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Guidance

# Outcome of the evaluation of rapid diagnostic assays for specific SARS-CoV-2 antigens (lateral flow devices)

Updated 21 September 2021



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## Background

Since its establishment in August 2020, the joint PHE Porton Down and University of Oxford SARS-CoV-2 lateral flow antigen test validation cell has evaluated over 140 lateral flow devices that have been referred by the Department of Health and Social Care (DHSC).

Approximately 30% of the tests that were referred for validation met the standards for phase 2 validation, which are set out in the protocol (<https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/protocol-for-evaluation-of-rapid-diagnostic-assays-for-specific-sars-cov-2-antigens-lateral-flow-devices>). PHE Porton Down subsequently performed phase 3 testing to assess whether the lateral flow devices that passed phase 2 displayed performance characteristics desirable for mass population, community-based testing. The desirable performance characteristics are:

- very high specificity
- very high sensitivity against viral loads associated with infectiousness

The lateral flow devices that display the desirable performance characteristics are summarised in table 1 below.

**Table 1: summary of lateral flow devices that have passed phase 3a validation**

Lateral flow device	Status	Date evaluation completed
Abbott Panbio COVID-19 Ag Rapid Test Device	Pass	29 September 2020
ACON Biotech Flowflex SARS-CoV-2 Antigen Rapid Test	Pass	19 February 2021
Ameda AMP Rapid Test SARS-CoV-2 Ag	Pass	12 March 2021
Anhui DeepBlue COVID-19 Antigen Test Kit	Pass	23 October 2020
Arista COVID-19 Antigen Rapid Test	Pass	25 June 2021

<b>Lateral flow device</b>	<b>Status</b>	<b>Date evaluation completed</b>
Assure Tech Ecotest COVID-19 Antigen Rapid Test Device	Pass	20 July 2021
Beijing Kewei COVID-19 Antigen Rapid Test Kit	Pass	21 May 2021
Biopanda COVID-19 Rapid Antigen Test	Pass	25 June 2021
Bioperfectus Technologies Novel Corona Virus Ag Rapid Test Kit	Pass	5 February 2021
DenScreen SARS CoV-2 Rapid Antigen Test: Non-Invasive Nostril Swab	Pass	3 August 2021
DNA Diagnostic COVID-19 Antigen Detection Kit	Pass	20 January 2021
Excalibur Rapid SARS-CoV-2 Antigen Test Card	Pass	22 January 2021
Fortress Diagnostics Coronavirus Ag Rapid Test	Pass	13 November 2020
GenSure COVID-19 Antigen Rapid Test Kit	Pass	25 June 2021
Getein Biotech One Step Test for SARS-CoV-2 Antigen	Pass	10 March 2021
Goldsite SARS-CoV-2 Antigen Kit (Colloidal Gold)	Pass	8 July 2021

<b>Lateral flow device</b>	<b>Status</b>	<b>Date evaluation completed</b>
Hughes Veritas Rapid Antigen Test for SARS-CoV-2	Pass	21 May 2021
Humasis COVID-19 Ag Test	Pass	25 June 2021
Innova (Xiamen Biotime) SARS-CoV-2 Antigen Rapid Qualitative Test	Pass	11 September 2020
Konsung COVID-19 Antigen Rapid Test Kit (Colloidal Gold)	Pass	8 July 2021
Liming Bio StrongStep SARS-CoV-2 Antigen Rapid Test	Pass	2 March 2021
Lyher Novel Coronavirus (COVID-19) Antigen Test Kit (Colloidal Gold)	Pass	21 May 2021
Mediport COVID-19 Antigen Rapid Test Kit	Pass	25 June 2021
MP Biomedical Rapid SARS-CoV-2 Antigen Test Card	Pass	5 February 2021
Nantong Diagnos Biotechnology COVID-19 Ag Test	Pass	21 January 2021
Orient Gene / Healgen Coronavirus Ag Rapid Test (swab)	Pass	2 October 2020
Roche SARS-CoV-2 Rapid Antigen Test Nasal / Self Test Nasal	Pass	21 May 2021

Lateral flow device	Status	Date evaluation completed
Roche SD Biosensor Standard Q COVID-19 Ag Test	Pass	2 December 2020
Roche SD Biosensor Standard Q COVID-19 Ag Saliva Test	Pass	9 February 2021
Shenzhen YHLO GLINE-2019-nCoV Ag test	Pass	25 June 2021
Surescreen SARS-CoV-2 Antigen Rapid Test Cassette	Pass	2 December 2020
Surescreen SARS-CoV-2 Antigen Rapid Test Cassette v2	Pass	15 March 2021
Surge COVID-19 Antigen Test Kit	Pass	3 August 2021
Wondfo 2019-nCoV Antigen Test (Lateral Flow Method)	Pass	25 June 2021
Wuhan EasyDiagnosis COVID-19 (SARS-CoV-2) Antigen Test Kit	Pass	21 May 2021
ZandCell COVID-19 Antigen Test	Pass	18 March 2021

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