



SARS-COV-2 ANTIGEN RAPID TEST KIT FAQ'S

Where are the Acon® Flowflex Test Kits manufactured?

The ACON Flowflex COVID-19 Antigen Rapid Test Kit delivers fast results to show if Acon Laboratories, Inc is a large global diagnostics company based in the US with manufacturing facilities in the US, China and Mexico. The factory in China has been inspected and approved by the FDA.

It is very important for us to understand exactly where these tests are made and by whom to ensure consistency of quality and supply.

Are these test approved for use in the UK?

All medical devices have to follow a standard testing and certification process before they can be sold in the EU.

The Acon® Flowflex SARS-Cov-2 AntiGen Rapid Test Kits for Covid-19 have been through this process and are CE marked.

These test kits are 'For professional in vitro diagnostic use only' and are sold for their intended use.

Is the Acon® Flowflex test kit approved by the MHRA?

The Medicines and Healthcare Products Regulatory Agency (MHRA) is the competent authority or regulatory body in the UK.

They do not approve tests on an individual basis but do allow manufacturers to put a CE mark on products that meet a target product profile set by the MHRA. This target product profile contains criteria that tests and test kits should meet. The Acon Flowflex Rapid AntiGen test kit meets all of the target profile provided by the MHRA.

Is the Acon® Flowflex test kit approved by Public Health England?

Public Health England is assessing tests in the UK at their laboratories in Porton Down. The Acon Flowflex Test Kits has been submitted for review, but has yet to be called up for evaluation. When this occurs we will update our information accordingly.



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What is the regulatory status of the Acon® Flowflex test kits?

The Acon® Flowflex test kit is approved 'For professional in vitro diagnostic use only'. This means that all testing should be carried out under the supervision of a healthcare professional.

These lateral flow antigen tests should not to be sold direct to the public for self-testing. Currently there isn't a lateral flow antigen test that has been approved for self-testing.

When should the Acon® Flowflex test kit be used?

The Acon® Flowflex tests detect moderate to high viral loads. Patients will have moderate to high viral loads about 3 days before symptoms start until between 7 and 10 days after symptoms start. In this window lateral flow tests, such as the Acon Flowflex tests are very effective.

A positive test should be repeated using a RT-PCR test for confirmation and entry into the national test and trace system. A negative test simply reflects a point in time, showing you do not have active COVID-19 today.

How often should the Acon® Flowflex test kit be used?

This is difficult to advise as regulatory advice differs. Some bodies advise testing twice a week, or perhaps every Monday in a standard five day week. Other guidance suggests testing every day.

How can we make the Acon® Flowflex test as effective as possible?

The testing process is very simple, however a few considerations need to be made to reduce issues with test accuracy including;

- Nasal mucus (snot) - If the patient is producing large amounts of nasal mucus, this can thicken the buffer and cause it to travel along the test cassette more slowly. Ask the patient to blow their nose before testing.
- Buffer - Flick the tube before removing the lid to ensure the buffer is at the bottom of the tube. Squeeze the walls of the tube around the swab (once inserted) to extract all of the sample and flick the side of the tube again before applying the sample into the sample well.
- Test Cassette - ensure it is used on a flat level surface.

How do I order the Acon® Flowflex AntiGen Rapid Test Kits?

If you are a medical professional or will be using the test kits under the supervision and care of a medical professional you may do so by contacting us using the contact details below.