Content of this Plain Language Summary

The objective of the Plain Language Summary is to help the general public understand EUnetHTA assessments. You can find the link to the full assessment report later in the summary.

What is included in this Plain Language Summary? First, this document explains what EUnetHTA is and what this network does. Second, you will find the summary of the assessment.

Please note that this assessment was performed as a rapid collaborative review – please refer to the EUnetHTA COVID-19 Response website for further information.

What is EUnetHTA?

EUnetHTA is the European Network for Health Technology Assessment (HTA). EUnetHTA was established to create an effective and sustainable network for HTA across Europe. Our partners work together to help develop information to contribute to HTA in European countries. For more information on our goals and how we work, please visit our website and our patient flyer.

EUnetHTA consists of over 80 partners that are all non-profit organisations. All partner organisations either produce or support the production of HTA reports. For more information on HTA, visit EUnetHTA's Frequently Asked Questions.

EUnetHTA does not give any advice on reimbursement of a specific health technology. The reimbursement decision is a national or regional decision. This means that reimbursement of health technologies can also differ between countries in Europe.

What does EUnetHTA do?

EUnetHTA supports national and regional research institutions and health ministries in their decision-making. For this task, EUnetHTA uses specific methods to assess health technologies. Health technologies that may be assessed by EUnetHTA include medicines and other health technologies such as specialist medical care, surgical interventions and diagnostic tests. The purpose of this plain language summary is to help the general public understand the findings from this assessment.

Summary of the assessment

This section provides a summary of the assessment and was published on 18/12/2020. To get a better understanding of commonly used HTA concepts, we advise you to look at the HTAi glossary.

Why did we conduct this assessment?

The purpose of this EUnetHTA assessment is to give national healthcare systems robust information about the technology under assessment.

What is the context of this assessment?

In December 2019, a novel coronavirus was discovered in Wuhan, Province of Hubei, China, which has rapidly spread across the world. This novel coronavirus was named severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and causes a disease called coronavirus disease 2019 (COVID-19).

The accurate detection of the SARS-CoV-2 virus and diagnosis of COVID-19 remains critical for the prevention, early intervention, treatment and control of the pandemic. Currently, The World Health Organization (WHO) recommends that routine confirmation of cases of COVID-19 should be based on the detection of unique sequences of the virus, by using nucleic acid amplification tests, also known as molecular tests. The dramatic increase in the number of suspected cases intensified the need for COVID-19 molecular testing, leading to a global shortage of materials used to test for COVID-19. Other significant limitations associated with the current WHO diagnostic guidelines for COVID-19 include the turnaround time for the production of results, requirement of skilled personnel and other resource requirements.

It is therefore necessary to consider alternative types of molecular tests.

What did EUnetHTA review?

Through this assessment, EUnetHTA reviewed how well alternative molecular tests and methods work to diagnose patients that are suspected to have COVID-19. These tests were compared to what is currently used to diagnose these patients.

What is the technology under review?	Any molecular test based on nucleic acid amplification tests that could detect the presence of SARS-CoV-2
What is the study group?	Possible or suspected cases of COVID-19 tested for diagnosis on the basis of symptoms, contact tracing or as part of mass screening
What is the technology compared to?	A test that follows the World Health Organization recommendations for the confirmation of COVID-19 cases
What are the outcomes this review investigates?	Outcomes on diagnostic performance: • Number of true/false positives and true/false negatives • Sensitivity and specificity • Other measures of diagnostic accuracy

What are the main findings?

The assessment consists of 103 studies, 3 reviews and 14 rapid assessments. These were found through a systematic literature search of this topic. This search included all studies published up until August 2020. The quality of the 103 studies was assessed to determine if the observations extracted could be considered valid and reliable. Statistical analysis approaches were applied in order to evaluate how well these tests perform. The number of participants/samples included in the studies ranged from a minimum of 10 to a maximum of 1186. The most common trial location was the USA, followed by China, Germany and the UK.

Very limited data was identified in the literature in order to evaluate the diagnostic accuracy of molecular tests in asymptomatic and recovering populations or as part of contact tracing. The performance of those tests in these populations still remains an area to be explored.

The analysis was therefore concentrated on people with suspected, active infections with SARS-CoV-2. A total of 12 diagnostic test classes were derived from the extracted data based on their shared characteristics. The diagnostic test classes showed a satisfactory diagnostic accuracy for almost all the technologies evaluated. However, it is vital to acknowledge that the current data may be not generalisable due to a number of factors.

The diagnostic accuracy studies were mainly conducted on symptomatic populations and many used control samples from non-infected individuals. This does not necessarily reflect the real-world application of these test. A significant risk of bias was found in the majority of the studies, especially in the evaluated test domain and in relation to patient selection. Furthermore, we aimed to categorise tests in a way that allowed results from similar studies to be pooled. As there is no standardised classification for tests that detect SARS-CoV-2 using molecular methods, we derived our own suitable categories and defintions for these. Although we attempted to closely match the observations and divide them into classes based on their shared characteristics, inevitably there will remain some differences between tests grouped within the same class.

The evaluation of the 12 identified test classes revealed generally comparable diagnostic accuracies and clinical utilities across different types of tests when used for the diagnosis of SARS-CoV-2. However, it is essential to acknowledge that the clinical relevance and performance of different diagnostic tests are highly dependent on the disease prevalence rates.

Nevertheless, alternative molecular tests have the potential to provide solutions in order to overcome issues associated with the current diagnostic guidelines and boost testing capacity. Policy makers should consider all the strengths and limitations when designing testing strategies based on alternative diagnostic platforms.

Adequate testing is essential for ascertaining the best ways to identify new infection, rule out the possibility of infection, identify people in need of care escalation for the management of the pandemic, suppress community transmission and will allow gradual reopening of economies and easing of lockdown restrictions.

Did EUnetHTA involve stakeholders?

EUnetHTA values involvement of stakeholders in the assessments. Owing to the urgency of the situation, the present assessment was performed very rapidly. Given the time constraints and the nature of the pragmatic approach for publishing evidence on COVID-19 during the pandemic, patient involvement or expert engagement was not deemed feasible.

Additional information

This report was written by HTA organisations from Wales, Scotland and Austria. Organisations from Italy, Belgium and Ireland have contributed in reviewing roles. The full scientific content is reported in EUnetHTA assessment RCROT02, and can be found here. EUnetHTA has received funding from the European Union's Health Programme (2014-2020). The content of this summary reflects the views of the authoring team. This cannot be considered to reflect the views of the entire EUnetHTA or any body of the European Union. Individuals involved in this assessment were cleared for any potential conflict of interests.

If you have further questions, please contact: eunethta@zinl.nl