

Policy Brief

Information design for diagnostics: ensuring confidence and accuracy for home testing

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Summary of the research

The research investigates the design and ease of use of instructions for carrying out Covid-19 Lateral Flow Tests (LFTs) at the point of use (rather than the mandatory instructions for use (IFUs) specified by regulations).

Working with users and test manufacturers, we designed prototype sets of instructions for point of use. Alternative ways of presenting the instruction steps and critical operations were reviewed by a user panel. Users of LFTs were observed following instructions to identify which parts of the test were challenging for users, and which designs were easiest and clearest to follow.

The resulting feedback has been incorporated into guidance and recommendations for producing effective point of use instructions, with the aim of reducing errors and false readings, whilst reassuring users. Although focused on current lateral flow rapid tests, the findings are applicable to any community-based testing technology.

Policy recommendations

IFUs are produced in line with a regulatory framework of principles and general guidance about the structure of information and its visual organisation (IEEE, 2019). Indeed, standards do mandate that diagnostic devices must be designed for usability (e.g. ISO 62366). While mandatory IFUs are accurate and concise, and reflecting research and good practice, they are primarily structured to meet regulatory requirements and conventions. They tend not to be designed with the needs of users in mind. This contrasts with the US regulators who are starting to encourage inclusion of a “getting started” document that guides the user, alongside strictly factual mandatory information.

Manufacturers, distributors of tests and service providers that offer testing need to be encouraged to make products that are as accessible as possible for people to use. The target audience of home tests are lay users, which means the requirement for clarity and usability of the test device and its instructions is higher than for trained diagnostic experts.

We are proposing that those who are responsible for acting on policy recommendations should consider the design of procedural instructions for lay people involved in home or community testing, to complement the legislative requirement for those embedded in the IFUs.

Our recommendations:

- promote the practice of preparing clear and easy-to-follow point of use instructions

- encourage test manufacturers and suppliers to consider point-of-use when creating instructional documentation for their tests.
- support manufacturers and distributors of tests in the preparation of point-of-use instructions to suit specific audiences and circumstances of use
- implement user-centred design research and practice in producing instructional documentation for users (as 'Toolkit' below)

Key findings

Findings from successive, focussed studies with final users about the visual presentation of point-of-use instructions suggest that a range of visual design practices can be used to improve the clarity of instructions for use for lateral flow tests. We have found that:

- the application of information design research and practice enhances user access to instructional text
- consistency in presentation of language and images is helpful to users
- an overview of procedural steps carrying out a test helps users
- it is beneficial to involve end users by asking what they think about draft versions of sets of instructions before finalising
- instructions are accessible to more audiences when both print and digital formats are available; video versions provide an accessible overview of the procedure, and print versions allows people to go at their own pace, and to review their progress
- particular care is needed for describing and illustrating action steps that may be perceived as challenging due to the dexterity needed
- a 'Toolkit approach' to the dissemination of recommendations for the design of user-centred procedural instructions for home-testing kits would fill a gap
- while regulations strive to ensure in-vitro diagnostic test products are usable, in some cases there is a discrepancy between mandatory requirements, and clear and simple instructions and guidance for use

Further information

Project website: <https://research.reading.ac.uk/design-research-for-testing-diagnostics/>

References

IEEE. (2019). Preparation of information for use (instructions for use) of products - Principles and general requirements. IEC/IEEE 82079-1.

ISO (2015), Medical devices — Part 1: Application of usability engineering to medical devices. IEC 62366-1

Contact details

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Images: Example of point-of-use instructions for Covid-19 Lateral Flow Test

Labelled images
of the kit contents
help the reader to
identify each one.

A test overview
advances the
main steps for the
reader.

Clear diagrams
clarify what needs
to be done at
each action.

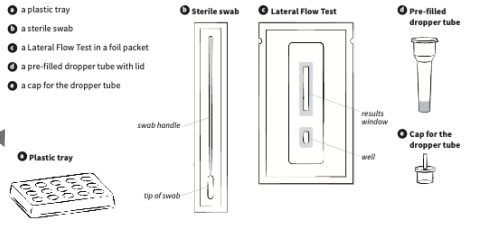
COVID-19 Lateral Flow Test

Thank you for taking your COVID-19 Lateral Flow Test.

Read the instructions in full before you begin. These instructions begin by telling you what is in your test kit, and give an overview of the steps you need to follow. Each step is then explained in detail.

Your test kit contains

- 1 a plastic tray
- 2 a sterile swab
- 3 a Lateral Flow Test in a foil packet
- 4 a pre-filled dropper tube with lid
- 5 a cap for the dropper tube



To carry out your test you need to follow these steps

Step 1 Get ready to do your test

Step 2 Take a sample from your nose

Step 3 Get the sample ready for the test


Step 4 Put the sample into the well in the test and wait for your result


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Step 1 Get ready to do your test

- 1 Find a clean flat surface to set out the test kit parts.
- 2 You will also need:
 - a timer or a smartphone to set the time for the test.
 - A mirror may help you take a sample from your nose.
- 3 Check the expiration date on the back of the foil packet.

Don't use the test if this date has passed. You will have to order another one.



expiration date
- 4 Wash your hands thoroughly.
- 5 Open the test kit and put all the parts on to the table. Remove the Lateral Flow test from its foil packet. It should look like this:
 - the test device is undamaged
 - the silica gel in the packet is yellow


silica gel

You are ready to do your test.

Step 2 Open the dropper tube and stand it upright

- 1 Open the pre-filled dropper tube.
- 2 Keep it upright by standing it in the tray provided.

Step 3 Take a sample from your nose

- 1 Open the sterile swab and hold it in your hand.
- 2 Swab one of your nostrils.
 - Tilt your head back and insert the swab 2 cm into the nostril until you feel resistance.
 - Roll the swab firmly around the inside of the nose, making 10 complete circles and remove it from the nostril.

Do not touch the swab tip.
- 3 Repeat with your other nostril.

Insert 2 cm and make 10 circles

Do not apply pressure.

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Preparation for the test is separated into discrete steps.

Each colour has a meaning, and this is consistent throughout.


The steps are clearly separated, numbered and grouped under sub-goals.

The precautions are salient, presented separate from the main text, and enhanced with colour.

Step 4 Get the sample ready for your test

- 1 Put the tip of the swab into the liquid in the dropper tube.
- 2 Turn the swab round and round pressing it against the tube wall for 10 seconds.
- 3 Remove the swab while squeezing the tube so that the liquid is removed from the tip of swab.
- 4 Put the dropper cap on the dropper tube.

the closed tube should look like this



Step 5 Put the sample into the well in the test and wait for your result

- 1 Hold the tube between your thumb and first finger.
- 2 Make sure the test is on a flat surface.
- 3 Squeeze the tube gently and put 4 drops into the well of the test.
- 4 Set your timer or phone to 15 minutes.

4 drops

15 minutes

5 When your timer goes off you can read your result.

6 When you have finished doing your test, put the swab, dropper tube and lateral flow test in the biohazard bin.

Make sure to read your result following the time indicated for your test. Results read outside the time should not be reported.

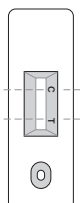
Handle all elements as if they are contagious.

biohazard bin

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What your results show




How to read your result:



Control line (C)
A colored line here means the test is working properly.

Test line (T)
A colored line will appear here in case of a positive result.

What your results show:

One colour line next to C (control)	Two colour lines	No lines
		
Your result is negative	Your result is positive	Your result is invalid

Even if the control line is faint, the test should be considered to have been performed properly. If no control line is visible the test is invalid.

Even if the test line is very faint or not uniform, the test result should be interpreted as a positive result.

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