

AusDiagnostics TODAY

AusDiagnostics
Multiplexed Diagnostics | Affordable Healthcare

COVID-19 Update Edition



Scientists Stuart Burton and Tiasha Lawson manufacturing COVID-19 assay plates at the AusDiagnostics manufacturing laboratory in Mascot, Australia. Photography by Monique Harmer.

The persistent COVID-19 global pandemic has led to almost 10 million confirmed infections and nearly 500,000 deaths worldwide as of the end of June, according to the World Health Organisation.¹

Since releasing the coronavirus SARS-CoV-2 diagnostic test which received Australian TGA approval and European CE marking in March earlier this year, AusDiagnostics has included this key target to existing respiratory pathogen MT-PCR panels to meet the consistently high demand for concurrent coronavirus testing.

A recent study demonstrated the reliability of these panels to detect SARS-CoV-2 in combination with four seasonal coronaviruses which cause less severe cold-like symptoms and the dangerous SARS and MERS coronaviruses (see article on page 2).

AusDiagnostics continues to develop and release new diagnostic tests for COVID-19. A comprehensive suite of coronavirus tests is now available, including an advanced broad spectrum respiratory pathogens panel that allows simultaneous detection of two SARS-CoV-2 targets alongside important respiratory pathogens,

which is critical during peak flu season.

Additionally, we recognise that despite the increase in number of available tests for coronavirus, patient sample processing continues to be a time-limiting factor, and presents a challenge for wide-scale patient screening. To help address this, especially in regions with escalating numbers of confirmed cases, AusDiagnostics has introduced MT-Prep FAST, a rapid way to extract nucleic acid in less than half the time of typical DNA or RNA extraction methods.

The company continues to produce and supply products from our manufacturing laboratories in Sydney, Australia and Chesham, United Kingdom.

MT-Prep FAST and the updated Respiratory Pathogen Panels are now available. Contact your local AusDiagnostics representative to find out more.

1. WHO. Coronavirus disease (COVID-19) outbreak situation. <https://www.who.int/emergencies/diseases/novel-coronavirus-2019>. Updated 28 June 2020. Accessed 29 June 2020.

**COVID-19
PANDEMIC**
>9.8 million
CONFIRMED CASES
>495,000
DEATHS

OUR RESPONSE

849,792
TESTS DELIVERED

FOR **44** LABS & HOSPITALS
ACROSS **9** COUNTRIES

- Jan** AusDiagnostics releases COVID-19 diagnostic tests
- Mar** Production ramps up to **250,000 tests a month**
- May** MT-Prep FAST released

INTRODUCING
MT-Prep FAST
— for rapid sample
purification.

BENEFITS

- **Save time**
Extract nucleic acids in 22 minutes.
- **Get started sooner**
Use everyday laboratory equipment.
- **Save resources**
Designed for better economy.

AusDiagnostics Respiratory Panel Clinically Shown to be Reliable in Detecting SARS-CoV-2

"This is the largest study of [non-supplier] sponsored review of a commercial assay for SARS-CoV-2."

The continuing global pandemic has led to the rapid emergence of a myriad of immunological and molecular diagnostic assays to detect SARS-CoV-2. Despite the wide Emergency Use Authorization of commercial nucleic acid amplification diagnostic assays, there exists limited peer-reviewed published studies which evaluate their reliability in real-world clinical applications.

In a recent publication² in the Journal of Clinical Virology, Lucy Attwood and colleagues evaluated the clinical performance of the AusDiagnostics Respiratory MT-PCR assay which included SARS-CoV-2 at their diagnostic laboratory which services Monash Health, a large metropolitan health care network in Melbourne,

Australia with 2,150 inpatient beds, three emergency departments and four community respiratory assessment clinics.

99.98%
Specificity

Only 2/7,839 (0.02%) of SARS-CoV-2 tests unable to be confirmed as positive results.

98.4%
Sensitivity

AusDiagnostics MT-PCR assay has high sensitivity: 98.4% of positive samples confirmed.

The study compared the reliability of the AusDiagnostics Respiratory MT-PCR assay which includes SARS-CoV-2 with an in-house RT-PCR assay from the State Reference Laboratory.

A total of 7,839 samples were tested over the one-month study period. The results from the AusDiagnostics™ MT-PCR assay showed good concordance (92.9%) with the in-

house RT-PCR assay.

Using the AusDiagnostics Respiratory assay, SARS-CoV-2 was detected in 127 patient samples. Of these, the State Reference Laboratory detected SARS-CoV-2 in 118/127 (92.9%). After resolution of the nine discrepancies by pyrosequencing, 125/127 (98.4%) of AusDiagnostics results were determined to be true positive results.

Out of 7,839 samples tested for SARS-CoV-2 during this study, only 2 tests (0.02%) were unable to be confirmed as positives due to insufficient amplicon for sequencing, and a lack of further positive samples.

The study concluded that the AusDiagnostics Respiratory MT-PCR assay is reliable for the detection of SARS-CoV-2, as well as concurrently aiding the detection of other respiratory pathogens.

- Attwood LO, Francis MJ, Hamblin J, et al. Clinical evaluation of AusDiagnostics SARS-CoV-2 multiplex tandem PCR assay. J Clin Virol (2020). doi: <https://doi.org/10.1016/j.jcv.2020.104448>.

ARE YOU READY FOR FLU SEASON?

**SARS-CoV-2 now available with
Respiratory MT-PCR panels.**

Contact your local AusDiagnostics representative for more information.

RESPIRATORY PATHOGEN PANELS

Respiratory Pathogens (24-well)
Universal. Ref 80617

Respiratory Pathogens C (16-well)
High-Plex™. Ref 20613

Upper Respiratory Pathogens (16-well)
High-Plex™. Ref 20616

Respiratory Viruses (16-well)
High-Plex™. Ref 20602

Respiratory Pathogens (12-well)
Universal. Ref 80618

Influenza, RSV, COVID-19 (8-well)
Universal. Ref 80614*

*Includes two SARS-CoV-2 targets