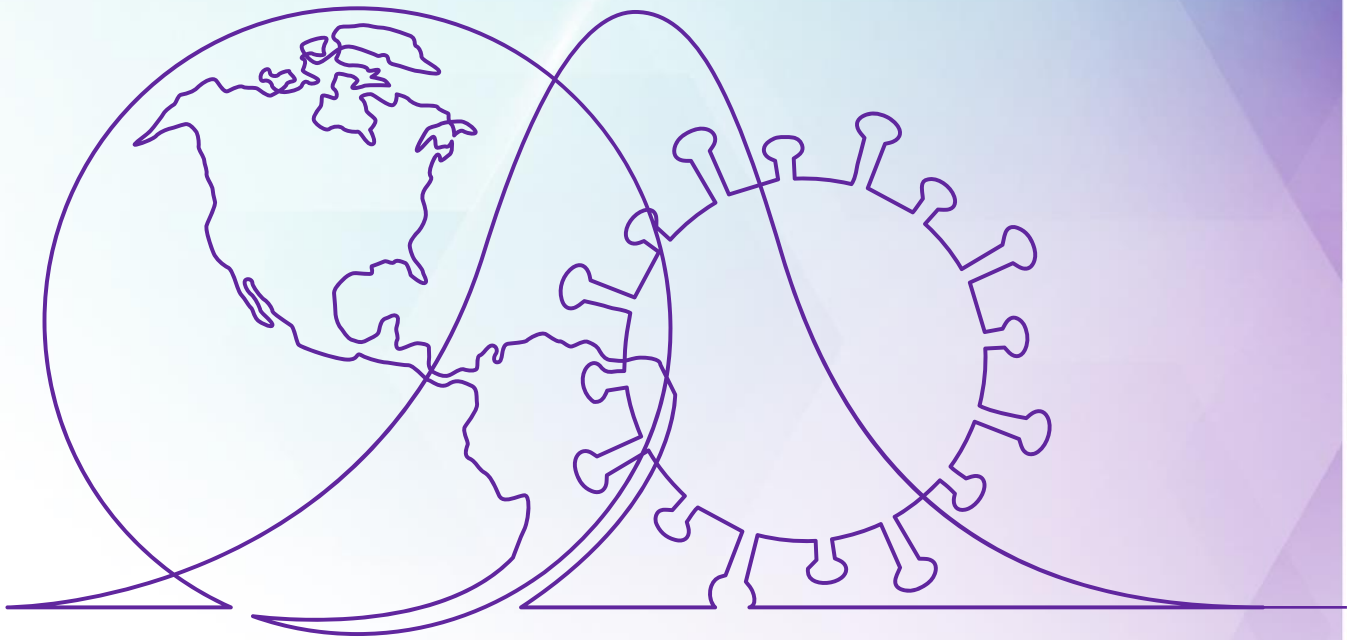
MedTech Europe
from diagnosis to cure

COVID-19 PANDEMIC RESPONSE
THE DIAGNOSTIC INDUSTRY ANGLE

Updated: December 2020



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Introduction

Testing has become a **crucial component for safe exit strategies** across countries for **pandemic management**.

In this presentation we look at some of the key, most common questions related to testing and how it can unlock pathways out of the lockdowns.

How does testing work?

Why are different tests needed at different times?

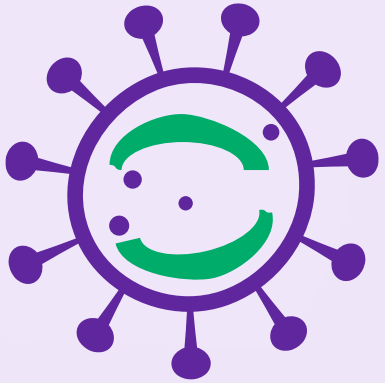
What are the key learnings so far?

In this global health emergency, the **diagnostics industry plays a crucial role**, and is committed to doing its part so that life can move forward to a new kind of normal.

Contents

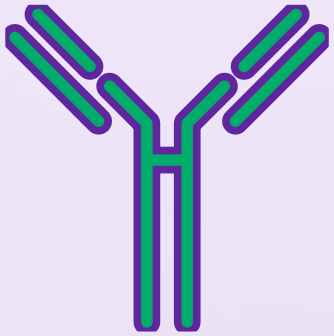
Different types of COVID-19 tests:

Molecular tests



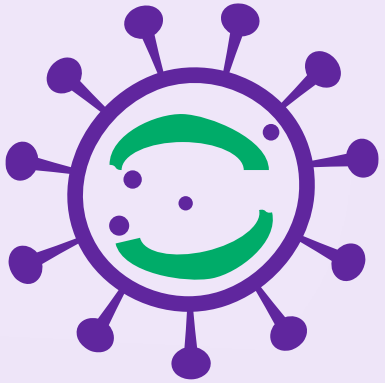
Antigen tests

Serology tests



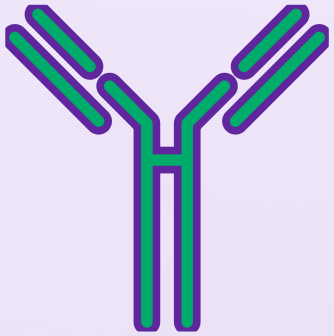
Different types of COVID-19 tests:

Molecular tests



Antigen tests

Serology tests

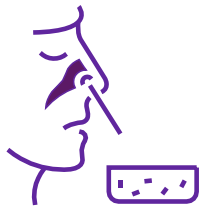


Current presence of virus
(but not previous contact)

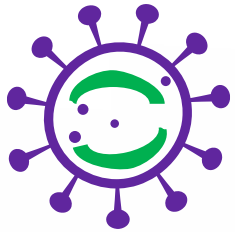
Immune response
(previous contact with COVID-19)

Molecular-based tests – How do they work?

Sample collection → **Detection** → **What these tests say**



Nose / nasopharyngeal (NP) / throat swab



Zoom in on the genetic signature of the virus (RNA)

Detect current COVID-19 infection

Why they are helpful

1. Molecular tests are highly sensitive and specific
2. Allow for testing people at an early stage of the infection
3. Can inform on the spread of the virus
4. Provide relevant information for case confirmation and isolation guidance

Antigen-based tests – How do they work?

Sample collection → **Detection** → **What these tests say** → **Why they are helpful**

Sample types vary according to technology used (e.g., upper respiratory tract swabs or other biological fluid collectors)

Identify presence of proteins of the virus **(antigens)**

Detect current COVID-19 infection

Access:

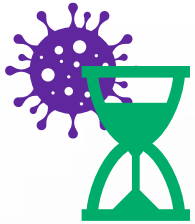
- Can be done in a doctor's office
- Laboratories can run large batches
- Could be developed and validated for self-testing

Serology tests – How do they work?

Sample collection → **Detection** → **What these tests say** → **Why they are helpful**

Blood samples (venous, capillary or serum)

Detect if person has developed antibodies

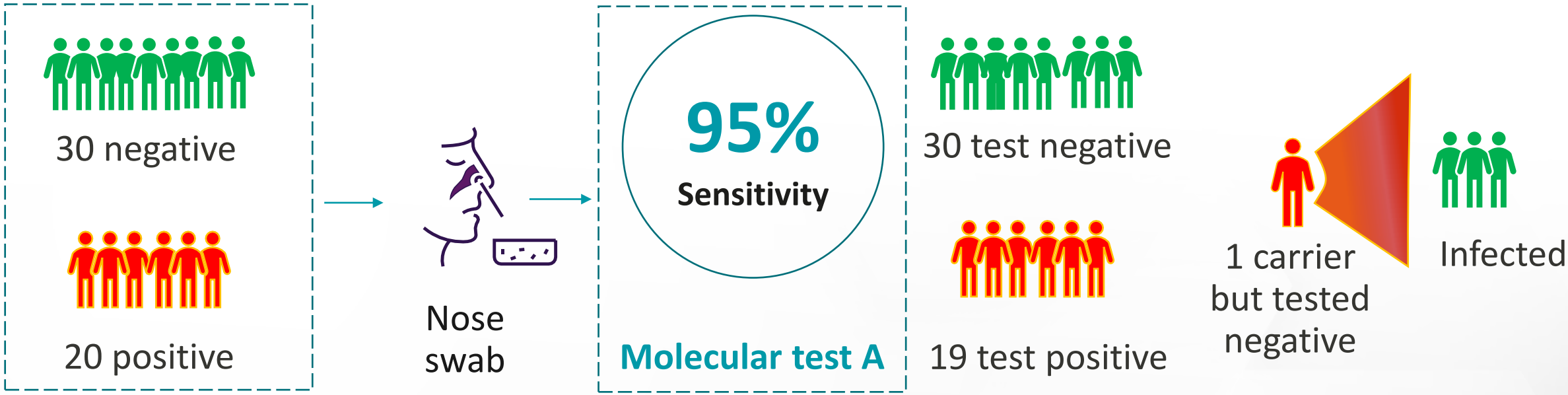


Detect previous contact with COVID-19

Presence of IgM antibodies suggests that the person is in the early stage of the infection. Presence of both IgM and IgG (which develop later during the course of infection) suggest that the patient is in a later stage of the disease.

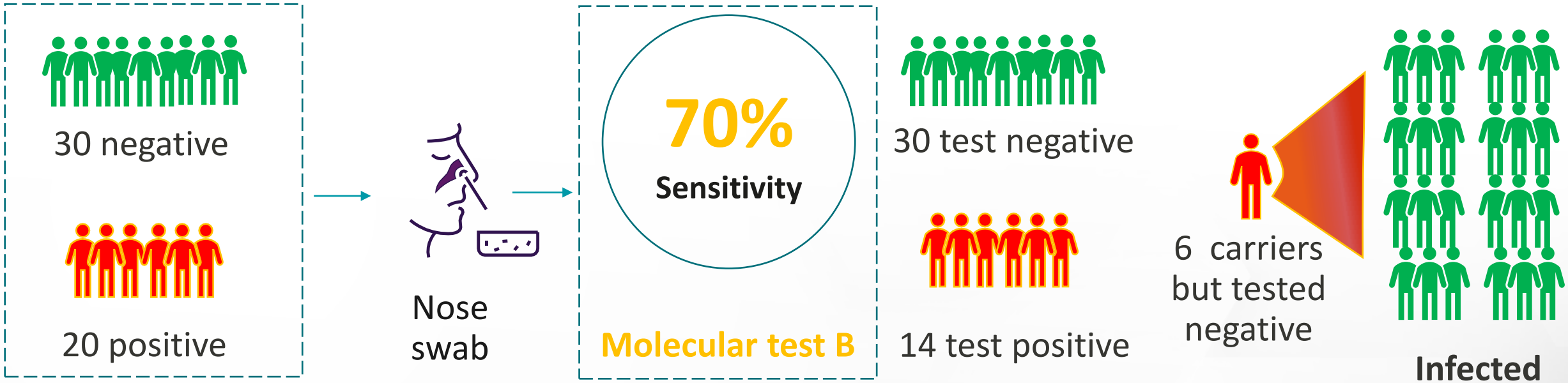
1. Provide important information on diffusion of infection for large portions of populations
2. Will play a major role in vaccine development, including monitoring pre / post vaccinal immunity

Why test sensitivity is important (molecular tests)



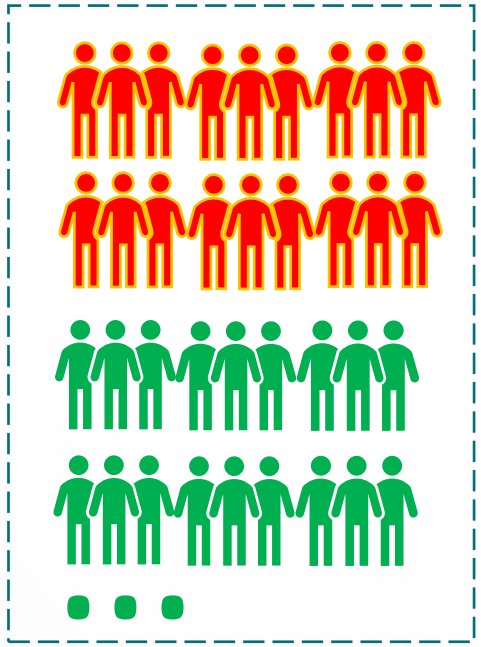
1 carrier will test negative and infect others

Why test sensitivity is important (molecular tests)



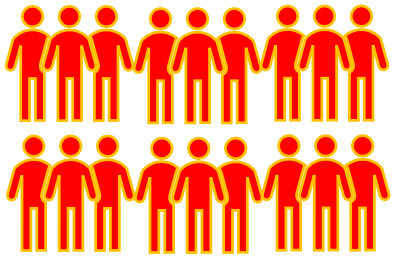
6 carriers will test negative and infect others

Why test specificity is important (serology tests)



Population of 100

Blood or capillary sample



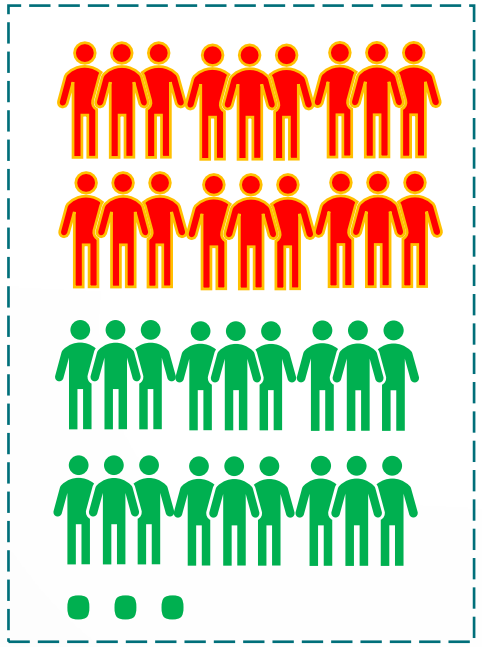
18 patients infected and tested positive

All patients that tested positive **had actually been infected** (correct result), and there are no false positive.

Correct information **optimally guides virus containment management**

All patients were correctly diagnosed

Why test specificity is important (serology tests)



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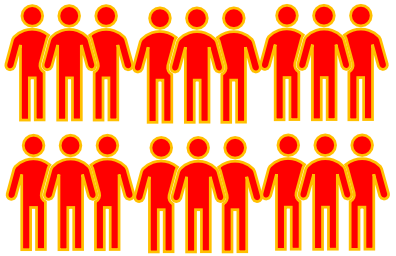

18 patients infected and tested positive

2 patients tested false positive

A subset of patients tested positive, but **in reality had not been infected.**

False information **misleads virus containment management**

2 patients were given false information

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Ensuring test reliability / performance

Manufacturers carry out a number of evaluation measures **to check and guarantee** the reliability of the final test. These include:

1

Validation

- Assays are **validated**
- Assays are also carried out by **confirming their performance** against available samples

2

Batch release

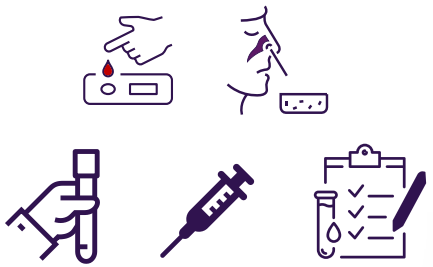
- Individual batch performance is **verified by manufacturers**
- Done **before tests shipment**

3

Verification

- Labs verify that **performance is met**
- This ensures **test reliability**
- Done **before delivery to patients**

Reliability of test depends on its components



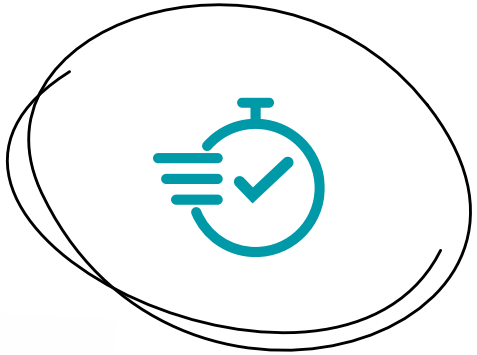
If a single component of the process fails (e.g. swabs, quality controls) patients may receive incorrect results.

Patients are **forced to needlessly quarantine** themselves

Patients **neglect necessary caution** as they are not aware of infection

Safety of lab workers is at risk

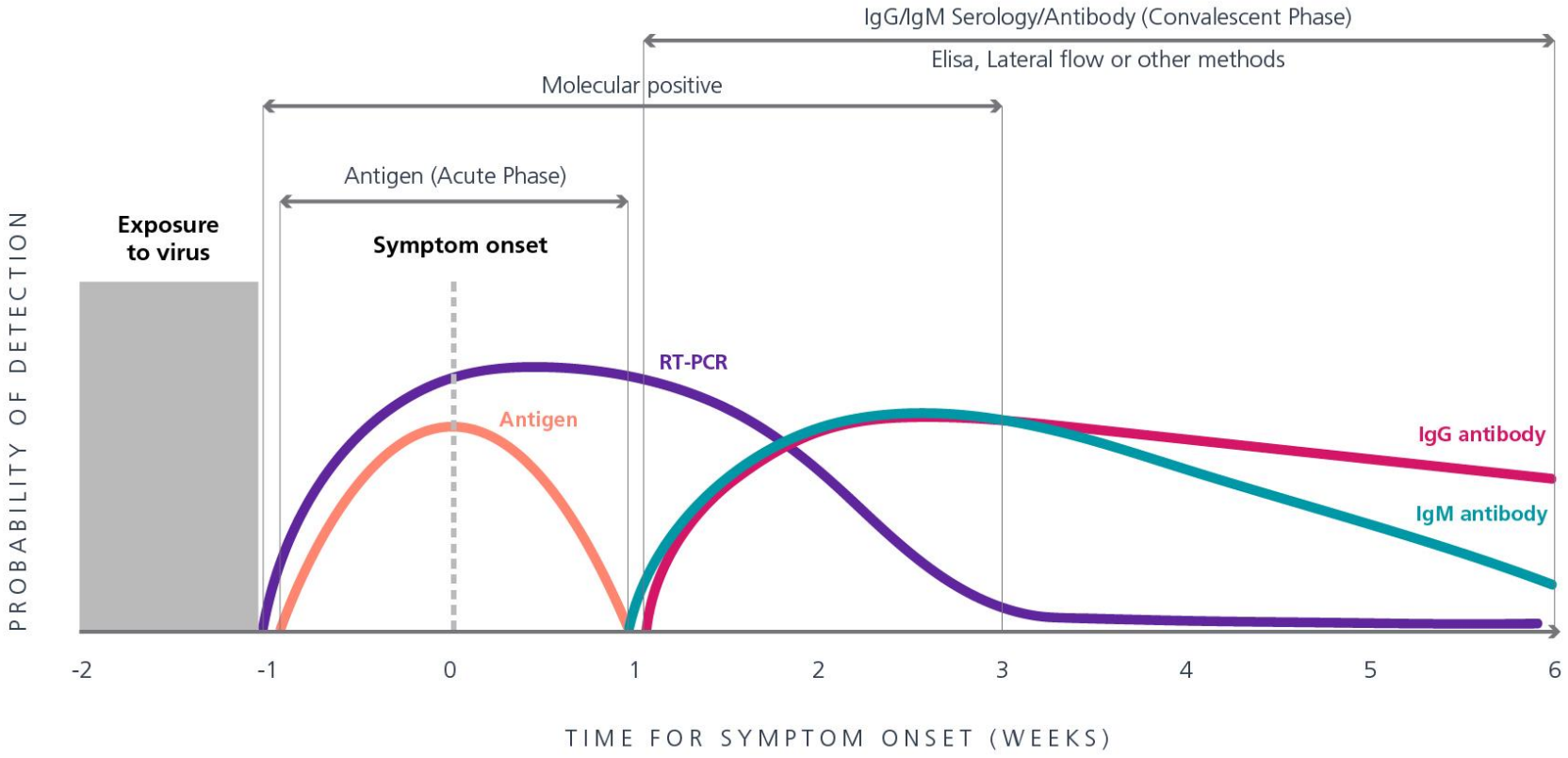
Keeping up with demand: developing and producing tests



Whereas **rapid response** is critical during a pandemic, delivering tests of the **highest quality** remains the industry's top priority

The diagnostic industry response will continue to **evolve and adapt to the increasing demand for COVID-19 tests**, and ensure our resources and experience support safe exit strategies and robust public health measures

The tests are for different points of disease progression



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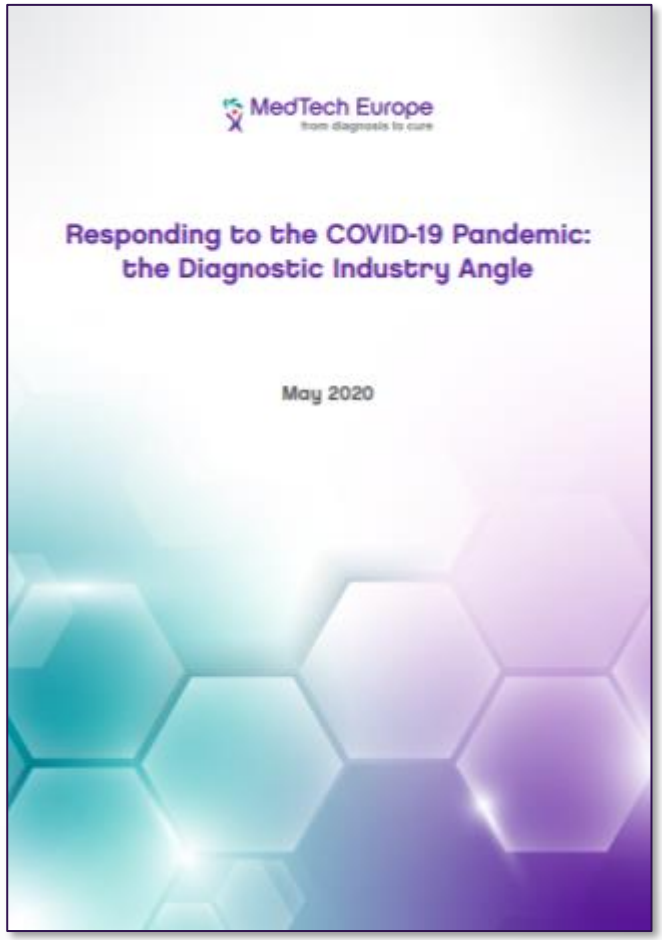
References



- This presentation gives an overview of the **Diagnostic Industry response to COVID-19**
- It aims to offer to relevant stakeholders some **key answers drawn from the experience** of industry post-lockdown on testing, including diagnosis, capacity, and exit strategies in place
- Core elements are drawn from the **response paper** published by MedTech Europe website **in May 2020**

For more information

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