Role of Diagnostics in the COVID-19 Outbreak Response

Rosanna W Peeling
Professor and Chair, Diagnostic Research
London School of Hygiene & Tropical Medicine
Director, International Diagnostics Centre

Role of Diagnostics in an Outbreak Response

"The right test for the right patient in the right place and at the right time"

4 main use cases for diagnostics:

- **Confirm** infection in patients fulfilling the COVID-19 clinical case definition
- **Rapid triage** of suspected cases
- **Screen** for infection in asymptomatic contacts of confirmed cases
- **Determine exposure** (current and past) to the SARS CoV-2 to understand the true extent of the outbreak, map the pandemic, monitor trends and for contact tracing

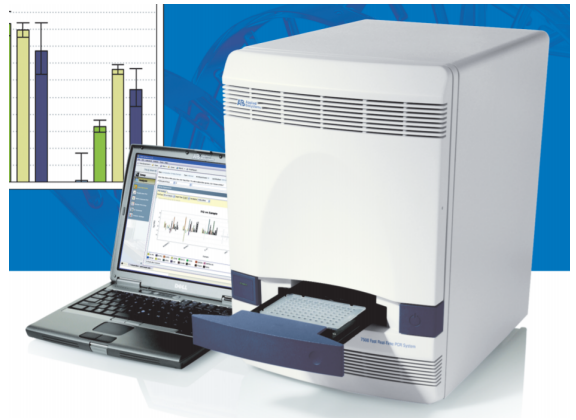
Use Case 1: Confirm Infection in Patients fulfilling the COVID-19 Case Definition

- What type of test is needed?

Molecular tests with high sensitivity and specificity to detect viral RNA (optimally within 5-7 days post onset of fever)

- Where can it be done and by whom?

Typically in a laboratory by trained laboratory staff using specialised equipment



- How long does it take?

1-2 hours before the results are available

Use Case 2: Rapid Triage of Suspect Cases

- What type of test is needed?

Rapid tests for detecting viral RNA or proteins

- Where can it be done and by whom?

Tests performed at the point-of-care (POC) by anyone who can follow simple instructions

- How long does it take to get results?

5-45 minutes for POC molecular tests and 15-20 minutes for POC antigen tests

Use Case 3: Screen Asymptomatic Individuals who are contacts of COVID-19 Cases

- What type of test is needed?

Depends on timing of exposure:

Within 7-14 days: use lab or POC assays to detect viral RNA or antigen

More than 7-14 days: use serology (IgM/IgG/IgA) tests to detect antibodies to SARS CoV-2 as a marker of exposure

OR

a combination of molecular + serology tests

OR

a combination of antigen + serology tests

Use Case 4: to Determine Current and Past Exposure

- What type of test is needed?

Tests for detecting antibodies specific to SARS CoV-2

- Where can it be done and by whom?

Enzyme immunoassays performed in the laboratory by technologists or rapid tests in POC settings by health care providers or as self- or home tests

IgM/IgG duo test

- How long does it take to get results?

2-3 hours for laboratory tests (high-throughput immunoassays) and 10-20 minutes for rapid POC tests

- What type of specimens are needed?
- Enzyme immunoassays need serum but rapid POC test can use finger pricked whole blood, plasma and serum

Testing Strategy depends on the stage of the epidemic and laboratory capacity in country

WHO has defined the 4 Cs as:

- No cases
- Sporadic cases
- Clusters of cases
- Community transmission

Africa CDC Testing Strategy -1

in early outbreak, test:

- Anyone with fever and acute respiratory symptoms who have been in a place in the last 14 days where COVID-19 is transmitting
- All symptomatic contacts of a confirmed/probable cases of COVID-19
- All cases of Severe Acute Respiratory Infection (SARI) surveillance systems and selected Influenza-like illness (ILI) samples reported through National Influenza Sentinel Surveillance System
- Healthcare workers with symptoms consistent with COVID-19 disease regardless of exposure

Africa CDC Testing Strategy -2

When community transmission is established, prioritise testing:

- All cases of SARI and ILI reported through the Influenza Sentinel Surveillance System to identify undetected transmission areas
- Severe acute respiratory infections presenting to hospitals
- Healthcare workers with symptoms consistent with COVID-19 disease regardless of exposure

See Africa CDC's "Step up to Control COVID-19": guideline for timing COVID-19 interventions
See Africa CDC's " Protocol for Enhanced ILI/SARI Surveillance for COVID-19 in Africa"

Discussion: What use cases might be considered for serology tests?

- All cases of SARI and ILI reported through the Influenza Sentinel Surveillance System to identify undetected transmission areas
- map the extent of the epidemic to inform public health measures?
- Determine at risk populations and attack rate?
- Discharge of COVID-19 cases from hospital when PCR is not available?
- Infected person who test IgM/IgG positive can return to work, esp. health care workers?