

Government sets out laws to validate accuracy of private COVID-19 tests

- All private COVID-19 tests released onto UK market will need to meet a revised set of standards in line with those used by government
- Regular and accurate testing is at the heart of the government's roadmap out of the pandemic

From 1 September 2021 all COVID-19 molecular and antigen tests available to purchase will require validation prior to sale on the UK market under new draft legislation set out today, bringing them in line with NHS Test and Trace test standards.

The government already has rigorous safety measures in place for all PCR and LFD tests provided through NHS Test and Trace, and for all tests used for international travel.

The new legislation will help consumers who choose to use private tests by giving them clear, comparable information so they can confidently choose a test in a rapidly expanding market.

The proposed laws will mean all private tests must pass through a new rigorous and efficient validation process to guarantee they will give reliable results. This will ensure that all COVID-19 tests available on the UK market meet one uniform standard.

This validation process is in addition to the existing UKAS accreditation scheme launched in December 2020, which ensures that private test providers meet the uniform minimum standards to provide testing services. UKAS accreditation has focused on the services of tests providers whereas validation will focus on ensuring there are minimum standards for the test products used as well.

Under the new scheme, all private testing suppliers will need to go through the validation process ahead of selling tests, bringing them into line with NHS Test & Trace standards. Providers who fail to meet required minimum standards will incur penalties. Retailers, distributors and manufacturers who attempt to sell unvalidated tests could face punitive sanctions based on the current regulatory requirements for medical devices.

Parliamentary Undersecretary for Health and Social Care Lord Bethell said:

British innovation and ingenuity allowed us to rapidly produce tests capable of quickly spotting COVID-19 outbreaks.

We now complete millions of tests across the country every week and these new laws will provide businesses and consumers with a common

set of high standards, like those used in the NHS, as we battle this virus.

Testing has helped children to return to the classroom and reunited us with our friends and loved ones. I know reliable tests will continue to play a critical role as we continue to work towards resuming normal life.

The UK has built an international reputation for COVID-19 testing. The combined work of the public sector and private sector has enabled the development of the largest diagnostics network in UK history and implementation of testing for international arrivals into the UK. At border control alone over 350,000 have been conducted which require independent validation of the test product performance which is needed before tests are approved for borders testing. They also set higher thresholds for performance given the specific use case and need for greater accuracy.

To grow the private market for testing, it is imperative that tests can be relied upon, and the government recognises that the testing market needs to be well regulated so it can keep pace with the evolving COVID-19 situation. These new laws will aim to facilitate and empower that market and bring it in line with Department of Health and Social Care (DHSC) procurement standards.

The DHSC has previously consulted with industry on the new proposals, listening to advice on how to provide safe reliable tests and how to ensure a world leading regulatory process in the future.

The consultation looked at the performance of all tests sold on the UK market to mirror standards used in NHS Test and Trace, whether purchased in the UK or overseas. It set out proposals for a UK-wide policy on the design of the validation process, the fees regime and the proposed enforcement approach.

Separately, the DHSC is also publishing a threshold paper setting out performance expectations for testing for COVID-19. The performance thresholds set out in this paper [link] are used as the framework for the new laws on the validation of tests.

Over the course of the last year, it has developed and adjusted these thresholds based on evolving scientific data, which has then informed internal policy decisions as the response to COVID-19 has evolved during this time.

1. Producers of tests currently on the market will need to apply for validation by 1st September 2021 and have passed successfully by 31 October 2021 in order to continue selling tests past 31 October 2021. Tests currently supplied to the NHS under DHSC procurement will be exempted in recognition of prior equivalent assessment.