Coronavirus testing: information on test devices and methods in a single place

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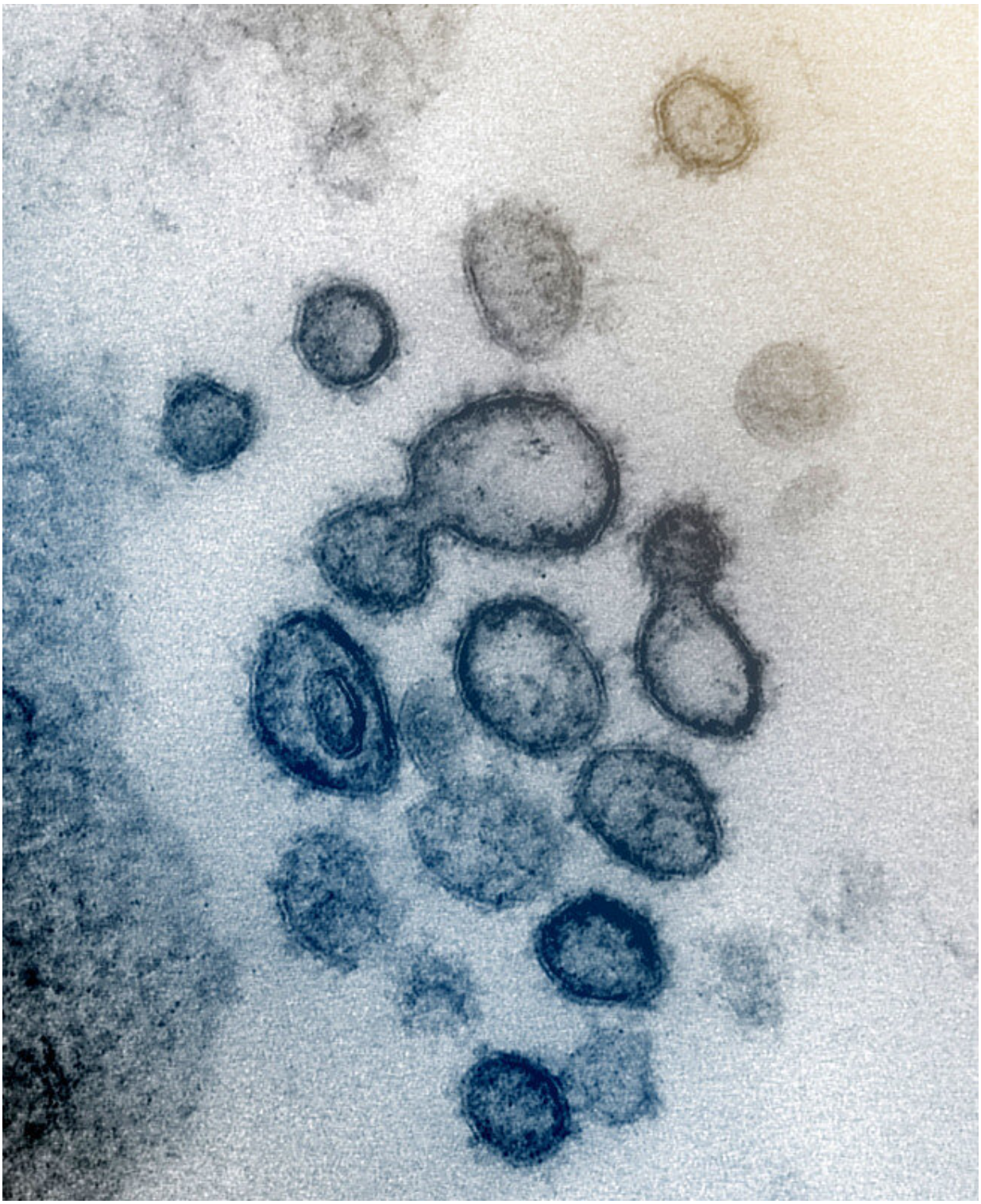

This transmission electron microscope image shows SARS-CoV-2 -- also known as 2019-nCoV, the virus that causes COVID-19 -- isolated from a patient in the US. Virus particles are shown emerging from the surface of cells cultured in the

lab. The spikes on the outer edge of the virus particles give coronaviruses their name, crown-like. Credit: NIAID-RML

The European Commission's Joint Research Centre has created a database of COVID-19 in vitro diagnostic devices and test methods

As part of EU efforts to provide guidance on the use of coronavirus tests, the JRC has created a database of COVID-19 in vitro diagnostic devices and test methods that gathers information on available tests in one place.

Testing for the presence of the SARS-CoV-2 virus or past exposure to it is an essential aspect of combatting the COVID-19 outbreak, and for efficient strategies for gradually lifting the confinement measures.

At the moment, a large number of tests already exist in the EU, and new tests are being developed.

Different tests are suitable in different contexts. Information on their performance, i.e. how well they work to achieve their intended purpose, is important for making choices, for instance as part of national strategies.

As a follow up action to the Guidelines on in vitro diagnostic tests and their performance, the JRC has developed a database, which gathers in a single place information on the currently available tests.

The database contains publicly available information on devices, including elements of performance, and a collation of relevant scientific literature.

It does not include manufacturer technical documentation, which is not publicly available.

About COVID-19 tests

The COVID-19 tests fall broadly into two categories: those detecting the presence of the SARS-CoV-2 virus and those detecting past exposure to the virus, i.e. the body's immune response to the infection.

If a person is infected, nasal or throat swabs can be used to reveal the presence of the virus.

This can be done by either focussing on the specific genetic material of the virus (in a so-called RT-PCR or reverse transcriptase polymerase chain reaction) or on certain specific molecules that are present on the surface of the virus (referred to as antigen tests).

The tests detecting past exposure to the virus—also called serological tests—reveal the presence of antibodies in the blood of an infected person, produced in response to the virus.

Antibody tests are abundant on the EU market, but their effectiveness for the diagnosis of COVID-19 is limited because antibodies become detectable in the patient's blood only several days after infection.

Nevertheless, antibody tests could become essential for performing large-scale population surveys and for guiding de-escalation strategies when the pandemic is under control.

Ensuring good test performance

EU law (Directive 98/79/EC) stipulates that CE-marked devices must be

manufactured so that they are suitable for the purpose intended by the manufacturer, taking account the generally acknowledged state of the art.

The manufacturer is responsible for evaluating the performance of the tests before placing the device on the market. This must be reflected in the technical documentation of the device.

National competent authorities are responsible for the surveillance of devices on the market, and for taking appropriate action against devices that do not conform with the legislation.

Given the rapid development of the COVID-19 pandemic, the performance of the device in the clinical practice may differ from the initial performance study carried out by the manufacturer.

Therefore, the European Commission recommends carrying out additional validation of COVID-19 tests.

Validation refers to confirmation that the test achieves the performance levels specified by the manufacturer.

Such studies are carried out by laboratories in the EU Member States.

The JRC has recently developed a positive control material for the validation of RT-PCR tests, which is available to laboratories in Europe.

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