9 June 2021

Dr Tedros Adhanom Ghebreyesus Director-General, World Health Organization
Dr Maria van Kerkhove, Health Emergencies Programme, World Health Organization
Dr Soumya Swaminathan, Chief Scientist, World Health Organization

RE: Upcoming WHO COVID-19 Testing Guidelines and use of Ag RDTs

Within the past six months, we have seen significant expansion of the use of antigen rapid diagnostic tests (Ag RDTs) in the Global North, including with use in workplaces, schools, and even self-testing at home. In contrast, the current WHO guidelines for use of Ag RDTs in LMICs recommends the use of Ag RDTs only within specific circumstances (hospitals, prisons) and does not explicitly provide guidance for community-based testing with Ag RDTs.

Without explicit guidance around community-testing, including self-testing, and broader use recommendations, we are concerned that the opportunity offered by the C19RM funding will not be maximised. Moreover, the lack of community-based testing impacts marginalized populations the hardest as individuals from these communities face the greatest obstacles to accessing facility-based services.

We've seen governments demonstrating reluctance to budget for Ag RDTs, citing the current WHO guidelines. We have also seen little uptake of Ag RDTs reserved by the ACT-Accelerator Diagnostics Pillar, again attributable, at least in part, to unclear and out-of-date guidance. We have also received feedback from C/CSO colleagues engaged at the country level that the complex language in the current guidelines undermines implementation in countries. Many terms in the guidelines are vague or jargon (e.g. "available", "prolonged turnaround times", "trained operator", "remote settings", "confirmed case", "low prevalence", etc). It is important to acknowledge that countries may translate and define such vague terms into national guidelines (either on paper or in practice) in ways that can lead to complicated, costly, and/or delayed paths to testing protocols for facilities and/or patients on the ground.

Gross disparities in testing rates and test availability are currently leading to a misleading undercount of COVID-19 incidence in LMICs and associated morbidity and mortality figures. As we look forward to the hopeful prospect of an affordable, easy-to-administer antiviral medicine appropriate for use to treat mild and moderate disease on an outpatient basis, we see the need for early guidance that emphasizes the importance of early community-based detection and connection to care during any relevant outpatient treatment window.

We are deeply concerned about the equity impact of the contrasting guidance to use of COVID-19 Ag RDTs in the Global North versus the Global South.

To address the shortcomings of the current September 2020 WHO guidelines to countries on the use of Ag RDTs, we - the CSO representatives in the ACT-A Diagnostics pillar - urgently appeal to WHO to:

1. Urgently issue updated guidelines with expanded use recommendations to close the yawning gap in recommendations in the Global North versus the Global South;
2. Ensure that all members of the ACT-A Dx Pillar, including CSO representatives, have the opportunity to review and provide feedback to upcoming updates of the WHO guidelines on the use of Ag RDTs;
3. Decrease complexity in language in the WHO guidelines to guarantee successful implementation in countries.

Specific recommendations are contained in the Annex to this letter.

Providing for greater clarity in the guidelines and increased flexibility in Ag RDT mobilisation allows us to scale-up testing, minimise issues with equitable access between the Global North and the Global South, and would empower governments to eliminate bottlenecks to testing.

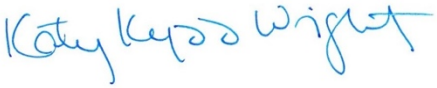
We cannot condone the inequity in testing that exists today.

We look forward to your response on these requests.

Yours Sincerely,

On behalf of the C/CSO representatives to the ACT-A diagnostics pillar:

Dr Fifa A Rahman



Katy Kydd Wright.

Dr Carolyn Gomes

Chase Perfect

Peter Owiti

CC to: Peter Sands, Executive Director, GFATM

Emma Hannay, Chief Access Officer, FIND

Owen Demke, Senior Program Manager, Global Diagnostics, CHAI

Alex Costa, HIV/AIDS Specialist and Lead of ACT-A Dx Country Support Working Group, UNICEF

Brooke Nichols, Department of Global Health, Boston University School of Public Health

Brian Tisdall, ACT-A Hub Team, WHO

ANNEX

POINTS REQUIRING DETAIL AND/OR FURTHER CLARITY IN THE SEPTEMBER GUIDELINES, IN VIEW OF THE UPCOMING TESTING GUIDELINES

Issue	Feedback/Recommendation
No opportunity to review upcoming testing guidelines	Members of the diagnostics pillar of the ACT-A have accumulated a wealth of knowledge specifically on COVID-19 diagnostics and bottlenecks in countries. The CSO delegation to the ACT-A diagnostics pillar finds itself in the uncomfortable position of providing feedback on the September 2020 guidance when there is already an advanced draft of the next guidance to which the CSO representatives do not have access. We request that all members of the ACT-A Dx Pillar, including CSO representatives, have the opportunity to review and provide feedback to upcoming updates of the WHO guidelines on the use of Ag RDTs.
No explicit recommendations on community-based testing	Add recommendations to use Ag RDTs for community-based testing, including frequency of testing with Ag RDTs to minimise risks due to low sensitivity. In evaluating the public health impact of such recommendations, we ask that the WHO consider input from the modelling working group.
No recommendations on self-testing	Add specific recommendations around self-testing that include emphasis on reporting results and connecting to care if testing positive.
Presenting countries with evidence around use in multiple different use cases	Present evidence around use of Ag RDTs in workplaces, schools, transportation centers especially long-distance truck drivers, within homes, and other settings, in an infographic or visual diagram within the upcoming guidelines.
Need to expand use of AgRDTs beyond 'remote settings'	Expand the recommended use of Ag RDTs beyond 'remote settings' and to all communities, and clarify language around 'where NAAT (PCR) is not available' to mean that Ag RDTs can be used in any circumstance where timely NAAT (PCR) test results are not available or when volumes of NAAT (PCR) are restricted.
No language around impact of extended turnaround times	Add language about the impact of time delays due to inappropriate access to testing and extended turnaround times; e.g. there is currently no guidance on how facilities should change their antigen RDT versus NAAT (PCR) approach when considering turnaround times. Add that Ag RDTs have the potential to rapidly identify infections and take appropriate control measures in communities, with evidence recently emerged through CHAI projects that the expanded use of Ag RDTs have enabled targeted lockdowns in specific areas in Rwanda;[1] where NAAT (PCR) may offer greater test-for-test sensitivity and specificity for surveillance, antigen RDTs allow for more flexible and more responsive (i.e. real-time) monitoring.
No reference to AgRDTs vis-a-vis test-and-treat strategies	Add that Ag RDTs will have a key role to play in any eventual outpatient test-and-treat strategies for mild and moderate disease, emphasizing the importance

[1] Presented by Owen Demke, Global Diagnostics Advisor at CHAI, during an ACT-A Dx Country Preparedness working group call

	of testing, testing readout, and connection to care during the relevant treatment window.
Vague scope of "trained operators"	The guidance says that "To optimize performance, testing with Ag-RDTs should be conducted by trained operators" but there is no clarification on what training is needed and what scope of individuals may be trained; it is essential that community health workers be explicitly recognized as eligible to receive such training and that such training/service delivery should be considered in testing strategy budgets.
Implications of definition of a confirmed case	In the final table of the September 2020 guidelines, the guidance says that antigen RDTs should not be used for individuals "unless the person is a contact of a confirmed case", yet the standard for a confirmed case is not defined. Given the issues of availability and delays (where "available"), it is imperative that antigen RDT positive tests qualify as a confirmed case for the purposes of this recommendation. Moreover, it is no longer appropriate to use language that antigen RDTs "should not be used unless." Such language suggests restrictions on uses that is no longer justified. There is insufficient clarity on the importance of timely confirmation testing for clinical management (either outpatient or inpatient). Moreover, there is lack of clarity over use of antigen RDTs for confirmation testing in clinical settings. In Figure 1 of the 9/2021 guidance, the title reads "where there is no NAAT (PCR) capacity"; this is an overly restrictive threshold for application of antigen RDTs for clinical management. For example, a patient may come to a hospital that requires NAAT (PCR) confirmation before admission or before initiation of clinical interventions (either to address COVID-related issues or to address non-COVID health issues). It is not practical for patients to spend the money or time to stay at a hospital while waiting for a test result; we may even imagine scenarios where certain interventions require a positive COVID test, meaning patients degrade as they wait for the NAAT (PCR) confirmation (when antigen RDT confirmation could have led to rapid admission).
Insufficient clarity on the impact of time delays for defining "availability" and "prolonged turnaround times"	We see two windows of time that are crucial to the impact of testing strategies and we believe it important to emphasize in the guidelines that the length of these windows will impact the tradeoffs between antigen RDT testing and NAAT (PCR) testing. The first window is the "availability window", which could be defined as the time it takes from the moment an individual decides to seek a test and the moment they are tested; the second window is the turnaround time. For turnaround times, we think it is important to clarify that turnaround time must extend from sample collection to the moment of informing the patient (or in inpatient settings, the health professional) of the result (i.e. as opposed to the mere completion of the assay).
Implication of vague definition of term "availability"	The vagueness of the terms "available" and "availability" give too much margin for policymakers to use guidelines to defend overly restrictive implementation of antigen RDTs. NAAT (PCR) testing may be "available" at a facility in the sense that there may be some capacity to conduct NAAT (PCR) testing at the given site (although it really may simply mean there is local sample collection at that site) but such a definition of availability ignores that it cannot be scaled up to meet all needs and/or the sample collection is not available to all soon enough (or tests cannot be processed fast enough) from the "available site" to maximize clinical management and/or infection control.
Need to account for contexts with low surveillance capacity, and other problematic scenarios	There are many problematic scenarios that can emerge from overly restrictive guidelines that demand certain thresholds for antigen RDT but local capacities and/or local protocols mean that those thresholds won't ever be triggered.

	● The document references low and high prevalence settings but provides little guidance on how such prevalence levels may be monitored/established/triggered. One could encounter a situation where application of the guidelines cannot be enacted because a high prevalence rate has not yet been documented due to slow/insufficient surveillance capacity. ● At the patient level, demand for NAAT (PCR) confirmation for specific interventions or inpatient admission can create problematic scenarios for individuals on the ground. Patients may require NAAT (PCR) confirmation tests to enter facilities with COVID care under certain existing protocols, but in many settings NAAT (PCR) confirmation is not possible in a timeline that allows the most effective clinical management. In the end, these NAAT (PCR)-intensive protocols may not fully prevent access to care, but they may delay access to care soon enough to prevent severe degradation in clinical progression. Systematically long turnaround times for NAAT (PCR) results may also increase risk of infection transmission within hospital settings. Alternatively, policies that restrict patients to certain wards "until cleared as COVID negative" may saturate wards with COVID negative patients and block admission of patients in need.