaccinations, **testing must be reprioritised as the essential first line of defence against the virus. Unlike vaccines, PCR and antigen tests are minimally, if at all, affected by variations in strains.**
- **PCR (molecular) tests continue to be the most widely used in most African countries, but they are resource intensive, time-consuming, centralised and expensive.** This prohibits most countries from scaling testing to the size of their outbreaks or using tests to safely reopen economies.
- Antigen Rapid Diagnostic Tests (**Ag-RDTs**) **provide accurate results in minutes using few resources in decentralised settings.** Advancements in Ag-RDTs are a breakthrough in testing scalability – and signal the need to reorient testing strategies.
- Because of speed and accessibility, **Ag-RDTs are effective at identifying asymptomatic infectious individuals, and the ability to test frequently with Ag-RDTs outweighs the relatively higher accuracy of PCR tests. Ag-RDTs are most effective when applied as a recurring testing system,** rather than driven by individual demand. This necessitates a culture of testing and compliance.
- **Ag-RDT testing may be used as a supplemental surveillance tool** to determine whether to tighten or relax public-health mitigation measures, allowing for targeted restrictions, rather than measures. **Ag-RDTs may also alleviate pressure on PCR resources** used for genome sequencing to identify emerging strains, or laboratory resources to provide essential health services.
- Given improved accuracy, **Ag-RDTs are now recommended for use in all settings** (assuming a test meets WHO standards). An increasing number of Ag-RDTs have been authorised and are available for commercial purchase. Hundreds more are in development.

# A TBI survey\* indicates that PCR tests remain the most widely used. But the populations targeted for PCR testing have shifted, reflecting changing priorities and resource constraints.



- Compared to a July survey, TBI countries continue to concentrate PCR testing resources on symptomatic individuals and their contacts. They have tended to scale back testing of frontline health workers and certain high-risk groups and scaled up testing at air/land borders.
- Fewer than 50% of reporting countries are systematically testing frontline health-care workers, while 100% are testing air travellers and nearly 40% are testing travellers at land borders – pointing to a strategic shift in priorities as countries began to reopen their economies.
- Fewer than 50% of countries are using PCR tests on asymptomatic contacts of positive cases. One country does not test symptomatic or asymptomatic contacts.
- Three countries have moved to public surveillance testing, compared to one in July, but implementation has been hampered by resource constraints and high demand.
- Despite PCR resource shortages, only one country is conducting pooled PCR testing.
- Fewer than 50% have implemented rapid diagnostic testing – and only in limited settings.



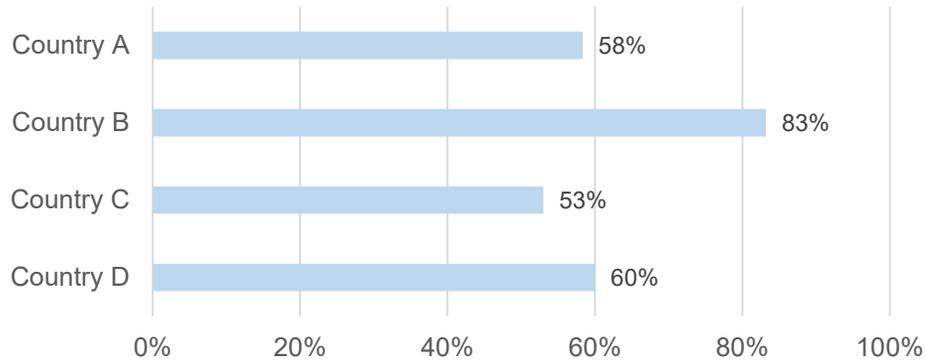
\*\*100% of countries are testing individuals with symptoms presenting to health-care facilities, but one country (Rwanda) is using RDTs, not PCR tests

\*Based on responses to a December 2020 survey of nine TBI countries: Angola, the Gambia, Kenya, Mali, Mozambique, Nigeria, Rwanda, Senegal, Sierra Leone; previous testing survey conducted in July 2020

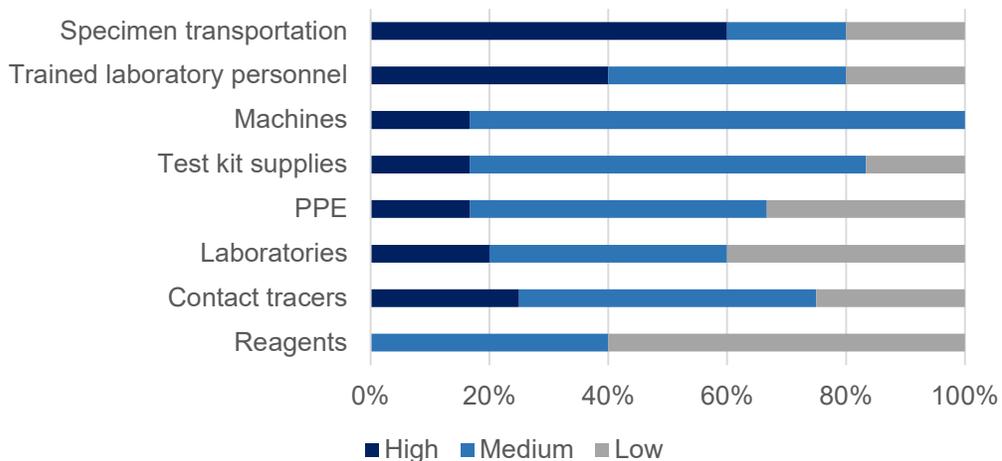
# Scaling up testing has been hindered by resource constraints associated with PCR processing. Testing rates in Africa are ten times lower than high-income countries on average.



% PCR testing capacity used



PCR resource constraints



- A majority of countries\* identified testing as a **“high” government priority**, yet **none are at or near using 100%** of current PCR capacity.
- **Percentage of testing capacity utilisation has essentially remained unchanged** compared to the results of TBI’s July survey.
- **Machines continue to be the most scarce resource.** All respondents identified either high or medium levels of shortages of machines, followed by **testing kits**, but **60% of countries now identify specimen transportation as highly constrained**, compared to 43% in July.
- Multiple countries identified **centralised lab systems as a contributing factor to specimen transportation constraints**, noting delays from the time it takes to transport specimens from point of collection to processing hubs and vehicle scarcity, especially as demand has increased.
- One country specifically cited **lack of incentives for lab personnel** as a key driver of scarcity and that some machines and laboratories have stopped testing for Covid-19 – possibly signalling that those **resources have been redirected to original or alternative use**, for example, in order to maintain **essential health services**.
- Countries are **still facing shortages of reagents**, the resource with the highest scarcity in July, but to a less severe extent.

\*Based on responses to December 2020 survey of nine TBI countries: Angola, the Gambia, Kenya, Mali, Mozambique, Nigeria, Rwanda, Senegal, Sierra Leone; previous testing survey conducted in July 2020

Like PCR tests, Antigen Rapid Diagnostic Tests (Ag-RDTs) can detect an active infection but do not require processing in a lab and return results in under 30 minutes.



- **Ag-RDTs detect antigens produced by the virus** when it replicates in the body, triggering an immune response, whether symptomatic or asymptomatic.
- Like PCR tests, Ag-RDTs are diagnostic tests used to **inform individuals of an infection, prompting isolation from the community** (and treatment, if needed) and **contact tracing to stop transmission**.
- Reducing transmission depends on **fast turnaround of test results in order to isolate and trace** within the window of contagion.
- Unlike PCR tests, **Ag-RDTs are cheap, easy to administer, do not require laboratory processing and return results in under 30 minutes**.

	Advantages	Disadvantages
<b>PCR</b>	<ul style="list-style-type: none"> <li>✓ High sensitivity and specificity – considered the “gold standard” in Covid-19 diagnostic testing</li> </ul>	<ul style="list-style-type: none"> <li>× Resource-intensive: require laboratory facilities and trained technicians, machines and equipment, reagents and supplemental kit materials</li> <li>× Expensive: &gt; \$20; price and access barriers for general public</li> <li>× Centralised: laboratories required for processing</li> <li>× Produce results in ~six hours if no delays, but global supply shortages of test materials and constrained resources create backlogs and delay result turnaround for days</li> <li>× Comparatively higher sensitivity catches positive cases that are no longer contagious, resulting in unnecessary isolation</li> </ul>
<b>Ag-RDT</b>	<ul style="list-style-type: none"> <li>✓ Sensitivity and specificity exceed WHO minimum performance standards</li> <li>✓ Require minimal resources</li> <li>✓ Affordable: &lt; \$5</li> <li>✓ Decentralised: portable and easy to perform (minimal training if administered at point of care; can be self-administered)</li> <li>✓ Produce results in &lt; 30 minutes, facilitating rapid contact tracing</li> <li>✓ Comparatively lower sensitivity excludes positive cases that are no longer contagious, avoiding unnecessary isolation</li> </ul>	<ul style="list-style-type: none"> <li>× Sensitivity marginally lower than PCR* (<i>variable according to the tests used</i>), resulting in some missed positive cases</li> </ul>



With global scarcity of resources, constrained laboratory capacity, delayed turnaround times and high costs, **PCR testing is not a scalable testing solution.**

Cheap, portable and fast, **Ag-RDTs are a scalable and sustainable testing solution.**

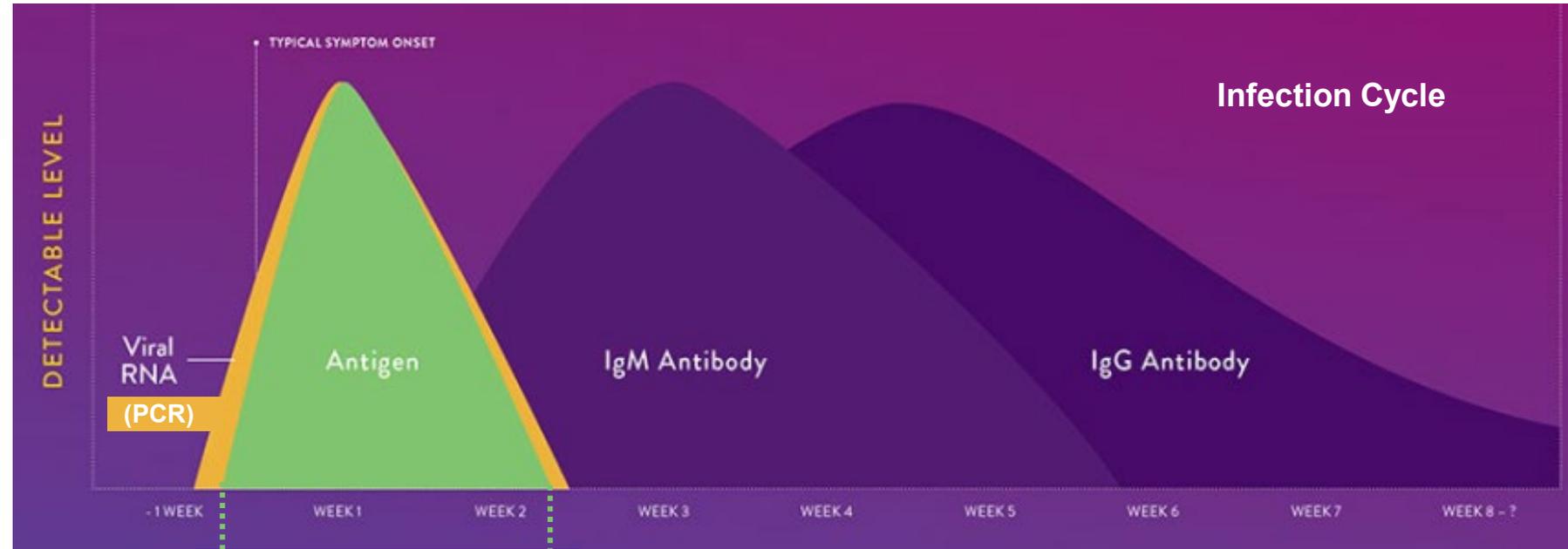


# Ongoing innovations in rapid test (lateral flow assay) technology have significantly improved both sensitivity and specificity of Ag-RDTs.

Though molecular PCR tests are still relatively more accurate, an assessment of 13 Ag-RDT brands authorised for use shows **average sensitivity = 93.4%** and **average specificity = 99.3%** (see [slide 9](#)), with all exceeding the WHO minimum performance threshold.\*

However, effectiveness of Ag-RDTs also depends on **viral load**, **disease prevalence**, and **quality of the collected specimen**.

- Ag-RDTs are **most sensitive when the viral load is relatively high**.
- In high-prevalence settings, there is an increased likelihood of false negatives; in low-prevalence settings, there is an increased likelihood of false positives. **Tolerance for and consequences of misdiagnosis must be considered when evaluating results.**
- Though administration of Ag-RDTs requires minimal technical training, it is **important that procedures for acquiring the sample specimen are properly followed.**



*Infectious period is approximately 10 days*

Ag-RDT results are most likely to be positive when viral loads are highest and patients are most infectious (for symptomatic individuals, about 1-3 days prior to symptoms and 5-7 days after onset of symptoms)

PCR test likely to be positive

Because Ag-RDTs are most sensitive when viral loads are high, the tests identify cases that are infectious and have the highest risk of transmission.

PCR tests are more sensitive to lower viral loads than Ag-RDTs, and also identify positive but non-infectious cases with low risk of transmission.

**Relatively lower sensitivity of Ag-RDTs may be an advantage as they are more likely to exclude non-infectious cases, avoiding unnecessary isolation.**

Antibody tests start to be positive around one week after infection; these tests are not diagnostic, but can be useful for understanding overall extent of community transmission and possible immunity.

\*WHO set Ag-RDT minimum performance requirements at sensitivity  $\geq 80\%$  and specificity  $\geq 97\%$ ; Sensitivity = ability to exclude false negatives; Specificity = ability to exclude false positives

Ag-RDTs are now recommended for use in all settings. Because of their speed and accessibility, they are better than PCR tests for identifying asymptomatic infectious individuals.



### Evaluating Ag-RDT Results in High-Prevalence Settings (Symptomatic or Known Exposure Risk)

Ag-RDT* Population/Setting	Test Objective	Test Result	Immediate Action	Next Steps	Comments
<b>Symptomatic individuals</b> <hr/> <b>Frontline health-care and essential workers (symptomatic and asymptomatic)</b> <hr/> <b>High-risk populations in outbreak areas (elderly, individuals with comorbidities, closed settings (e.g., prisons))</b> <hr/> <b>Contacts of confirmed cases (symptomatic and asymptomatic)</b>	✓ Diagnosis ✓ Transmission control ✓ Transmission control ✓ Transmission control ✓ Transmission control	 <b>Positive</b>	<b><i>There is high probability result is a true positive given high-prevalence setting</i></b> <input type="checkbox"/> Manage as positive for Covid-19	<input type="checkbox"/> Isolate and treat as needed <input type="checkbox"/> Contact trace	In outbreak areas, <b>frontline health-care and essential workers</b> should be tested regularly because they have a higher exposure risk: <b>→ Twice-weekly routine testing</b> (independent of symptoms) is recommended  Where there is limited or no suspected or confirmed outbreak: <b>→ Once-a-week routine asymptomatic testing</b> is recommended  When used frequently, Ag-RDTs are better than PCRs at identifying asymptomatic but contagious individuals.
		 <b>Negative</b>	<input type="checkbox"/> If no clinical suspicion (asymptomatic) and no known positive contacts, manage as negative for Covid-19 <input type="checkbox"/> If clinical suspicion (symptomatic) or known positive contacts, conduct second Ag-RDT OR <input type="checkbox"/> If available, conduct PCR test; isolate while awaiting results <input type="checkbox"/> If symptomatic, evaluate for other potential causes of illness	<input type="checkbox"/> If second Ag-RDT test is still negative, but there is a high degree of clinical suspicion and other diseases have been ruled out, manage as presumptive positive for Covid-19 <input type="checkbox"/> Isolate and treat as needed <input type="checkbox"/> Contact trace <input type="checkbox"/> Consider conducting third Ag-RDT to confirm results OR <input type="checkbox"/> If PCR test is negative, manage as negative for Covid-19	

\*Assumes sensitivity and specificity of Ag-RDT meets WHO minimum performance standards

# Repeating an Ag-RDT test on the same individual to confirm results can be as effective as PCR tests.



## Evaluating Ag-RDT Results in Low-Prevalence Settings (Low or Unknown Exposure Risk) (If outbreak scenario, manage as high-prevalence setting)

Ag-RDT* Population/Setting	Test Objective	Test Result	Actions	Next Steps	Comments
Travellers at border points of entry	✓ Transmission control	 <b>Positive</b>	<input type="checkbox"/> Conduct second Ag-RDT OR <input type="checkbox"/> If available, conduct PCR test; isolate while awaiting results  <input type="checkbox"/> If a second Ag-RDT or PCR test are both unavailable, manage as positive for Covid-19 <input type="checkbox"/> Isolate and treat as needed <input type="checkbox"/> Contact trace	<input type="checkbox"/> If second Ag-RDT is still positive, manage as positive for Covid-19 <input type="checkbox"/> Isolate and treat as needed <input type="checkbox"/> Contact trace  <input type="checkbox"/> If second test is negative, manage as negative for Covid-19 <input type="checkbox"/> Consider conducting third Ag-RDT to confirm results	Testing at points of entry and among in-patients enables early identification of new cases and prevents new outbreaks  Schools and workplaces are high-risk settings for transmission and potential outbreaks due to the close and prolonged contact among large groups of people, often indoors.. Where there is no suspected or confirmed outbreak: → <b>Once-a-week routine asymptomatic testing</b> is recommended to prevent outbreaks
In-patients at hospitals admitted for other conditions	✓ Transmission control				
Schoolteachers, students, staff	✓ Transmission control ✓ Safe reopening of select activities	 <b>Negative</b>	<p><b><i>There is high probability result is true negative given low-prevalence setting</i></b></p> <input type="checkbox"/> Manage as negative for Covid-19	None	In situations with limited supply of PCR tests to confirm Ag-RDT results, prioritisation of use is recommended for frontline health-care workers.
Factory workers, government employees, religious institutions and private-sector employees at workplaces	✓ Transmission control ✓ Safe reopening of select activities				
Other general populations (e.g. random community screening)	✓ Transmission control ✓ Surveillance				

\*Assumes sensitivity and specificity of Ag-RDT meets WHO minimum performance standards



An increasing number of Ag-RDTs have been authorised for use and are now available for commercial purchase, with hundreds of other tests in development globally.

Manufacturer	Test Name	Origin	Regulatory Approval	Analysis Location (Point of Care/Self)	Total Sensitivity (%)	Total Specificity (%)	Time to result (<minutes)	Comments
Abbott	Panbio	US	WHO EUL; US FDA EUA	POC	91.4	99.8	20	Abbott and SD Biosensor tests are available for \$5/unit; they are currently the only tests with WHO EUL standing
SD BIOSENSOR	STANDARD Q	S. Korea	WHO EUL; US FDA EUA	POC	84	100	15	
AccessBio	CareStart	US	US FDA EUA	POC	87.8	100	10	<p>This list continues to grow and is non-exhaustive but covers the key Ag-RDTs meeting WHO minimum performance standards and authorised by select regulatory bodies.</p> <p>Africa CDC recommends that Ag-RDTs assessed through the WHO Emergency Use Listing or a national Emergency Use Authorisation procedure should be prioritised.</p>
Abbott	BinaxNow & Navica App	US	US FDA EUA	POC/Self	97.1	98.5	15	
BD	BD-BD Veritor	US	US FDA EUA	POC	84	100	15	
ellume	COVID-19 Home Test	Australia	US FDA EUA	Self	95	97	15	
LUMINOSTICS	Clip	US	US FDA EUA	POC	96.9	100	30	
lumiraDx	SARS-CoV-2 Ag Test	UK	US FDA EUA	POC	97.6	96.6	12	
QUIDEL	Sofia	US	US FDA EUA	POC	96.7	100	16	
QUIDEL	QuickVue	US	US FDA EUA	POC	98.6	99.3	11	
EXCALIBUR	Rapid Antigen Test	UK	UK MHRA	POC	96	100	15	
SureScreen Diagnostics	COVID-19 Antigen Test	UK	UK MHRA	POC	97.1	99.9	15	
MOLOGIC	Rapid Antigen Test	UK	CE-IVD	Self	92	100	20	

\*WHO EUL: WHO Emergency Use List; US FDA EUA: US Food and Drug Administration Emergency Use Authorisation; UK MHRA: UK Medicines and Healthcare products Regulatory Agency; CE-IVD: EU CE-Approved In Vitro Diagnostics

The [FindDX website](#) has details of all commercially available tests and those in development.

Source: TBI analysis; [TestingCommons](#); [WHO](#); [AMSP](#)

Ag-RDTs can be procured directly from manufacturers or through a number of multilateral procurement channels.



**Multilateral Procurement Channels:** *Regardless of funding source, any of these multilateral platforms may be used to procure Ag-RDTs. (This list is non-exhaustive.)*



AMSP is accessible to registered country users. Available Ag-RDTs and terms for ordering, supply and delivery are provided on the [website](#). Donations of [LumiraDx](#) tests are available equitably through the AMSP platform.



Orders can be placed through the [WAMBO platform](#). Countries may be eligible for funding through the COVID-19 Response Mechanism (C19RM) or grant flexibilities instrument. Countries should contact their Global Fund (GFATM) representative to register for the platform and/or initiate the order process.



All countries are eligible to procure from the Stop TB Partnership Global Drug Facility by following these [instructions](#). Contact: [gdf@stoptb.org](mailto:gdf@stoptb.org)



If agreements are already in place and/or UNDP is the Global Fund Principal Receipt, countries can access consortium-eligible tests by contacting their local UNDP representative.



Countries should contact their local UNICEF Country Office to submit a request via the online request [form](#). Contact: [covid19\\_dx@unicef.org](mailto:covid19_dx@unicef.org)



Countries can make requests on the [Portal](#). The Supply Portal is not restricted to only WHO funding sources. Contact: [COVID19Enquiry-Diagnostics@who.int](mailto:COVID19Enquiry-Diagnostics@who.int)

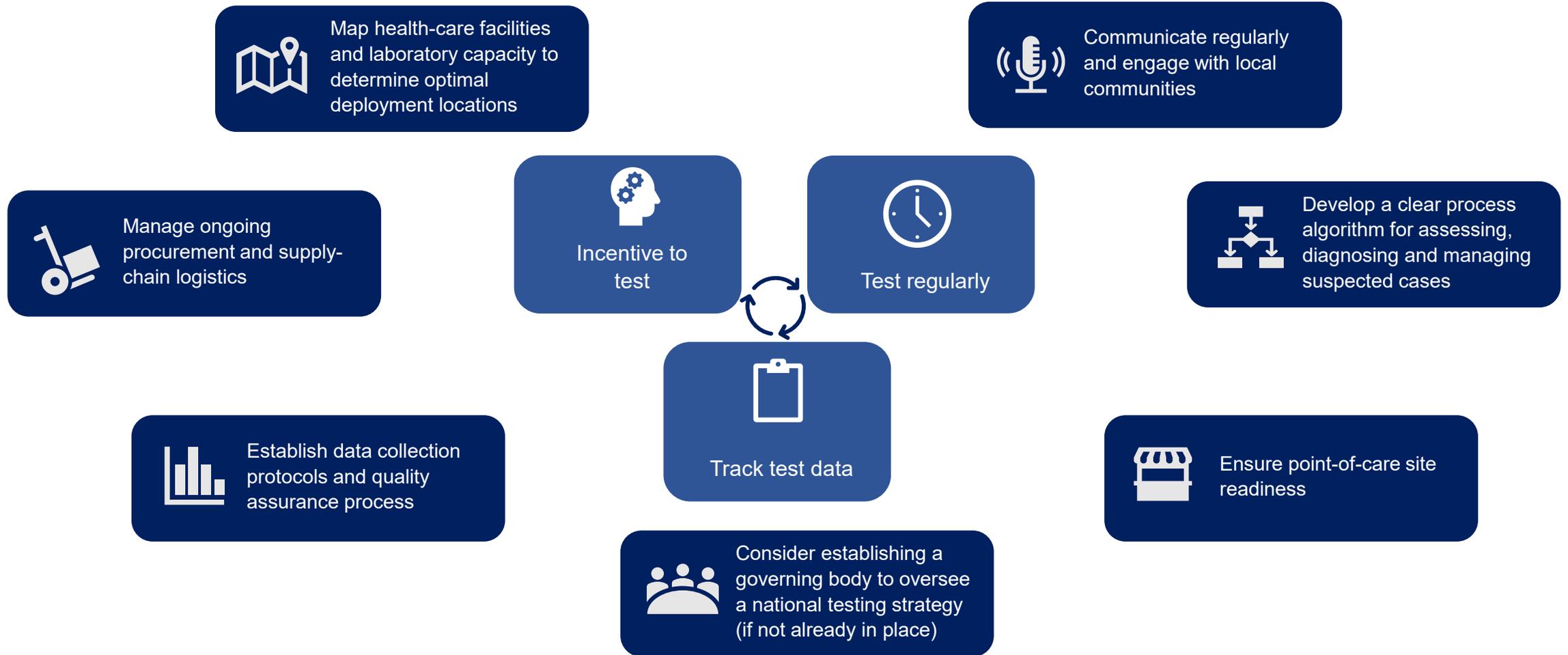
**Direct Procurement from Manufacturers, including:**



**Others:** *Supply agreements led by FIND and Unitaid (under the ACT-A consortium) are being negotiated with other manufacturers to expand and automate Ag-RDT production capacity, targeting \$2.50 per test – but contingent on WHO EUL test approval.*



Ag-RDTs should be implemented as a testing system. For the system to function, testing must be regular, valued, properly tracked and supported by effective implementation.



[ASLM](#) offers online training courses for implementing and managing antigen testing

Sources: [African Society for Laboratory Medicine \(ASLM\)](#); [FINDDx](#)