



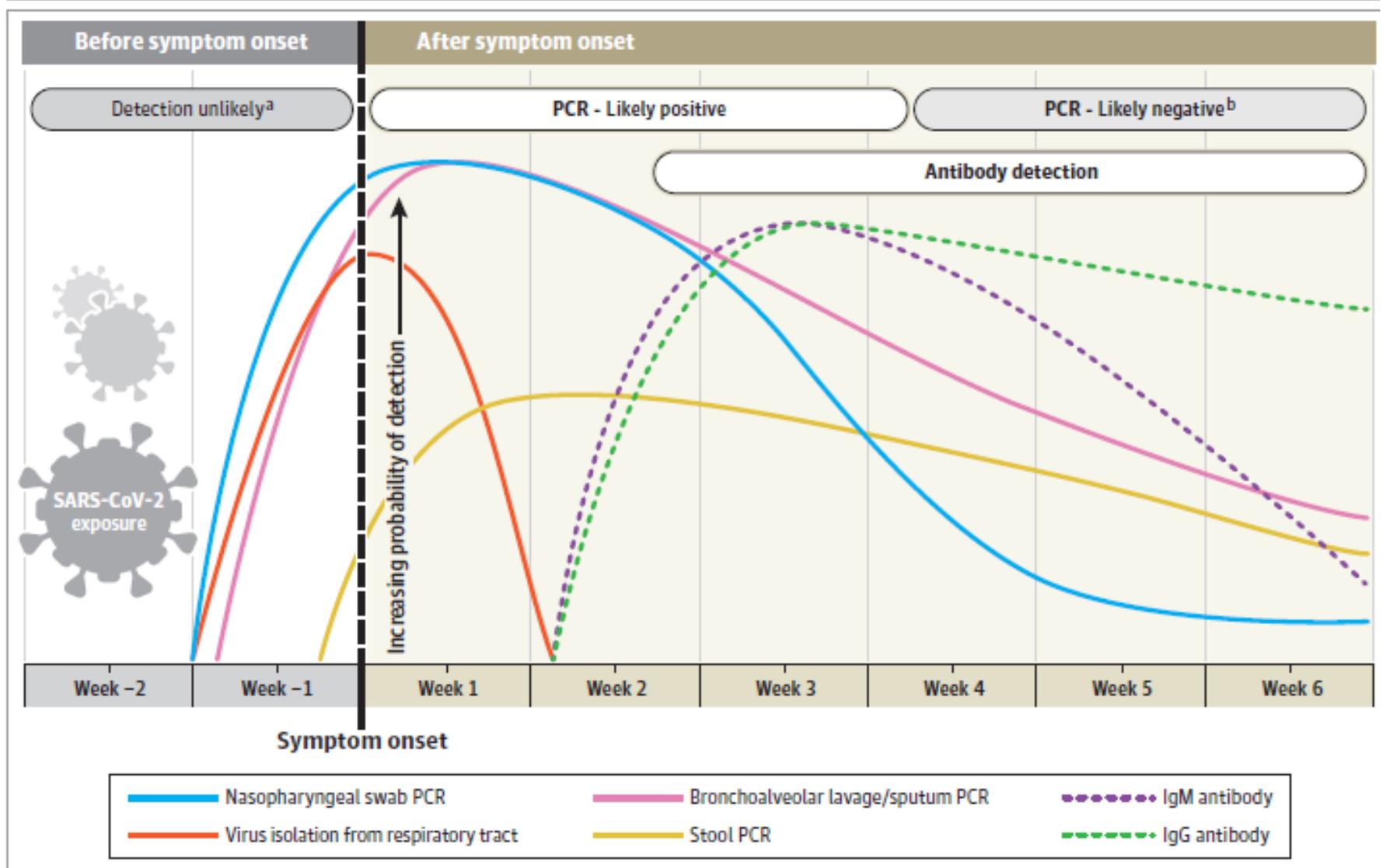
Laboratory diagnosis of a new coronavirus infection - a few comments

Ewa Wysocka

Chair and Department of Laboratory Diagnostics,
Poznan University of Medical Sciences

2020, 28th of May

Figure. Estimated Variation Over Time in Diagnostic Tests for Detection of SARS-CoV-2 Infection Relative to Symptom Onset



WHO recommendations

SARS-CoV-2 infection must be confirmed using molecular biology methods rRT-PCR („gold standard”) – is this a challenge for medicine?

Poland: The regular „before COVID-19” standards for prevention and combating of infectious disease were used at the beginning of the epidemic, including:

- the type of laboratory (the Government permission),
- biosafety level (BSL),
- analytical method.

Poland: 2020, 3rd of April - Regulation of the Minister of Health

Team for the Coordination of COVID Laboratory Networks was established; Team's tasks:

- Keeping the list of authorized laboratories
- Checking that the laboratory meets the criteria for being included in the network,
- Develops diagnostic standards
- Responsibility for the training activities
- Conducting analysis of laboratory resources (including allocation)
- Giving opinions on equipment and reagent investments

- **Supervises the quality of the testing**

Continuing the epidemia status

Poland: 2020, 3rd of April - Regulation of the Minister of Health

Team for the Coordination of COVID Laboratory Networks was established;

Team tasks are increasing:

- Keeping the list of authorized laboratories
- Checking that the laboratory meets the criteria for being included in the network,
- Develops diagnostic standards
- Responsibility for the training activities
- Conducting analysis of laboratory resources (including allocation)
- *From: Giving opinions on equipment and reagent investments*
- ***To: Setting requirements for the quality of reagents used and verification at central level of the approval of the test kit***
- **Setting requirements for professional laboratory staff – laboratory diagnostic specialists**

- **Supervises the quality of the testing**

... we have the central verification system of COVID laboratory diagnostics

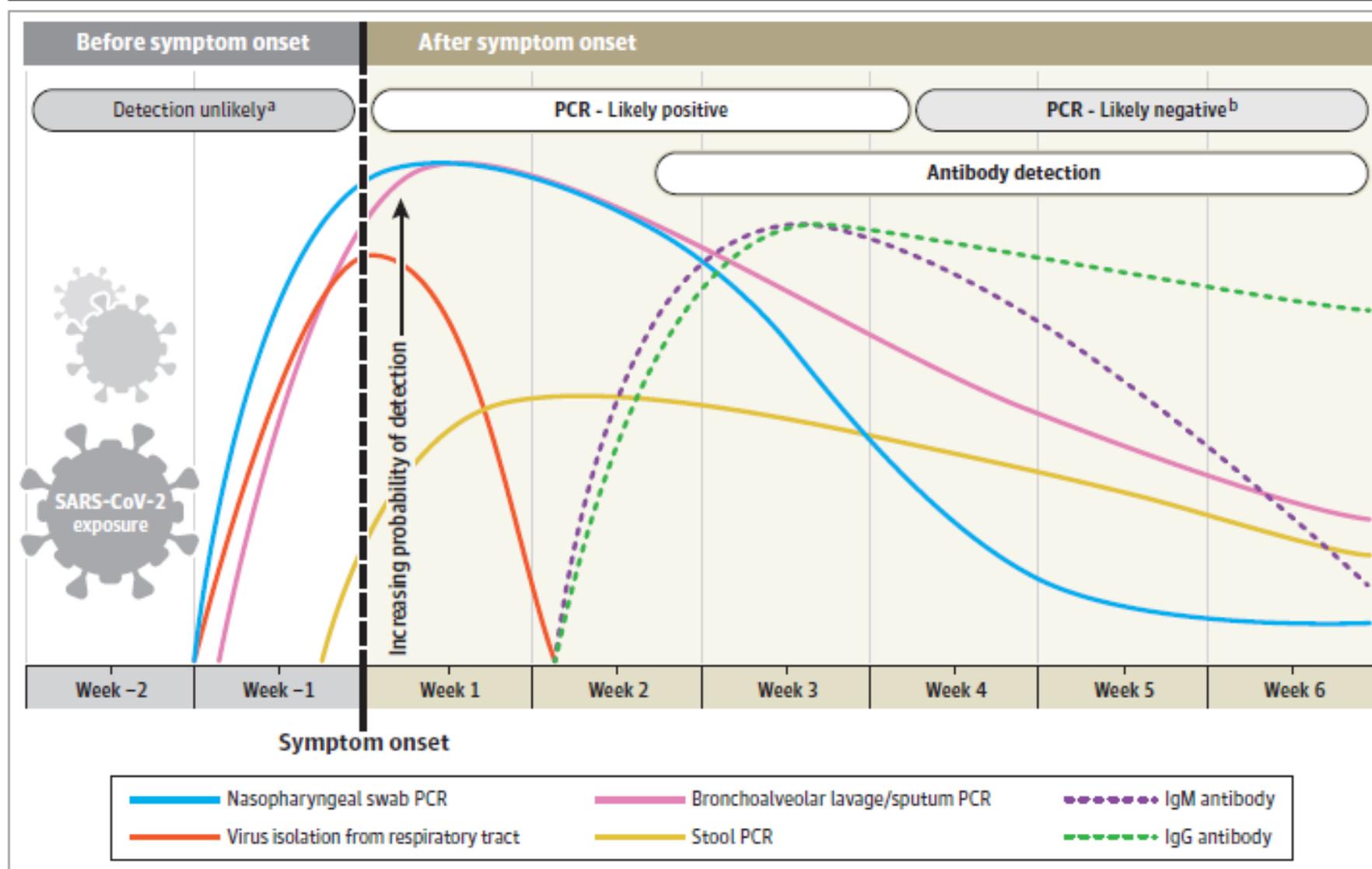
High-performance and reliable diagnostics systems, including laboratory diagnostics

Challenges – with the duration of the infection, the sensitivity of molecular diagnostics decreases

Necessary concepts:

- Diagnostic sensitivity
- Diagnostic specificity
- Analytic sensitivity
- Analytic specificity

Figure. Estimated Variation Over Time in Diagnostic Tests for Detection of SARS-CoV-2 Infection Relative to Symptom Onset



Necessary concepts:

- **Diagnostic sensitivity:** the true positive rate, measures the proportion of actual positives that are correctly identified (the percentage of sick people who are correctly identified as having the condition)
- **Diagnostic specificity:** the true negative rate, measures the proportion of actual negatives that are correctly identified (the percentage of healthy people who are correctly identified as not having the condition)

In medical diagnostic tests sensitivity is the extent to which actual positives are not overlooked (so false negatives are few), and specificity is the extent to which actual negatives are classified as such (so false positives are few).

- **Analytic sensitivity** – referred to as the limit of detection
- **Analytic specificity** - The assay's ability to detect the intended target. It is critical to verify that the assay's primers are specific to the target. There are two components to analytical specificity, cross reactivity and interference

Diagnostic Sensitivity and specificity

		Positive results	Negative results		
Sensitivity 99%	100 Patients diagnosed with the disease	99 Truly pos (+)	1 False neg (-)		
		1 False pos (+)	99 Truly neg. (-)	100 healthy	specificity 99%

rRT-PCR for COVID diagnosis

Analytical sensitivity is very high (10-100 virus particles)

Diagnostic sensitivity depends on:

- the correctness of collecting the biological material
- the phase of infection (the highest between 7 and 14 day after the contact with virus)
- The place of collection from the respiratory tract (pharynx and nosopharynx 65-70% of diagnostic sensitivity)

IgG antibody titer in blood after infection

- Is this the perspective for the following time ?**

Thank you
for the attention