



COVID-19 Testing Technologies: How do they work and why that is important

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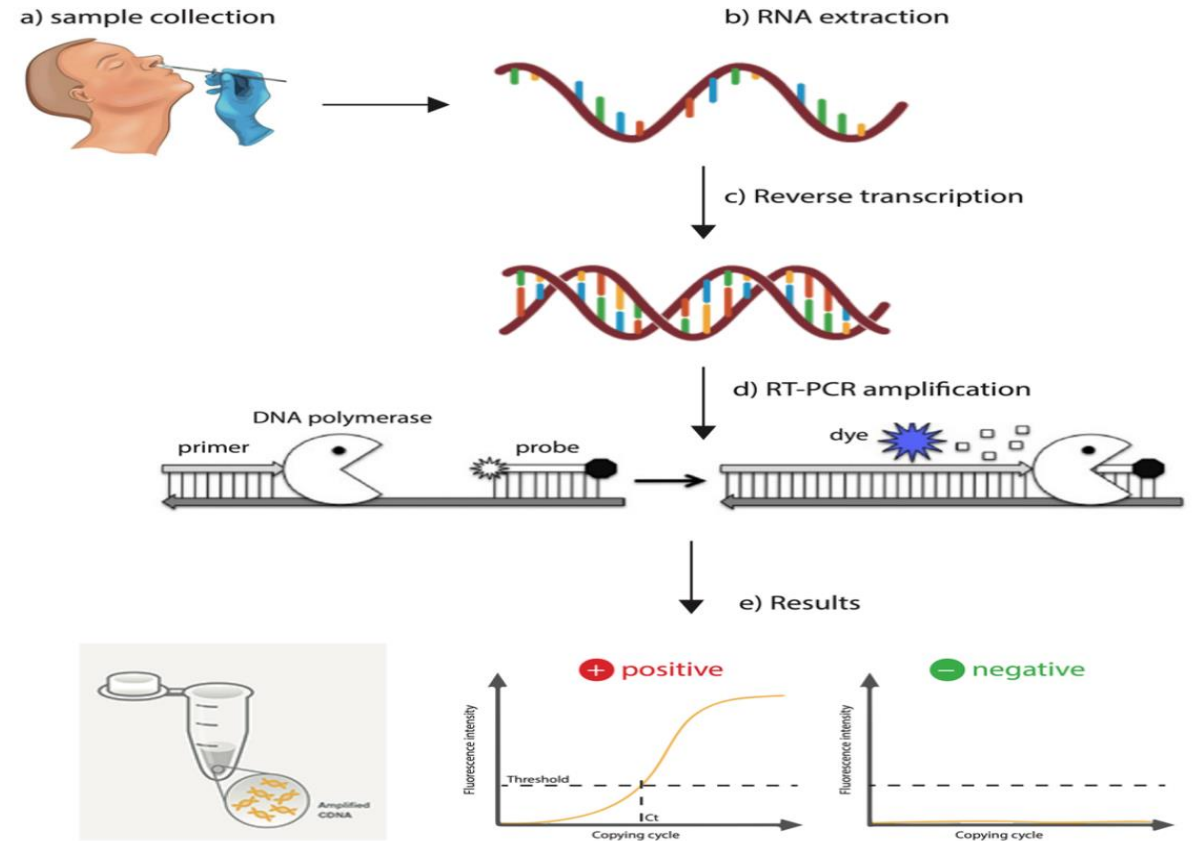


Objectives

- Overview of Current Testing Tools
 - RT-PCR
 - Point-of-care tests
 - Antigen detection
 - Serology
 - Sequencing
- Understanding Testing Technologies through Variants of Concern

Core Testing Tool: RT-PCR

- RT-PCR remains the gold standard for the detection of SARS-CoV-2
- Able to amplify very small amounts of genetic material
- First Canadian test developed at NML within 5 days of the sequence being published by Chinese researchers
- Requires a whole supply chain, which has proven challenging to navigate, particularly early in the pandemic



Lab-based PCR versus Point of Care

- PCR testing can be performed both in “brick & mortar” laboratories and by point-of-care portable machines
- Lab-based tests enable large scale volume but add complexity in terms of sample collection, shipping and processing
- Point-of-care tests are generally able to be run with easily accessible training but have the limited throughput and have limited supply and are relatively expensive



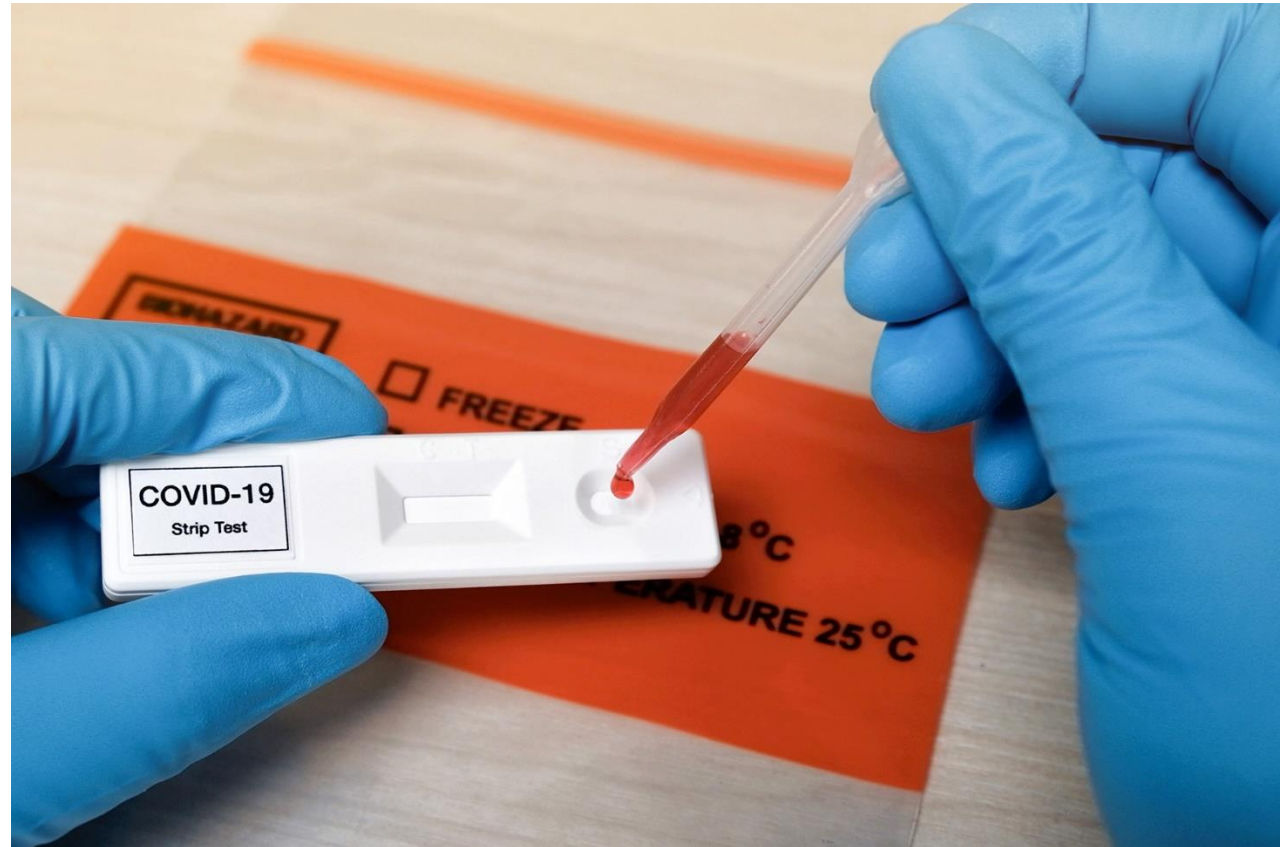
PCR's Cousin – Abbott ID Now

- Molecular technology that is different from RT-PCR
 - So-called “LAMP” assay
- Slightly less sensitive & specific but limited hard data for clinical performance
- Very easy to use; system prompts users through the process
- Samples have to be processed within an hour, so truly dedicated to “point-of-care” use

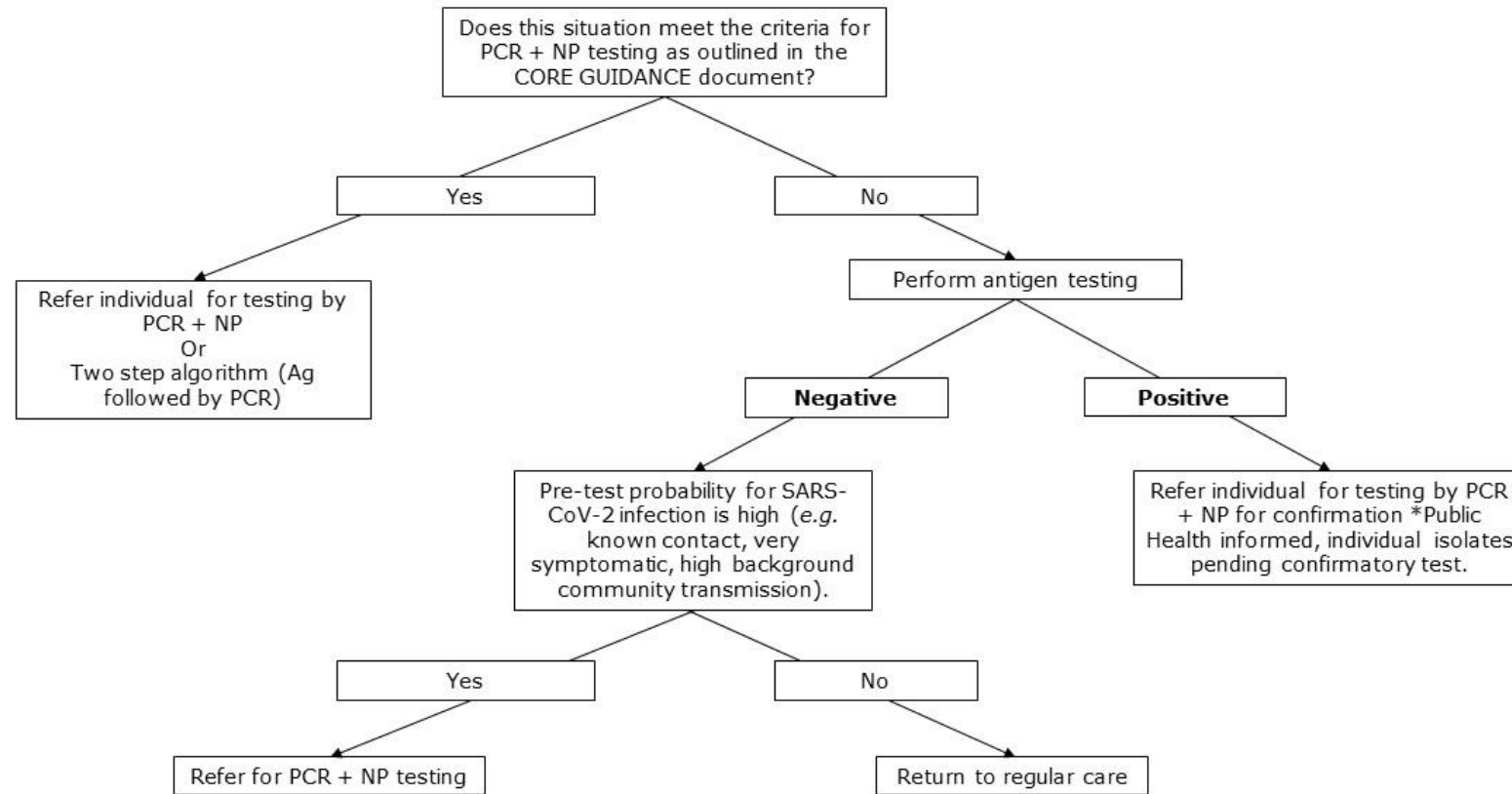


Antigen testing

- Tests for presence of the virus
- No amplification step therefore have lower sensitivity
- Lower sensitivity isn't consistent over the course of illness – better concordance in early disease
- Some devices need electronic readers, others do not
- False positive issues raised in some areas in the US



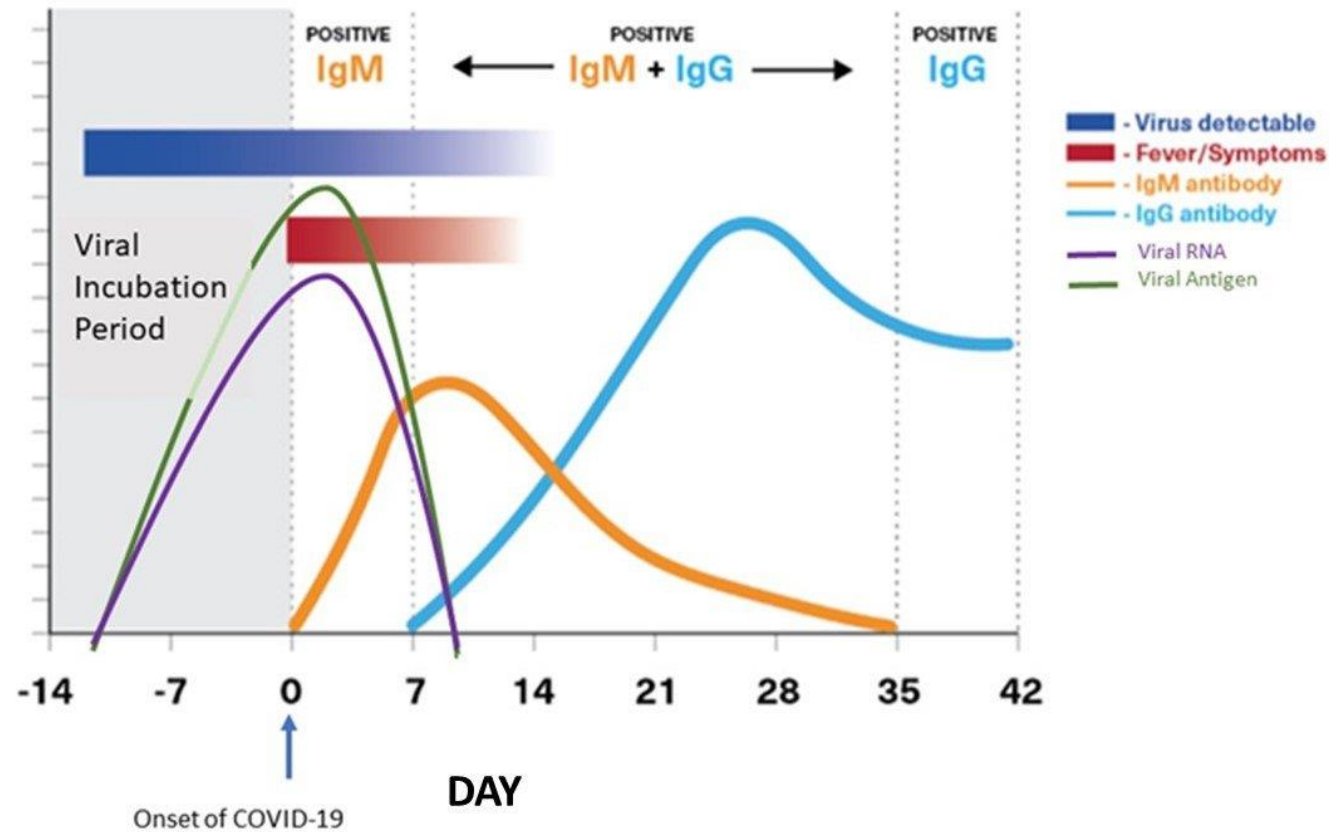
Interim Guidance on the Use of Antigen Tests for COVID



*At this time positive RADTs will require confirmatory testing by RT-PCR. Following further evaluation, confirmatory testing during periods of high prevalence might be discontinued provided specificity was sufficient.

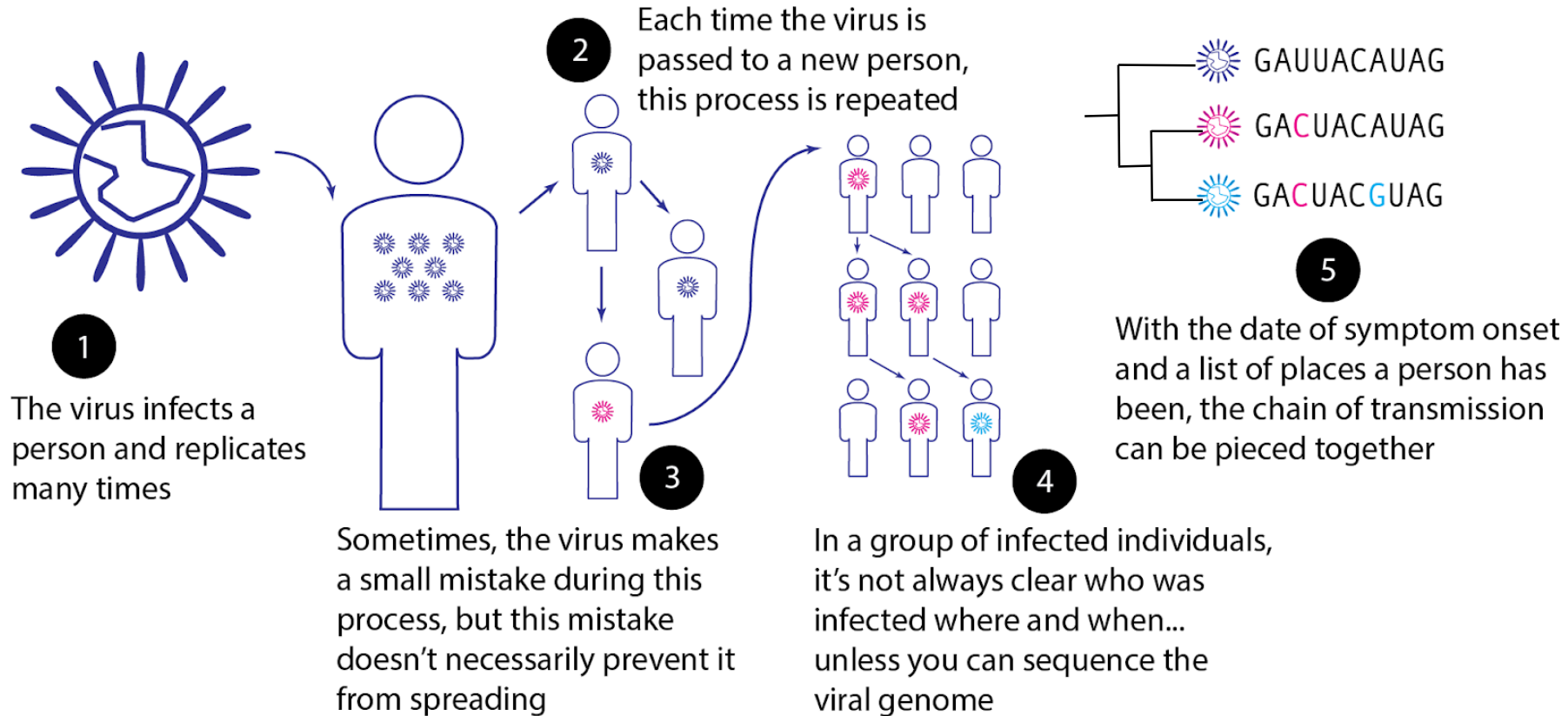
Serology

- Relies on detecting antibodies
- Timing not amenable for detection of active cases
- Uncertain impact of “antigenic sin” phenomenon



Genomic Surveillance 101

Understanding Transmission and Variants



Variants of Concern – Technologies in Context

- Variants can impact diagnostics in a number of different ways:
- Mutation could arise in the area of the genome that is targeted by the PCR target
 - Generally this is mitigated by having multiple targets (2-3) as part of the test
 - LAMP assays used 4-6 targets, so are less vulnerable
- Antigen tests in Canada target the nucleoprotein; so far the mutations have not been occurring in this region, but could become an issue in the future
- Serology generally targets the spike protein, which is under significant evolutionary pressure, so are generally more vulnerable to VoCs
- Sequencing reads the full genome, so is key to detecting variants but is generally slow and requires significant resources and specialized equipment