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# Lateral flow validation prioritisation criteria for rapid diagnostic assays for specific SARS-CoV-2 antigens

An overview of the future requirements for rapid COVID-19 diagnostic assays for antigen lateral flow devices.

Published 8 February 2021

From:
Department of Health and Social Care (https://www.gov.uk/government/organisations/department-of-health-and-social-care)

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## Overview

The Department of Health and Social Care (DHSC) has concluded a review of the most likely future requirements and use cases for rapid diagnostic assays for specific SARS-CoV-2 antigens (lateral flow devices).

The review has enabled the development of selection criteria. The selection criteria will be applied to decide which lateral flow devices should proceed through the validation process and the basis on which the validation of certain types of lateral flow devices should be prioritised.

The rationale for this approach is that DHSC will only seek to validate lateral flow devices that have predicted future use cases and that the resources available for validation will be best deployed to align with the national strategy for Test and Trace.

This page sets out the selection criteria for lateral flow devices. The validation will continue to follow the government 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).

## Sample type

DHSC will no longer validate lateral flow devices that only allow for a nasopharyngeal specimen collection method. Instead, the instructions for use (IFU) for the lateral flow device must contain a specimen collection method that allows for one or more of the following sample types:

- anterior nares

- mid-turbinate
- oropharyngeal
- saliva

This list is written in priority order: lateral flow devices submitted with a specimen collection method higher up on the list will be prioritised for validation. A lateral flow device will only be considered for validation when all lateral flow devices with a higher priority specimen collection method have been considered for validation.

Other sample types, which are not included in the list above, will be evaluated on a case by case basis.

## Symptomatic and asymptomatic testing

Priority will be given to lateral flow devices where the IFUs or other packaging labels do not restrict the use to symptomatic individuals only or other wording to this effect (for example, ‘patients suspected of having COVID-19’). Lateral flow devices will ideally allow for both asymptomatic testing and symptomatic testing.

## Users and administrators of lateral flow devices

Priority will be given in the following order for lateral flow devices where the IFU and CE mark allow for:

- self-test: a test that can be performed by any individual at home without receiving prior training
- self-swab and the test is then performed by a trained individual: the IFU allows for a patient to collect their own sample, either supervised or unsupervised − the test procedure can then be performed by an individual who has received training
- test performed by a trained individual: the test can be performed by someone who has received training − this person does not have to be a medically trained professional or have experience working in a laboratory setting
- tests administered by a healthcare or medical professional

## Other characteristics for lateral flow devices

DHSC has identified other desirable characteristics for lateral flow devices that are in addition to the selection criteria that are outlined above.

The desirable characteristics will not inform the prioritisation for validation, but are included to provide suppliers of lateral flow devices with a better understanding of DHSC's likely requirements for predicted future use cases:

- the ability to supply lateral flow tests in various pack sizes − for example, pack sizes of 1, 3, 5, 7 and 25 tests
- proof that the test was run with actual human sample − for example, the inclusion of a control line specific to human mucosal antigens
- each sterile swab has an individual containment tube with recappable lid, providing the ability to store the swab for quality review
- the ability to provide a response in 15 minutes or less

- an individual QR code on the test cassette − this is essential

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