



Public Health  
England

Protecting and improving the nation's health

# Rapid assessment of the AusDiagnostics Coronavirus Typing (8-well) assay for the detection of SARS-CoV-2 (COVID-19)

V01.20. Uncontrolled when printed or downloaded

Current version available at: <https://www.gov.uk/government/publications/covid-19-phe-laboratory-assessments-of-molecular-tests>

# About Public Health England

Public Health England exists to protect and improve the nation's health and wellbeing, and reduce health inequalities. We do this through world-leading science, research, knowledge and intelligence, advocacy, partnerships and the delivery of specialist public health services. We are an executive agency of the Department of Health and Social Care, and a distinct delivery organisation with operational autonomy. We provide government, local government, the NHS, Parliament, industry and the public with evidence-based professional, scientific and delivery expertise and support.

Public Health England  
Wellington House  
133-155 Waterloo Road  
London SE1 8UG  
Tel: 020 7654 8000  
[www.gov.uk/phe](http://www.gov.uk/phe)  
Twitter: [@PHE\\_uk](https://twitter.com/PHE_uk)  
Facebook: [www.facebook.com/PublicHealthEngland](https://www.facebook.com/PublicHealthEngland)

Prepared by NIS Laboratories, National Infection Service, Public Health England



© Crown copyright 2020

You may re-use this information (excluding logos) free of charge in any format or medium, under the terms of the Open Government Licence v3.0. To view this licence, visit [OGL](https://www.ogilive.com/). Where we have identified any third party copyright information you will need to obtain permission from the copyright holders concerned.

Published June 2020

PHE publications  
gateway number: GW-1316

PHE supports the UN  
Sustainable Development Goals



# Rapid assessment of Coronavirus Typing (8-well) assay for the detection of SARS-CoV-2 (COVID-19), AusDiagnostics.

## Introduction

The emergence of the SARS-CoV-2 virus in humans and spread of the associated disease, COVID-19, has been declared a Public Health Emergency of International Concern by the World Health Organization (WHO). In the UK, the deployment of a PHE in-house real-time PCR assay in PHE, PHE collaborating laboratories as well as in Devolved Administrations is being followed up with assessments of commercially developed and provided diagnostic tests for SARS-CoV-2 detection.

This assessment examined the AusDiagnostics Coronavirus Typing assay (8-WELL) (AusDiagnostics #20619), targeting SARS-CoV-2 orf1ab.

## The assessment panel

The assessment sample-panel totalled 195 specimens, including upper or lower respiratory clinical specimens negative for SARS-CoV-2 as determined by the validated in-house PHE PCR assay and dilutions of SARS-CoV-2. Statistical assessment of the panel size determined that when the measured specificity for 195 samples is 100% that the true specificity of the test is at least 98.1%.

## Performing and analysing the assay

Amplification was performed using the proprietary AusDiagnostics High-Plex 24 System according to the High-Plex 24 System (using reagent cassettes). Nucleic acid extracts were aliquoted into 2ml Sarstedt tubes and loaded into the Sample Processor in batches of 24 (22 samples; positive control (AusDiagnostics); negative control).

The SARS-CoV-2 results were automatically categorised by the software as 'Present', 'Check' or 'blank' (not detected) based on predefined parameters (Coronavirus IFU Section 8; high-Plex IFU section 11). The automated 'blank/not-detected' and 'Present' calls were confirmed visually. Results flagged as 'check' were inspected according to the manufacturer's instructions for use for the high-plex system and readily determined as 'negative'. These interpretations were agreed by the manufacturer also.

## Results

From a challenge with positive material, all samples for a three-step dilution series were found positive for SARS-CoV-2.

Compared with the results from the PHE COVID-19 assay the following was found:

	<b>Samples (n)</b>	<b>True positive</b>	<b>False positive</b>	<b>True negative</b>	<b>False negative</b>	<b>Negative percentage agreement</b>
<b>AusDx SARS-CoV-2</b>	195	0	0	195	0	100% (195/195)

## Report date

A version of the report was distributed by PHE's COVID-19 Incident Virology Cell on 13/03/2020.

## Disclaimer

PHE's assessments of commercial products for diagnosing COVID-19 infection have been carried out primarily for PHE's own use and under agreement; the reports of such assessments are shared solely for the readers' information; PHE does not in any way recommend any particular COVID-19 diagnostic assay or extraction platform; PHE shall not be responsible for any choice of COVID-19 diagnostic assay or extraction platform, and it is the testing laboratory's responsibility to ensure that any such assay or platform implemented has undergone the necessary verification and validation; and PHE shall not be liable, to the greatest extent possible under any applicable law, for any claim, loss or damage arising out of or connected with the use of this and related reports and any choice of COVID-19 diagnostic assay products or extraction platforms.

A position statement regarding COVID-19 tests evaluated by PHE is available at: <https://www.gov.uk/government/publications/position-statement-regarding-covid-19-tests-evaluated-by-phe>

## Further information

Queries about our assessments of SARS-CoV-2 (COVID-19) diagnostics should be sent to [labvalidation.cov@phe.gov.uk](mailto:labvalidation.cov@phe.gov.uk)

## Table of changes

<b>Date</b>	<b>New version no.</b>	<b>Details of changes</b>
27/04/2020	1.2	Changes to disclaimer
27/04/2020	1.2	Consistency for use of the term “assessment”
27/04/2020	1.2	Tables of changes added
12/05/2020	1.2	Change of template
12/05/2020	1.2	Version number and website added (footer)
12/05/2020	1.2	Addition of date reported by Virology Cell
26/05/2020	1.2	Minor changes for consistency with other reports