

21 July 2020

GPhC position on COVID-19 rapid antibody tests

Dear pharmacy owner / superintendent pharmacist

Many thanks for all your hard work and dedication to supporting your patients and the public during this unprecedented time.

I want to highlight our position concerning the provision and sale of COVID-19 rapid antibody tests from community pharmacies: in the light of current public health advice, it is not appropriate for them to be sold in community pharmacies or recommended by pharmacy professionals at this point in time.

We are aware that there are manufacturers selling and supplying COVID-19 rapid antibody testing kits and that these tests are being offered privately in several community pharmacies across Great Britain.

Several regulatory and public bodies have leading roles with respect to: the regulation of test kits as medical devices (The Medicines and Healthcare products Regulatory Agency); legality of retail sales generally (Trading Standards); regulation of medical services (Care Quality Commission, Healthcare Improvement Scotland and Healthcare Inspectorate Wales) and authoritative public health guidance from the national public health agencies.

Our position

Although the GPhC does not have jurisdiction over the legality, safety or efficacy of particular types of tests or kits, we do have responsibility as the regulator of pharmacy professionals, in relation to the standards that must be met by pharmacists and pharmacy technicians in all settings in which they work, and the standards that must be met by the owners of registered pharmacies.

Pharmacists, pharmacy technicians and pharmacy owners work to protect public health as well as the health of individuals using pharmacy services. Likewise, we as the pharmacy regulator are concerned with public health as well as patient and service user health, safety and wellbeing.

Public health

We expect pharmacists and pharmacy technicians, and those who own pharmacy premises, to protect public health at all times. They need to be aware of and uphold any recommended national guidance available at the relevant time, for example the advice issued by Public Health England.ⁱ In addition, we

expect them to consider all the evidence but moreover consider the national landscape including key government updates and publications such as the communication to Scotland's health service by the Chief Medical Officerⁱⁱ and the information on the Welsh Government's website summarising the value of antibody testing,ⁱⁱⁱ the consequences of supplying or not and make informed choices about what is best for the patients and the public.

Professional responsibility

Although it may be legal to sell or supply a product, for example it may have a CE mark^{iv} this does not necessarily mean that it is appropriate for a health professional to supply it to a patient or member of the public. We would expect all pharmacy professionals to consider the wider public health impact. During this ongoing national public health crisis, any activity that may contribute to false results or assurances that then impact on public behaviour should not be supported. Both the World Health Organisation^v and SAGE, the Scientific Advisory Group for Emergencies,^{vi} have advised there are potentially negative impacts on public health if individuals assume immunity from a positive result and adapt their behaviour in a way which could increase the risk of continued transmission.

To date we have:

- worked closely with other regulators and public health agencies which have leading roles to play in relation to testing and test kits, to identify the latest guidance and information in this fast-moving area;
- shared this guidance and information with stakeholders, members of the public, pharmacy professionals and pharmacy owners, including through our coronavirus Q&A;
- when made aware that a pharmacy is providing tests which do not adhere to guidance from the public health agencies in Great Britain, written to the pharmacy to tell them to stop providing these tests. Our inspectors have been signposting pharmacy owners, superintendent pharmacists and pharmacy professionals to relevant guidance and reiterating our position on this topic.

Overall, we want to reiterate that, at this point in time, we do not regard it as appropriate for community pharmacy to be selling and recommending rapid antibody test kits. The UK Government as well as the Scottish and Welsh Governments, alongside the key public health bodies, WHO and SAGE have all intimated that:

- their use in the response to COVID-19 has not yet been established,
- that there is conflicting evidence in relation to the use and efficacy of these tests and
- the public health consequences potentially outweigh any benefit a patient or member of the public may gain from this type of test.

We are asking that you ensure your pharmacies support public health by not offering such services and stopping any current provision. We are aware that this is a fluid landscape and we will continue to work closely with other regulators with leading roles in relation to testing and provide an update if the situation changes.

Many thanks in advance for your cooperation.

Best wishes

A handwritten signature in black ink that reads "Duncan Rudkin". The signature is written in a cursive, slightly slanted style.

Duncan Rudkin
Chief Executive and Registrar

ⁱ <https://www.gov.uk/government/publications/covid-19-rapid-tests-for-use-in-community-pharmacies-or-at-home>

ⁱⁱ <https://www.gov.scot/news/covid-19-antibody-testing-1/>

ⁱⁱⁱ <https://gov.wales/antibody-testing-coronavirus-covid-19>

^{iv} https://www.gov.uk/government/publications/how-tests-and-testing-kits-for-coronavirus-covid-19-work/for-patients-the-public-and-professional-users-a-guide-to-covid-19-tests-and-testing-kits?utm_source=Gov&utm_medium=Email&utm_campaign=MHRA_COVID-19_updates&utm_content=HCP9

^v <https://www.who.int/publications/i/item/immunity-passports-in-the-context-of-covid-19>

^{vi} https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/887476/29-pre-empting-possible-negative-behavioural-responses-covid-19-antibody-testing-13042020.pdf