Summary of WHO’s COVID Ag RDT guidance

14 September 2020

#UnitedAgainstCoronavirus
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Ag RDTs can help countries expand access where PCR testing is limited.

**NAAT testing**
- Can **diagnose acute infection** through presence of SARS-CoV-2 virus and are a critical tool for COVID public health measures.
- Were able to be developed and **deployed rapidly**.
- Good **clinical performance**, with high sensitivity and specificity.
- But, requires **laboratory infrastructure** and highly trained staff.
- **Turn around time may be long**, often >48h, which could reduce benefits of a high performing test.
- May be **challenging to rapidly scale** in many LMICs.

**Antigen RDTs**
- Also used to **diagnose acute infection**.
- Typically perform less well than NAAT, however new tests reaching market **perform at levels of the WHO TPPs**.
- Can be deployed into **decentralized settings**, including clinics and communities by HCWs.
- Provide **rapid results** in under 30 minutes.
WHO has released new interim guidance on the use of COVID Ag RDTs

“Ag-RDTs that meet the minimum performance requirements of ≥80% sensitivity and ≥97% specificity compared to a NAAT .. can be used to diagnose SARS-CoV-2 infection in a range of settings where NAAT is unavailable or where prolonged turnaround times preclude clinical utility.

..Ag-RDTs should be conducted by trained operators in strict accordance with the manufacturer’s instructions and within the first 5-7 days following the onset of symptoms. “

## The interim guidance describes five scenarios

1. **Respond to suspected outbreaks** in remote settings, institutions and semi closed communities where multiple positive AgRDTs are highly suggestive of a COVID outbreak.

2. **Support outbreak investigations**, where Ag RDTs can help screen at-risk individuals and rapidly isolate positive cases.


4. Where there is widespread community transmission, RDTs may be used for early detection and isolation, including for contact tracing.

5. **Testing of asymptomatic contacts of cases** may be considered even if the Ag-RDT is not specifically authorized for this use.

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The interim guidance also highlights three practical considerations for Ag RDT roll-out

1. Consider initially deploying Ag RDTs in settings where NAAT is currently available to confirm performance & allow staff to gain confidence.

2. Where NAAT confirmation is not feasible, triangulation with clinical symptoms or settings is needed to confirm result validity.

3. Use of Ag-RDTs is not recommended in low prevalence settings until specificity of tests is >99% because of high rate of false positives.

### 10 factors are important when selecting which Ag RDTs to use

1. **Quality of available data** used to validate the test
2. **Reported performance** of the test
3. **Manufacturing quality and regulatory** status of the test
4. **Manufacturing capacity** and further evidence of quality, including other products manufacturers have on the market and surveillance capacity
5. **Distribution and technical support** provided by suppliers
6. Shipping and **storage conditions** and shelf life
7. **Specimen collection** requirements
8. Contents of test **kit**
9. The **cost** of the test
10. Availability, completeness and **clarity of instructions for use**.

The guidance also highlights 6 scenarios in which Ag RDT should **not** be used, based on expected initial test performance

<table>
<thead>
<tr>
<th>Scenario</th>
<th>Explanation</th>
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<tr>
<td>In individuals without symptoms unless the person is a contact of a confirmed case</td>
<td>Pre-test probability is low.</td>
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<tr>
<td>Where there are zero or only sporadic cases</td>
<td>Ag-RDTs are not recommended for routine surveillance purposes or case management in this setting. Positive test results would likely be false positives. Molecular testing is preferred.</td>
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<tr>
<td>Appropriate biosafety and infection prevention and control measures (IPC) are lacking</td>
<td>To safeguard health workers, testing requires that operators wear gloves, gown, mask and face shield or goggles</td>
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<td>Management of the patient does not change based on the result of the test</td>
<td>If test-positive and test-negative patients will be treated the same way because of unknown or low PPV and/or NPV, then there is no benefit to testing.</td>
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<td>For airport or border screening at points of entry</td>
<td>Prevalence of COVID-19 will be highly variable among travellers, and it is therefore not possible to determine PPV and NPV of test results.</td>
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<td>In screening prior to blood donation</td>
<td>A positive RDT result would not necessarily correlate with presence of viremia.</td>
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