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Coronavirus (COVID-19): what you need to do

#### Stay at home

- Only go outside for food, health reasons or work (but only if you cannot work from home)
- If you go out, stay 2 metres (6ft) away from other people at all times
- · Wash your hands as soon as you get home

Do not meet others, even friends or family.

You can spread the virus even if you don't have symptoms.

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Guidance

# Guidance for industry on evaluations of diagnostic products for coronavirus (COVID-19)

Updated 27 March 2020

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Public Health England (PHE) has established a capability to evaluate approaches from industry to encourage diagnostic and other scientific innovation.

This programme, led by a joint team working acrossPHE's Colindale and Porton Down scientific campuses and regional networks, will provide a single entry-point for all communication from industry and involves a two-stage rapid evaluation process, which is as follows.

# Stage 1

When we receive a submission of information on a diagnostic test or other product, we will undertake a systematic evaluation of the information provided to reach a decision on whether to progress to stage 2.

This will be communicated to submitters within 1 week and be based on:

- a desk-based evaluation of test performance
- whether the product does or does not have the potential to meet an unmet need for patient care and public health or be taken up by a number of laboratories in the UK that currently have no testing capabilities

We will also consider the supply chain and availability of reagents and equipment together with cost. It is important that we focus on clinical need.

It will not be possible to reconsider the outcome of our decision unless a fundamentally new test is proposed by the same company.

# Stage 2

For tests that are accepted into the programme following the stage 1 review process, evaluation will proceed through a testing framework.

This will be communicated through an initial conference call, in which plans for evaluation and timelines will be discussed.

#### Contact

Approaches from companies with diagnostic products they want to be considered for evaluation should use our dedicated email address <a href="mailto:covidtestingtriage@dhsc.gov.uk">covidtestingtriage@dhsc.gov.uk</a>.

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