

Coronavirus (COVID-19) (/coronavirus)

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 4. [Assessment and procurement of coronavirus \(COVID-19\) tests \(https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests\)](https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests)
- [UK Health Security Agency \(https://www.gov.uk/government/organisations/uk-health-security-agency\)](https://www.gov.uk/government/organisations/uk-health-security-agency)

Guidance

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

Updated 14 March 2022



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This publication is available at <https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/outcome-of-the-evaluation-of-rapid-diagnostic-assays-for-specific-sars-cov-2-antigens-lateral-flow-devices>

Background

Since its establishment in August 2020, the joint UK Health Security Agency (UKHSA) Porton Down and University of Oxford SARS-CoV-2 lateral flow antigen test validation cell has evaluated over 160 lateral flow devices that have been referred by the Department of Health and Social Care.

Approximately 30% of the tests that were referred for validation met the standards for phase 2 validation, which are set out in the [protocol for evaluation of rapid diagnostic assays for specific SARS-CoV-2 antigens \(https://www.gov.uk/government/publications/assessment-and-procurement-of-coronavirus-covid-19-tests/protocol-for-evaluation-of-rapid-diagnostic-assays-for-specific-sars-cov-2-antigens-lateral-flow-devices\)](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).

UKHSA 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
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
Assure Tech Ecotest COVID-19 Antigen Nasal Test Kit (Biosafe Nasal 'Pen' Device)	Pass	14 January 2022
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
BHM COVID-19 Antigen Sealing Tube Test Strip	Pass	14 January 2022
Biopanda COVID-19 Rapid Antigen Test	Pass	25 June 2021
Bioperfectus Technologies Novel Corona Virus Ag Rapid Test Kit	Pass	5 February 2021
Biosynex COVID-19 Ag+ BSS	Pass	29 September 2021

Lateral flow device	Status	Date evaluation completed
Biozek COVID-19 Antigen Rapid Test Cassette (Swab)	Pass	29 September 2021
Core Tests COVID-19 Ag Test	Pass	17 December 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
Hangzhou Clongene Biotech COVID-19 Antigen Rapid Test Cassette (Nasal Swab)	Pass	29 September 2021
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
Joysbio SARS-CoV-2 Antigen Rapid Test Kit (Colloidal Gold)	Pass	17 December 2021
Kisshealth Rapid COVID-19 Self-Test Antigen Lateral Flow Device	Pass	17 December 2021
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
NADAL COVID-19 Ag plus test	Pass	17 December 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
Tigsun COVID-19 Antigen Rapid Test	Pass	29 September 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
Xiamen Boson Biotech Rapid SARS-CoV-2 Antigen Test Card	Pass	29 September 2021
ZandCell COVID-19 Antigen Test	Pass	18 March 2021
Zhuhai ENCODE - SARS-COV-2 Antigen Rapid Test Device	Pass	29 September 2021

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