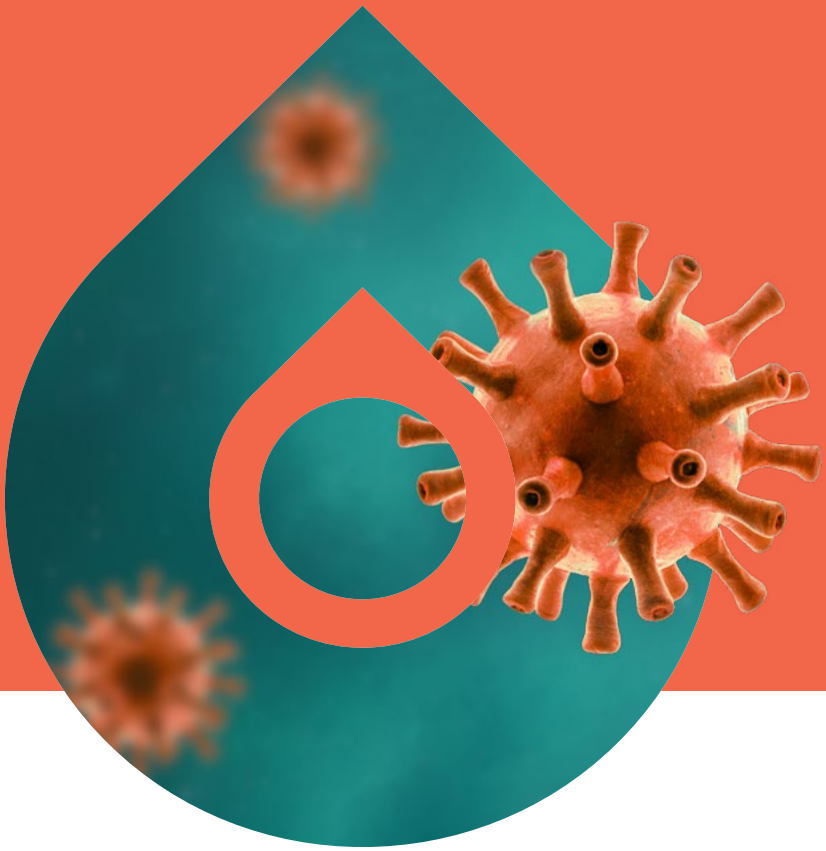
Effective.
Novel.
Easy to Use.



Microbio

InfectID-COVID-19-R
InfectID-COVID-19-D

"The only way to know if a person is actually still infectious — shedding or emitting what's known as "replication-competent virus" — is to try to grow virus from a specimen from that person. That process, called culturing, is time consuming and in the case of SARS-CoV-2, not so easy to do."

Dr John Brooks, Chief Medical Officer for the Covid-19 response at the Centres for Disease Control and Prevention[1]

A new way of testing

The ongoing global COVID-19 pandemic has highlighted the limitations of current SARS-CoV-2 diagnostic tests to prevent the spread of SARS-CoV-2 and to guide appropriate management and treatment of patients. Laboratory Reverse Transcription Real Time Polymerase Chain Reaction (RT-PCR) SARS-CoV-2 assays provide rapid, accurate diagnosis of the presence of the virus however current RT-PCR tests do not identify if the virus present is replicating or is simply 'dead' viral particles that the body is shedding as part of the recovery process.

Introducing two tests from Microbio specifically designed to address this problem:

InfectID-COVID-19-Replicating (-R)

InfectID-COVID-19- Detection (-D)

Replication-competent viruses contain the necessary genetic material to make copies of itself within the patient's cells, which can then be transmitted to others.[2]

1 Positive Covid-19 tests kept a mom and baby apart for 55 days. Experts see it as a bigger testing problem.

2 Inactivation of Replication-Competent Vesicular Stomatitis Virus as SARS-CoV-2 Surrogate on Common Surfaces by Disinfectants.

InfectID-COVID-19 Products

InfectID-COVID-19-R

InfectID-COVID-19-Replication identifies the presence of replication-competent (the 'live', multiplying) SARS-CoV-2 virus

The InfectID-COVID-19-R test is the first novel one-step RT-PCR assay to unambiguously identify Replication-competent (i.e. 'live' or 'active') virus using standard RT-PCR equipment and processes.

Knowing an individual's SARS-CoV-2 replication status will enable evidence-based, patient-specific clinical treatment and infection control decisions.

InfectID-COVID-19-D

InfectID-COVID-19-Detection identifies the presence of the SARS-CoV-2 virus

Detects a highly-conserved, highly-discriminatory region of the SARS-CoV-2 gene, remaining effective even as new variants emerge.

"Microbio's R test is a perfect complement to their D test, and indeed all of the PCR tests currently on the market. It has the potential to redefine how we monitor, manage and discharge patients back into the community."

Dr Stephen Young Ph.D., Medical Director of Research & Clinical Trials at TriCore Reference Laboratories

InfectID-COVID-19
Benefits

Effective	Detects the SARS-CoV-2 genome regardless of the variant
Novel	InfectID's test design brings together advanced molecular biology and bioinformatics
Easy to use	Follows the same sample preparation and run process as other RT-PCR tests
High quality	Designed in Australia using robust science, manufactured in Canada at an ISO13485 certified facility
Available	Released on to the market in Europe and India

InfectID-COVID-19's effectiveness is confirmed fortnightly and any time new variants of interest are identified. All newly published SARS-CoV-2 sequences are reviewed to establish that the performance of both R and D tests remain unaffected by any variations in the primer binding sites. All variants that have emerged since the assay's development have been reviewed.

Recent variant genomes*	**Detected by InfectID-COVID-19 assays**
Beta, V2	✓
Alpha, V1	✓
Gamma, V3	✓
Delta	✓
Epsilon	✓
Eta	✓
Iota	✓
Mu	✓

**published by nextstrain.org*

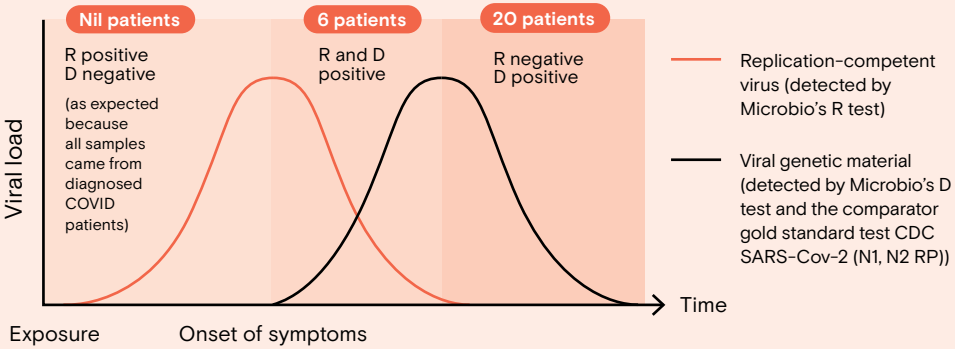
InfectID-COVID-19
Clinical Evaluations

TriCore Reference Laboratories, USA

Conducted using clinical samples and compared to the CDC SARS-CoV-2 RT-PCR test.

	CDC SARS-CoV-2 RT-PCR test	Microbio's InfectID-COVID-19	
	N1,N2,RP	D (Detection)	R (Replicating)
Positive	26 (100%)	26 (100%)	6 (23%)
Negative	0	0	20 (77%)^

^Replicating test is only positive when the sample contains replication-competent virus



"The lack of R positive/D negative samples was as expected because samples were collected from symptomatic patients tested at the hospital and depending on disease severity, were subsequently hospitalised. An R positive/D negative result would be expected in patients early in the infectious cycle and showing no symptoms; these patients may be either pre-symptomatic or asymptomatic and could go on to have COVID disease."

Dr Stephen Young Ph.D., Medical Director of Research & Clinical Trials at TriCore Reference Laboratories

InfectID-COVID-19
Clinical Evaluations

Rajiv Gandhi Centre for Biotechnology, India

InfectID-COVID-19-D

Conducted using clinical samples and compared to Altona Diagnostics RealStar®SARS-CoV-2 RT-PCR Kit

- Sensitivity: 95.23%
- Specificity: 100%
- Positive Predictive Value: 100%
- Negative Predictive Value: 95.45%

InfectID-COVID-19-R

Conducted using clinical samples and compared to Altona Diagnostics RealStar®SARS-CoV-2 RT-PCR Kit

- Sensitivity: 92.38%*
- Specificity: 95.23%*
- Positive Predictive Value: 95.09%
- Negative Predictive Value: 92.59%

*All RGCB clinical samples were taken from symptomatic patients, not asymptomatic or presymptomatic patients early in their infection. For this reason the D test showed 100% concordance with the comparitor tests in clinical evaluations, and the R test returned different results, affecting the Sensitivity and Specificity calculations that compare performance to the RealStar tests.

“59% of SARS-CoV-2 transmission originated from asymptomatic or pre-symptomatic patients.”[3]

3 SARS-CoV-2 Transmission From People Without COVID-19 Symptoms

InfectID-COVID-19
Technical Details

Limit of detection -R
180 copies of viral RNA/mL

Limit of detection -D
8000 copies of viral RNA/mL

Reactions per kit
400

Sample type
RNA extracted from nasopharyngeal swabs

Stability
6 months at -20°C

Suggested RNA extraction instruments
Roche MagNA Pure 96
Promega Maxwell® RSC

Suggested RNA extraction kits
QIAGEN RNeasy

Suggested RT-PCRs
Bio Molecular Systems Mic
QIAGEN Rotor-Gene Q
BioRad CFX96
QuantStudio

Kit Contents

Positive Control
Synthetic DNA

RT-PCR Mastermix
DNA polymerase, buffer, $MgCl_2$, intercalating dye, primers

Reverse Transcriptase
RT enzyme

For more information
microbio.com.au

Microbio

CE