User-friendly point-of-use instructions for home use diagnostic tests: guidance and tools

How to cite this publication:

Walker, Sue, Bravo, Josefina and Edwards, Al (2022): User-friendly point-of-use instructions for home use diagnostic tests. University of Reading. Other. https://doi.org/10.17864/1947.000419

This toolkit is an evidence-based, practical guide for writing and designing instructions for diagnostic home-testing kits.

This work derives from a UKRI/AHRC COVID-19 rapid response research project 'Information Design for Diagnostics: Ensuring Confidence and Accuracy for Home Sampling and Home Testing' / grant AH/V01500/1.

The project brings together a cross-disciplinary team, including information designers, diagnostic scientists and clinical practitioners. The project is a partnership between the University of Reading and the Oxford Academic Health Sciences Network, with creative and design support from Fraser Muggeridge studio, London.

Project team

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We are grateful to Dr Sarah Needs, Dr Gemma Little, and Sue Wallace and her colleagues at Roche Diagnostics Ltd for their support and engagement.

Sincere thanks are due to members of our user panel and our project partners and collaborators.

More information on this project can be found on the University of Reading research portal:

https://research.reading.ac.uk/design-research-for-testing-diagnostics/

Toolkit organisation and contents

The toolkit

The toolkit provides guidance for producing clear and user-friendly point-of-use instructions for testing kits. It is for:

- manufacturers and distributors of tests
- service providers who might want to brief designers and content specialists
- content specialists and designers who need information about producing instructional text

This guidance includes:

- information about what you should consider when producing user-friendly instructions, based on the findings of research and good practice
- examples of how the guidance has been applied by those who implement policy in diagnostic companies

The toolkit has been designed primarily to support instructions in a static/fixed page layout

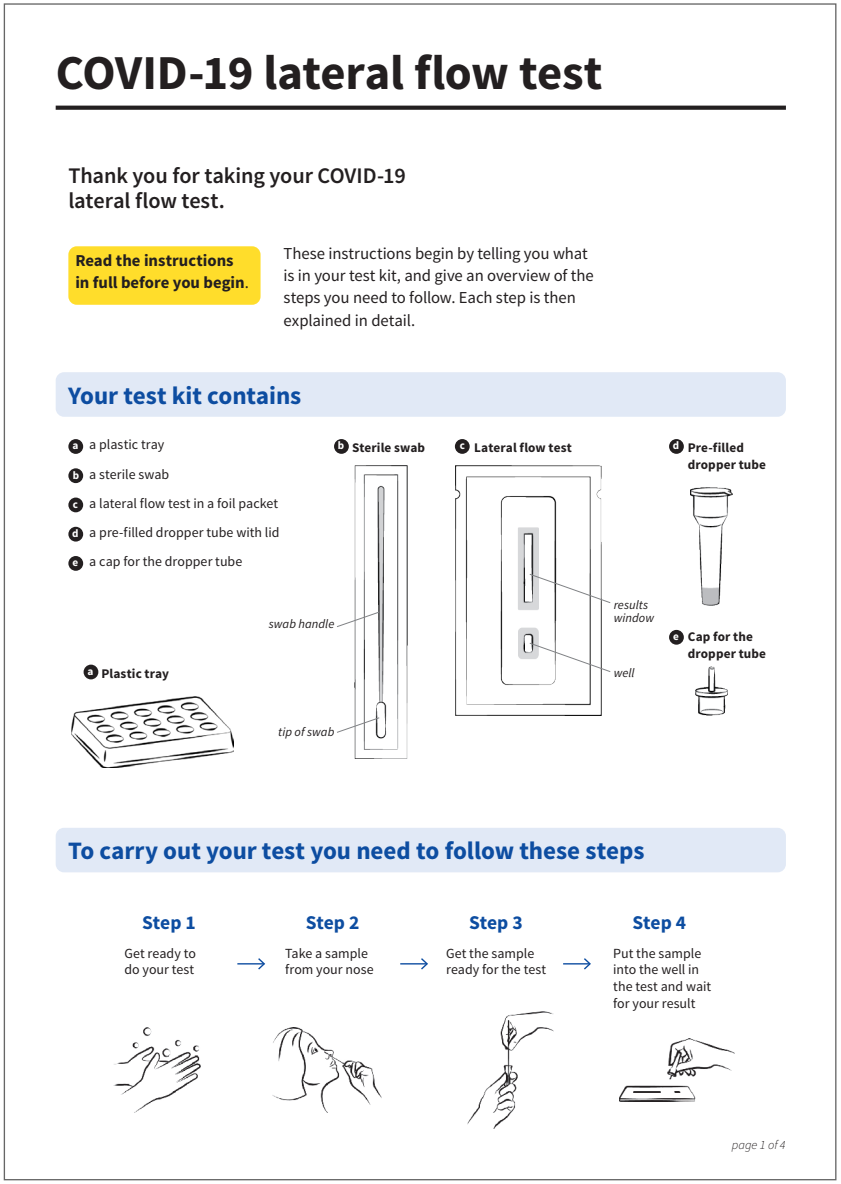
Contents

Point-of-use instructions

Prototype instructions

Our prototype for point-of-use instructions is based on our findings drawn from:

- research relevant to producing user-friendly instructional text
- successive, focused studies with final users about the visual presentation of point-of-use instructions



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

a a plastic tray
b a sterile swab
c a lateral flow test in a foil packet
d a pre-filled dropper tube with lid
e a cap for the dropper tube

b Sterile swab
swab handle
tip of swab
c Lateral flow test
results window
well
d Pre-filled dropper tube
e Cap for the dropper tube
a Plastic tray

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

page 1 of 4

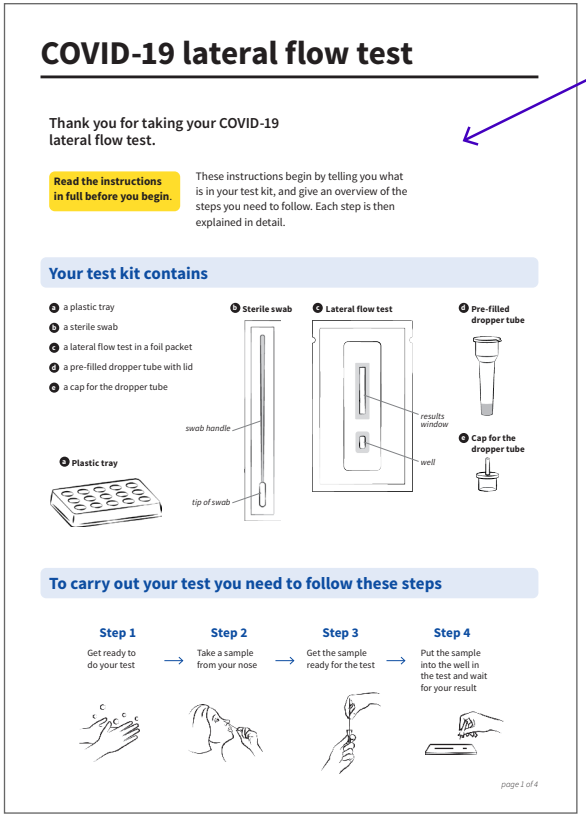
Prototype for point-of-use instructions for a COVID-19 lateral flow test, first page.

297 x 210 mm, 2020

Point-of-use instructions should be designed to be user friendly

This annotated example identifies some important elements of user-friendly instructions:

- The sections of the instructions are clearly indentified.
- The action steps are explained through words and pictures.
- The text is easy to read.



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swab handle
tip of swab
results window
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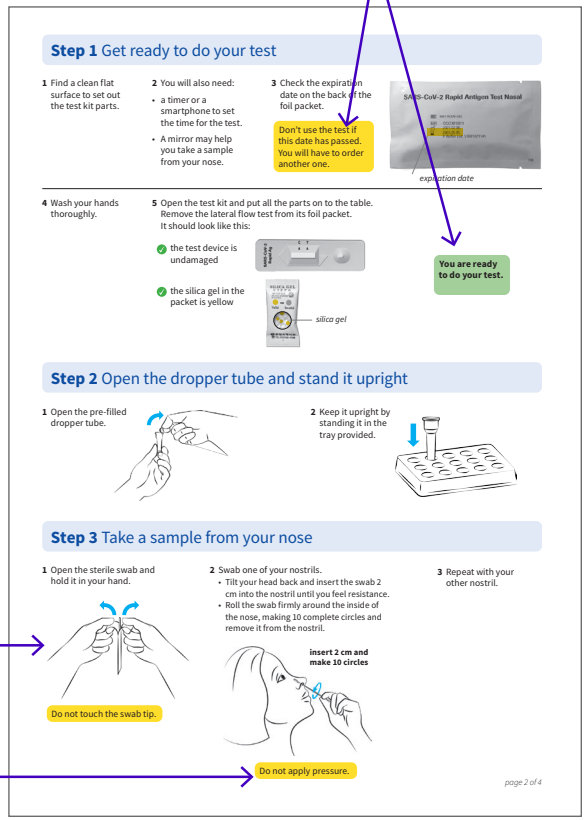
page 1 of 4

An introduction outlines the purpose of the instructions, using plain language.

The kit components are shown with labels to help people identify them.

The use of colour is consistent: green is used for confirmation and yellow for warnings.



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.

SARS-CoV-2 Rapid Antigen Test Nasal

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.

Do not touch the swab tip.

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.

insert 2 cm and make 10 circles

3 Repeat with your other nostril.

Do not apply pressure.

page 2 of 4

Images are placed next to their corresponding text, so that the reader can use them together to understand each step.

Warnings appear when the reader needs them ('just in time').

Supporting evidence from research

We reviewed existing research relevant to producing user-friendly instructions in two research briefings:

- Readers and instructions
- Language, typography, pictures and layout

We summarise the main points here; the links below provide more detail and references.

Research briefing: Readers and instructions

Research briefing: Language, typography, pictures and layout

Readers and instructions

To help people execute procedures successfully, instructions should:

- Tell readers to read all the instructions before starting the test.
- Start with an inventory of components that will be needed to carry out the task.
- Clearly set the goal of the procedure at the beginning.
- Provide step-by-step directives, focusing on actions around objects.
- Ensure each directive matches the order of the actions (‘First do this… Then do this’).
- Divide complex instructions into steps, and set a clear subgoal for each step.
- Include warnings, caveats, prerequisite information and information on common problems and how to solve them.
- Separate these from the action steps, but keep them together so that they appear when the reader needs them.

Language, typography and pictures

To help people locate, understand and apply information, instructions should:

- Identify all the components that will be used in the procedure with an image and a label to identify them.
- Include numbered action steps, organised clearly on the page.
- Position text and image so they support each other.
- Use goals and subgoals to create clear sections.
- Position warnings and supportive information close to their relative action step.
- Use colour, arrows and numbers to highlight areas, cue motion, or indicate order.
- Use typography to denote hierarchy and emphasis.

Engaging with your intended users

Who are you producing instructions for?

Design can help by making instructions accessible for people with different needs.

The environment where people will use the test will define some of the requirements for the instructions.

People doing a test may have different experiences from those who design the tests and the instructions.

To find out what information is needed, it is a good idea to ask the final users.

Think about the user and context of use

The content can be organised in different ways according to the target audience and, for example, whether the test is being carried out at home or in a workplace.

Different users have different needs

You may need to find out which languages are used in communities where English is not a first language.

The age of your users may influence whether they prefer to view instructions on paper or on a mobile phone.

Where the test is carried out may influence the information you need to include

For home tests, users will need access to a clean flat surface, a timing device and so on.

For community testing – in a GP surgery or community centre – it may be helpful to know if there is a wall to pin up poster versions of instructions.

Paper or screen?

Think about how the instructions will appear on both paper and on a phone or tablet.

Here is what our user panel thought when they saw instructions produced in static and video form:

Covid test instructions using line illustrations, photographs or video: A pilot study to find out about preference

Get feedback – ask people what they think

It is always good to get feedback from your intended users.

We carried out several small studies with our user panel. We showed them different ways in which information could be presented and asked for their views.

What to do with feedback

Not all user comments are helpful, but if you find that more than half the people prefer one option to another, it may inform your decision-making. If people make mistakes when they are carrying out a test, it suggests that the instructions could be clearer.

Watch people doing a test and see how they use instructions

When you have a version of the instructions that you are happy with, it's a good idea to watch people doing a test and note down any mistakes they make.

When they have finished, ask them what they found difficult, and what additional information they would have found helpful.

Understand if the instructions are fit for purpose

Asking about someone's confidence to carry out a test can tell us whether they have all the information they need to operate the test. Questions you could ask the user might include:

- How easy or difficult it was to do the test with the instructions?
- If you had to do the test tomorrow again, would you do it with these instructions? Why?

Find out if the instructions are clear and easy to read

When you have a draft version of your instructions, you can ask how easy or difficult it is to:

- identify the contents of the kit
- prepare for the test
- handle the test kit parts safely
- collect the sample and prepare it
- read the result

You can ask:

- Is the text comfortable to read?
- Is the text easy to understand?
- Are the diagrams easy to work out?
- Can you identify the warnings?
- Did the warnings come at the right time?
- Are the action steps clearly set out?
- Are there any words you find difficult to understand? Can you provide an alternative?

Content and structure

Problems with IFUs

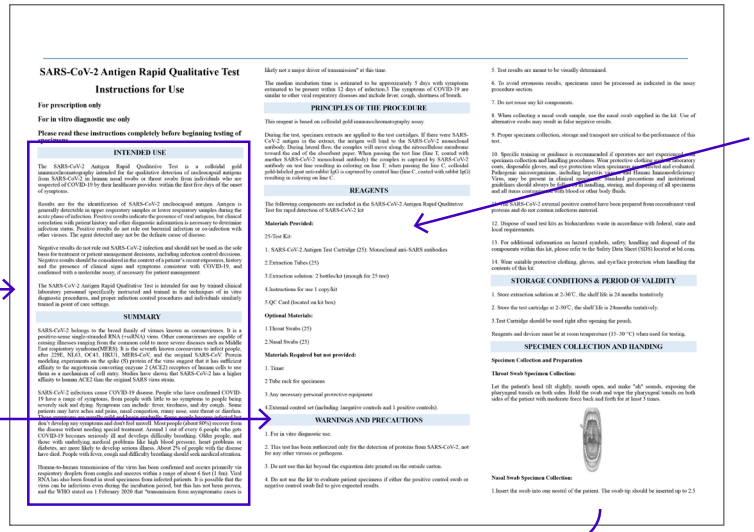
Point-of-use instructions are based on the manufacturer's Instructions for Use (IFUs), which include the information you need to help people carry out a test.

IFUs are often included in a leaflet that contains regulatory and technical information, and are not presented in a user-friendly way.

The example illustrated here shows a typical IFU. The annotations indicate the elements that may challenge the user.

Even though the IFU is broken down into sections, these do not relate to what the user needs to do.

Example of Instructions for Use

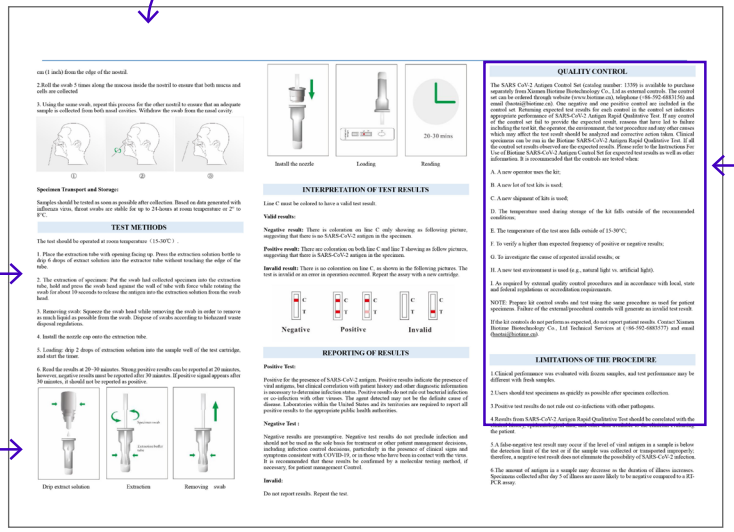


Long introduction is unlikely to be useful at point of use.

Warnings and precautions are set in the same text style as the rest of the information, making them more difficult to find.

The kit components are listed by name but not illustrated, making it difficult for people who are unfamiliar with the components to identify them.

The page break doesn't correspond to the sections.



Long lines of text are difficult to read.

Images are neither next to their corresponding text, nor numbered. This means the reader has to guess to which step they correspond.

Technical information unlikely to be needed by people at point of use.

Sections in point-of-use instructions

We have found that it is useful to structure the text by identifying the main sections. For a COVID-19 lateral flow test, the main sections are:

1 Information about getting ready to do the test

- a list of components in the test kit. This prompts users to check they have a complete test kit and helps them to identify each item before they need to use them.
- guidance on what else is needed before carrying out the test
- an overview of the procedure or a summary of the main goals

2 Instructions for carrying out the test

- a step-by-step explanation of actions necessary to complete the test, including feedback information so that users can monitor and check their progress.

3 Results and what to do next

- a clear explanation of what the test results mean and actions to be taken.

Look at the IFU

The manufacturer's IFU contains the information you need to create user-friendly instructions. Use them to work out:

- what the test kit contains
- what else is needed to carry out the test
- the action steps for carrying out the test
- results and what they mean

If you can, ask someone else to identify what should be included in each of the three sections and see if you agree.

The action steps

The second section, 'Instructions for carrying out the test', involves breaking down the procedure into individual actions.

It takes time to identify all the steps needed to ensure the test can be done carefully, accurately and safely. It helps if you carry out the test yourself and watch somebody doing it.

Looking at other procedural instructions can be helpful and we provide some examples in the appendix that we think align with good practice.

When you have the content, you can think how to incorporate:

- clear language
- images to help explain
- visual organisation of text and image

Using illustrations and text

Illustrations do different things

Illustrations in procedural instructions help readers in different ways:

- they can be used to help identify component parts
- they can explainf a procedure or specific action
- the user can refer to them for reassurance, or to check a written instruction

Kinds of text

Text may be in the form of:

- explanations
- labels
- warning
- emphasis

It helps the reader if each kind if text is differentiated and treated consistently throughout. Our use panel was positive about the use of a yellow panel to signal warning or precaution, for example.

Text and illustrations work together

Illustrations and related text should be placed close together.

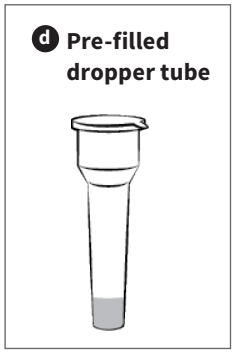


Illustration with label to identify each kit component.

Image to represent an overall task in the test.

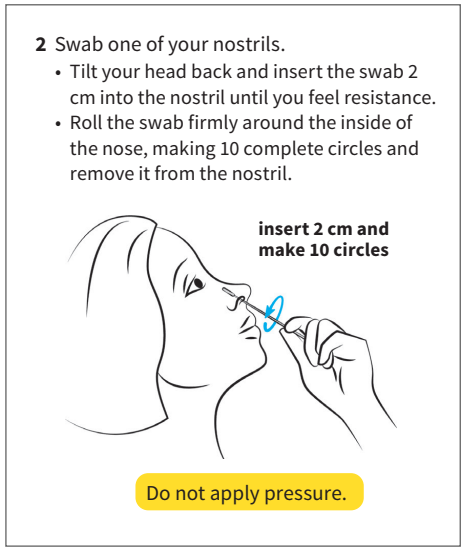
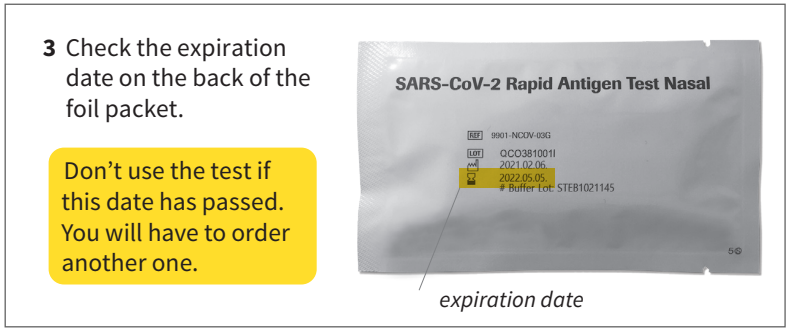


Image to demonstrate how to perform a specific action. Visual cues such as arrows and labels supplement the information.

Photograph of the object to help the user identify a detail of a component.

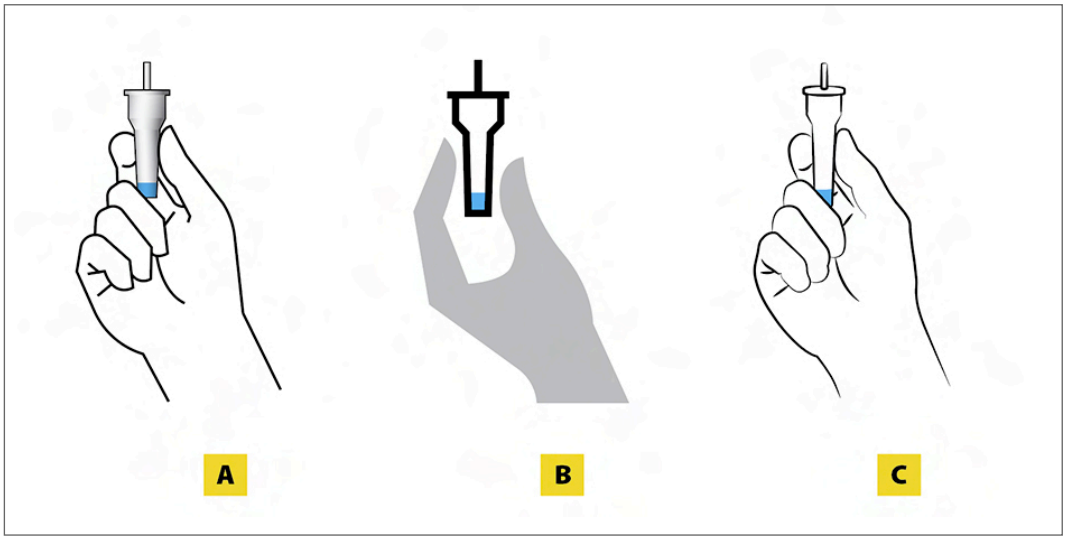


Illustrations can help to improve the clarity of procedural instructions

In our research, we concentrated on drawn images rather than photographs or video. The images in the toolkit are drawn in what we called a ‘sketchy’ style. The user panel preferred this style to the two others they were shown, which we called ‘clinical’ and ‘iconic’.

Our user panel described the ‘clinical’ and ‘sketchy’ styles as ‘clear’ and said both provided an ‘appropriate level of detail’. The panel suggested that linear drawing styles supported more detail, which was helpful in explaining unfamiliar procedural steps. The ‘iconic’ illustration style was described as ‘diagrammatic’, ‘abstract’ and ‘stylised’.

The sketchy style was thought to be ‘humanised’, in that it made the instruction more approachable and possibly less daunting.



From left to right: (A) ‘clinical’, (B) ‘iconic’ and (C) ‘sketchy’ styles.

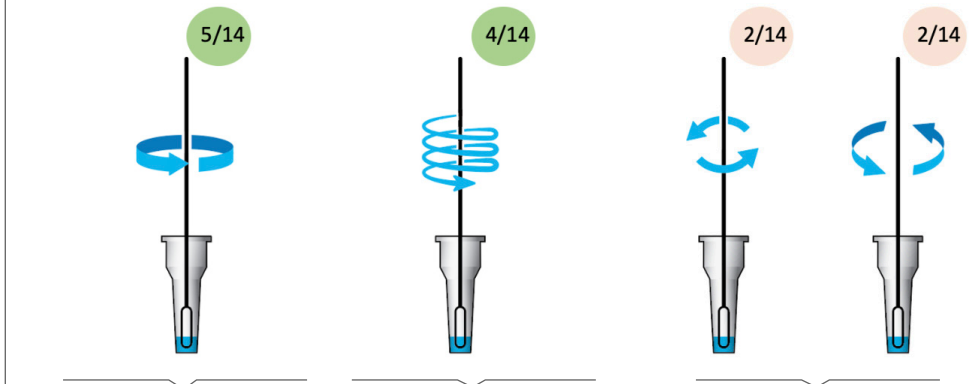
Using arrows to convey motion

Although there is no conventional way to indicate ‘rotation’ or ‘squeeze’, the way the arrows are drawn can help to get the message across.

We asked our user panel to look at different versions to convey the instructions ‘rotate the swab’ and ‘rotate the swab against the tube wall’.

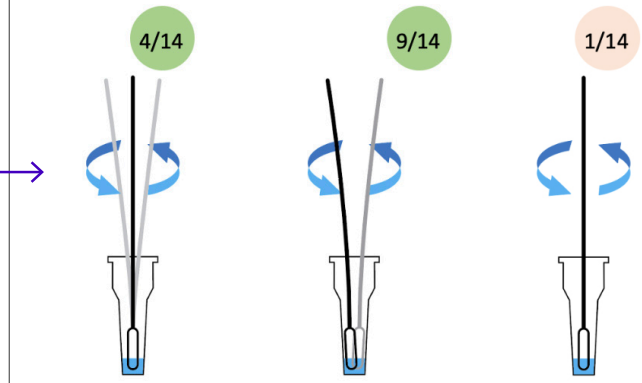
We asked them to choose which illustration best conveyed the instruction and to describe what each drawing suggested to them.

Which diagram represents the action ‘Rotate the swab’?



Participants from our feedback group preferred the arrows that clearly wrapped around the swab.

Which diagram represents the action ‘Rotate the swab agains the tube wall’?



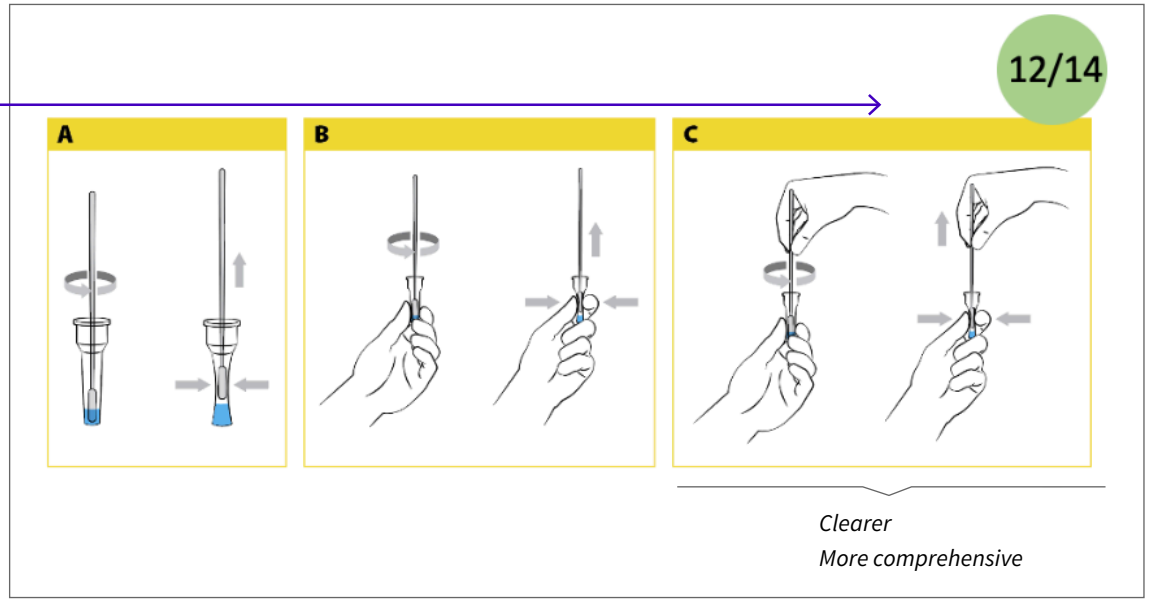
Indicating the path of the swab (for example with a greyed-out swab) was a clearer way to indicate the action for our participants.

Showing hands in actions

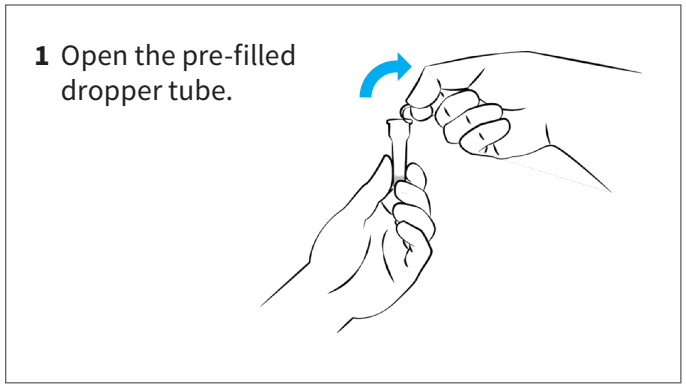
Many of the action steps involve the use of hands.

We asked our user panel whether it was helpful to show one, two or no hands.

There was clear preference for showing two hands, even though this reduced the size of the kit component in the illustration.



Including both hands in diagrams provides useful information for viewers about exactly how to interact with the kit.



The text needs to be clear and easy to understand

We know that using short sentences, ordinary words (rather than those that are scientific or technical), headings and active statements (rather than passive ones) are helpful.

The text in the IFUs is accurate and precise, but is sometimes not as clear as it could be. This text may not be suitable for point-of-use instructions.

The example on the right shows how the text of an instruction can be made clearer.

There are some good guides on writing clearly including:

https://readabilityguidelines.co.uk/clear-language/

https://www.nice.org.uk/corporate/ecd2/chapter/rules-of-clear-writing

Instructional text from an IFU

Tear open the buffer and add entire buffer to the tube with oral fluid.

It is not clear because:

- the word ‘buffer’ is not widely used. What does it mean?
- ‘buffer’ is used in different ways – as something to open, and as a substance to add
- ‘oral fluid’ is not a term used in everyday speech
- there are two actions in one sentence

Our revised version

1. *Tear open the tube that contains the test solution.*
2. *Put all the test solution into the tube that contains your saliva (spit).*

Here the text:

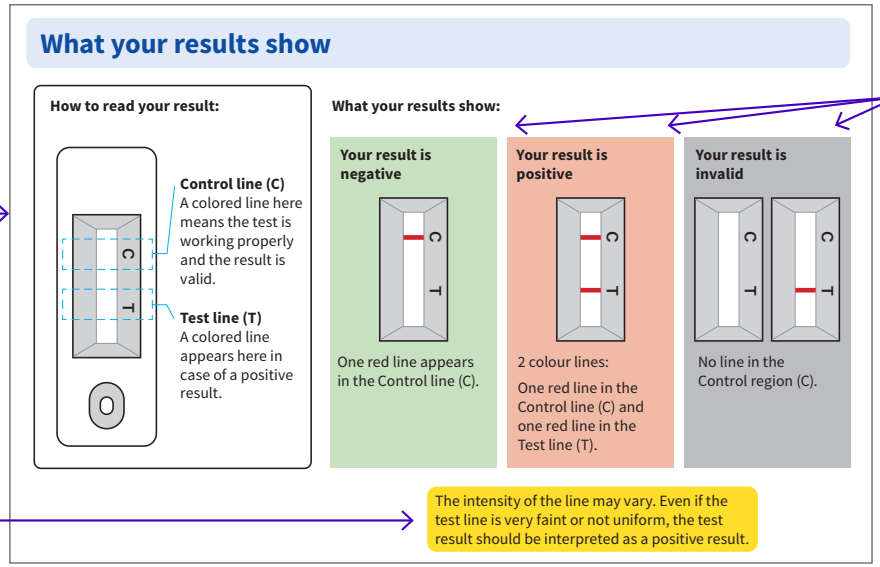
- is divided into two separate action steps
- uses the words ‘test solution’ instead of ‘buffer’
- makes it clear that the test solution is contained in a tube
- changes ‘oral solution’ to words that people are familiar with

Presenting and explaining test kit results

Explaining the results of a test is a key part of the procedure. Text and illustrations need to be presented clearly so they are not misinterpreted.

The two examples reproduced here show different ways of explaining results. The top one is from a COVID-19 saliva test, the bottom is from a set of instructions to test for influenza.

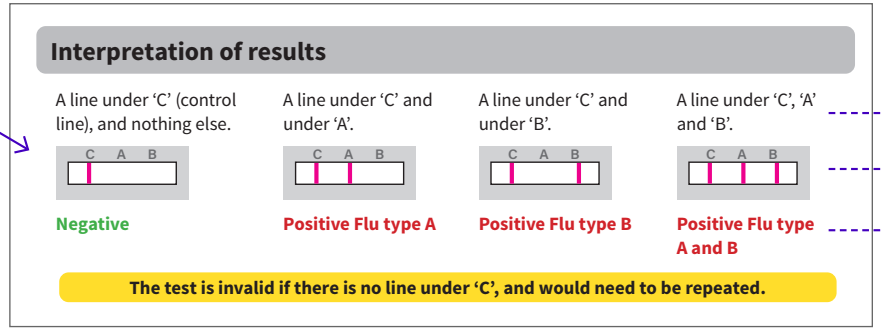
A diagram can be used to indicate the area where their result will appear.



Using colour is one way to distinguish different results.

Placing precautionary information in a yellow panel draws attention to it.

Each possible result is explained using a description of what the test will show, an image of the test, and a confirmation of the result produced.



Aligning the texts and images helps the person to compare the different results.

Application of findings for policy implementers

We worked with Roche Products Ltd, Roche Diagnostics Ltd and the Innovation Agency – Academic Health Science Network (AHSN) for the North West Coast to apply our guidelines to tests for influenza including the Standard Operating Procedure (SOP) and Internal Quality Control (IQC) that would be used by health professionals in GP surgeries as key texts.

We agreed to produce user-friendly instructions for a SD BIOSENSOR Standard Q Influenza A/B lateral flow test. These instructions form part of a procedural handbook.

Discussion with health professionals resulted in requests for 'quick guide' versions of the instructions that could be positioned, for example, on a wall for easy reference.

Roche Diagnostics agreed to provide:

- a sample kit and manufacturer's instructions for use (IFU)
- access to two health professionals to discuss the contents and function of the SOP and IQC.

How we applied the findings of our research

1. Reviewed the IFU to identify the main steps that were relevant to the SOP, and to carrying out the test
2. Carried out the test ourselves in order to gain a better understanding of the action points
3. Identifed the kit components and made drawings in chosen style
4. Drafted wording
5. Set out text and images using the format recommended by the research
6. Got feedback from the two health professionals and made relevant amends

Standard Operating Procedure (SOP)

This document, intended to be included in a handbook for health professionals working in GP surgeries, sets out the procedure that should be followed when carrying out an influenza lateral flow test.

The sections in the SOP are depicted in prominent orange bands.

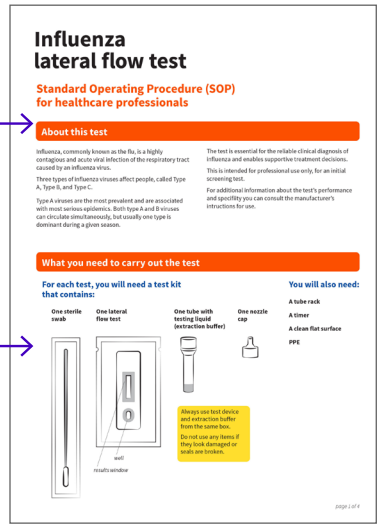
The action steps in the instructions for carrying out the test, in pale blue horizontal bands, are less prominent in this context.

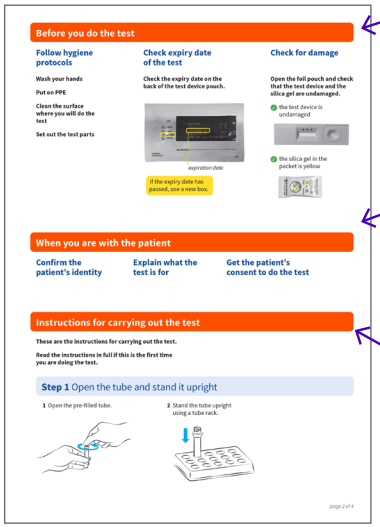
About this test

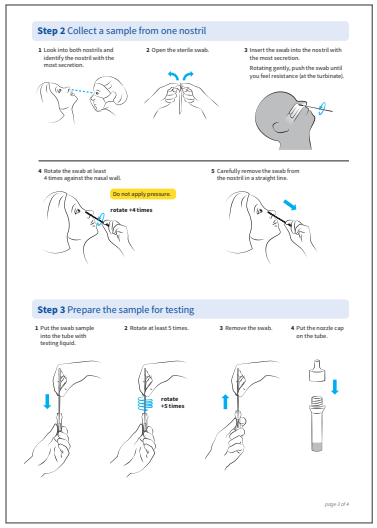
Short explanation of the purpose of the test to be carried out (taken from the IFU).

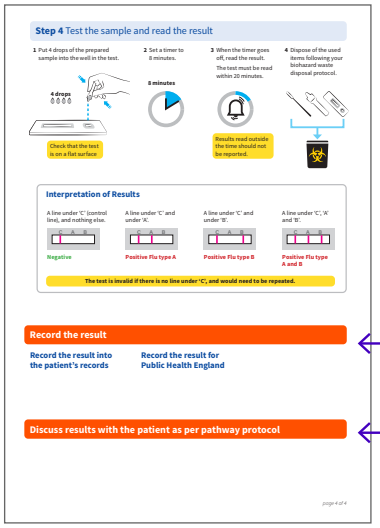
What you need to carry out the test

Description of the components of the test kit and other key items.









Before you do the test

Health and safety protocols.

When you are with the patient

Checking essential details.

Instructions for carrying out the test

While many health professionals will be aware of this procedure, clear explanation ensures consistent application.

The use of numbering, conventions for showing movement and cautions are based on our research findings.

Record the result

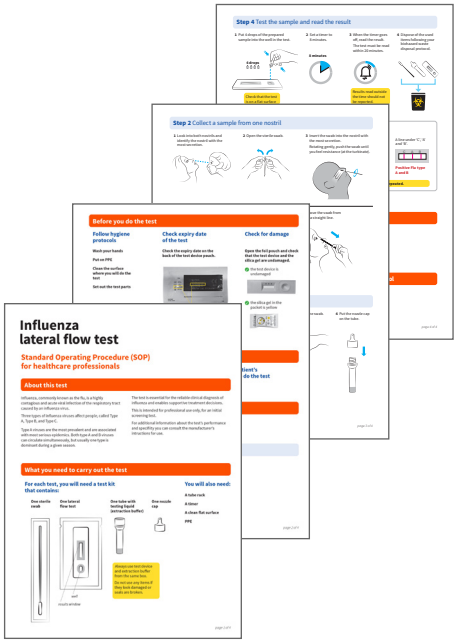
Discuss results with the patient as per pathway protocol

Quick Guide to put up on a wall

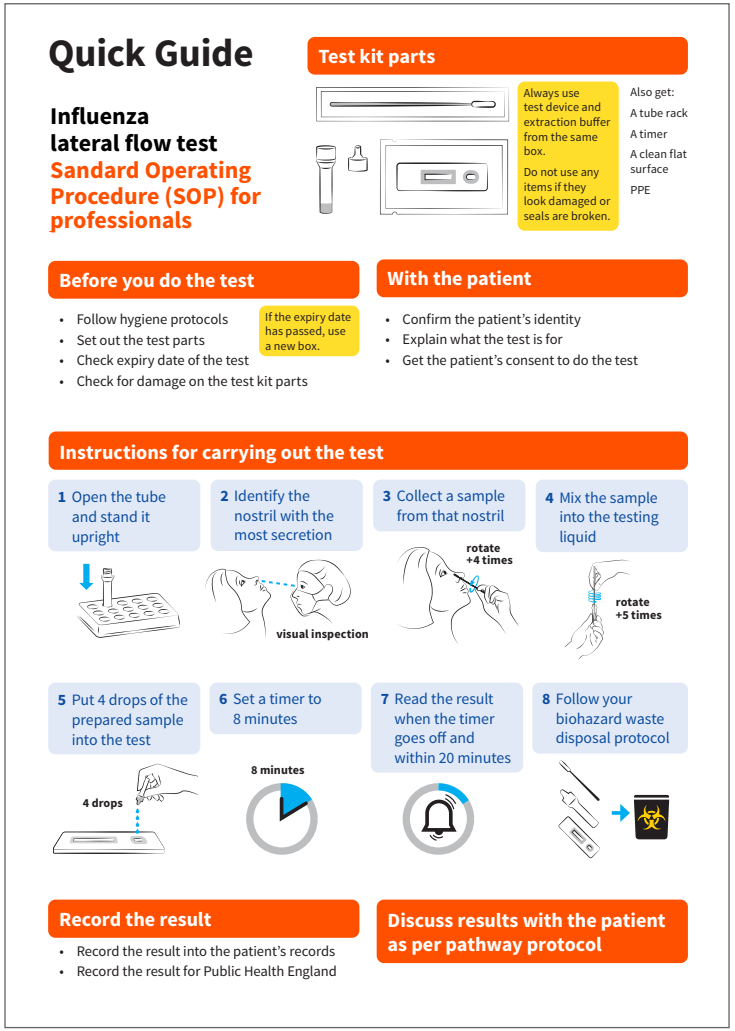
The Quick Guide identifies the key stages in the SOP, using the same conventions as in the full version.

Orange bands identify the key stages in the SOP.

The text and illustrations have been edited to include only the key elements.



The 4-page SOP was transformed into a Quick Guide.

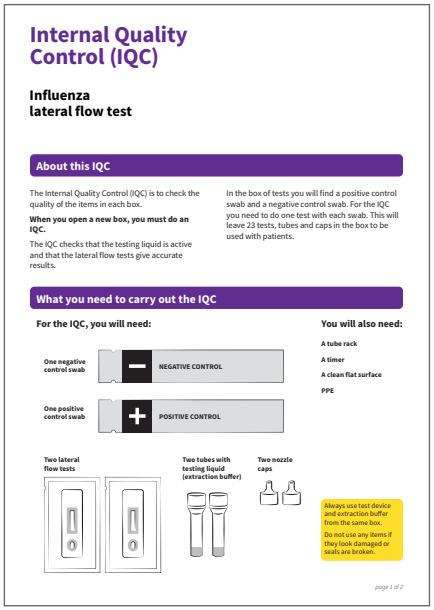


Internal Quality Control (IQC) procedure

GP surgeries receive testing kits in boxes and need to carry out an IQC for each box of tests.

This set of procedures uses the same conventions as the SOP, including horizontal bands, to separate the component parts.

To distinguish this document from the SOP and Quick Guide, a different colour is used for the key sections.



Internal Quality Control (IQC)

Influenza lateral flow test

About this IQC

The Internal Quality Control (IQC) is to check the quality of the items in each box.

When you open a new box, you must do an IQC.

The IQC checks that the testing liquid is active and that the lateral flow tests give accurate results.

In the box of tests you will find a positive control swab and a negative control swab. For the IQC you need to do one test with each swab. This will leave 23 tests, tubes and caps in the box to be used with patients.

What you need to carry out the IQC

For the IQC, you will need:

One negative control swab — NEGATIVE CONTROL

One positive control swab — POSITIVE CONTROL

Two lateral flow tests

Two tubes with testing liquid (extraction buffer)

Two nozzle caps

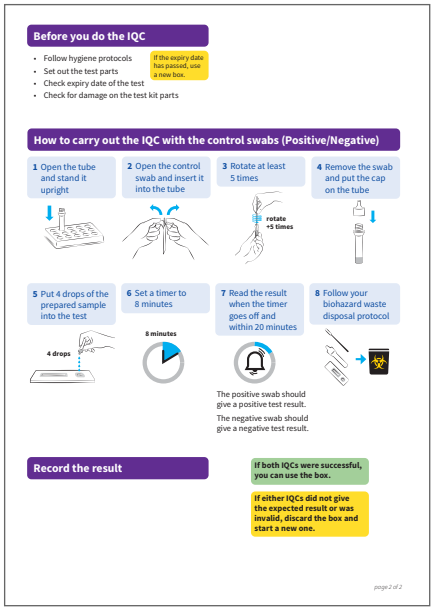
You will also need:

- A tube rack
- A timer
- A clean flat surface
- PPE

Always use test device and extraction buffer from the same box.

Do not use any items if they look damaged or seals are broken.

page 1 of 2



Before you do the IQC

- Follow hygiene protocols
- Set out the test parts
- Check expiry date of the test
- Check for damage on the test kit parts

If the expiry date has passed, use a new box.

How to carry out the IQC with the control swabs (Positive/Negative)

1 Open the tube and stand it upright

2 Open the control swab and insert it into the tube

3 Rotate at least 5 times — rotate +5 times

4 Remove the swab and put the cap on the tube

5 Put 4 drops of the prepared sample into the test — 4 drops

6 Set a timer to 8 minutes — 8 minutes

7 Read the result when the timer goes off and within 20 minutes

8 Follow your biohazard waste disposal protocol

The positive swab should give a positive test result.

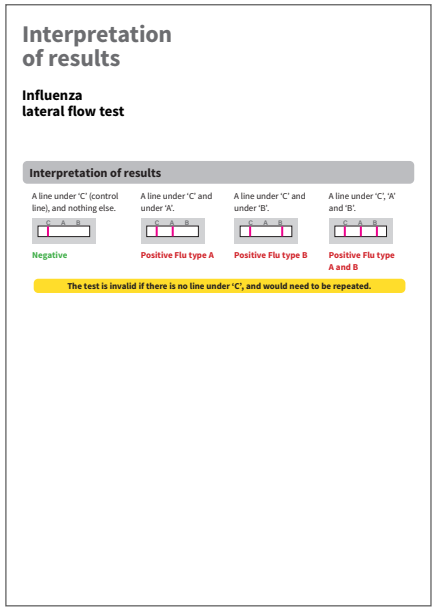
The negative swab should give a negative test result.

Record the result

If both IQCs were successful, you can use the box.

If either IQCs did not give the expected result or was invalid, discard the box and start a new one.

page 2 of 2



Interpretation of results

Influenza lateral flow test

Interpretation of results

A line under 'C' (control line), and nothing else.	A line under 'C' and under 'A'.	A line under 'C' and under 'B'.	A line under 'C', 'A' and 'B'.
Negative	Positive Flu type A	Positive Flu type B	Positive Flu type A and B

The test is invalid if there is no line under 'C', and would need to be repeated.

Appendix:
Examples of user-friendly procedural instructions

Examples of user-friendly procedural instructions

This summary gathers examples of instructional text in 3 formats: fixed page layout (printed sheets or pdfs), video and interactive formats (websites and mobile apps).

We have selected examples that illustrate effective approaches of clear and accessible instructions.

We identify good practice in presenting visual and verbal information and consider how websites and apps may support users in a range of different ways.

‘How to respond to an Opioid Overdose with Naloxone’

Design by Gillian Harvey and Dr Stephanie VandenBerg.

These instructions presented in a fixed page layout (as a printed sheet or PDF). They show the user how to administer Naloxone in response to an Opioid overdose.

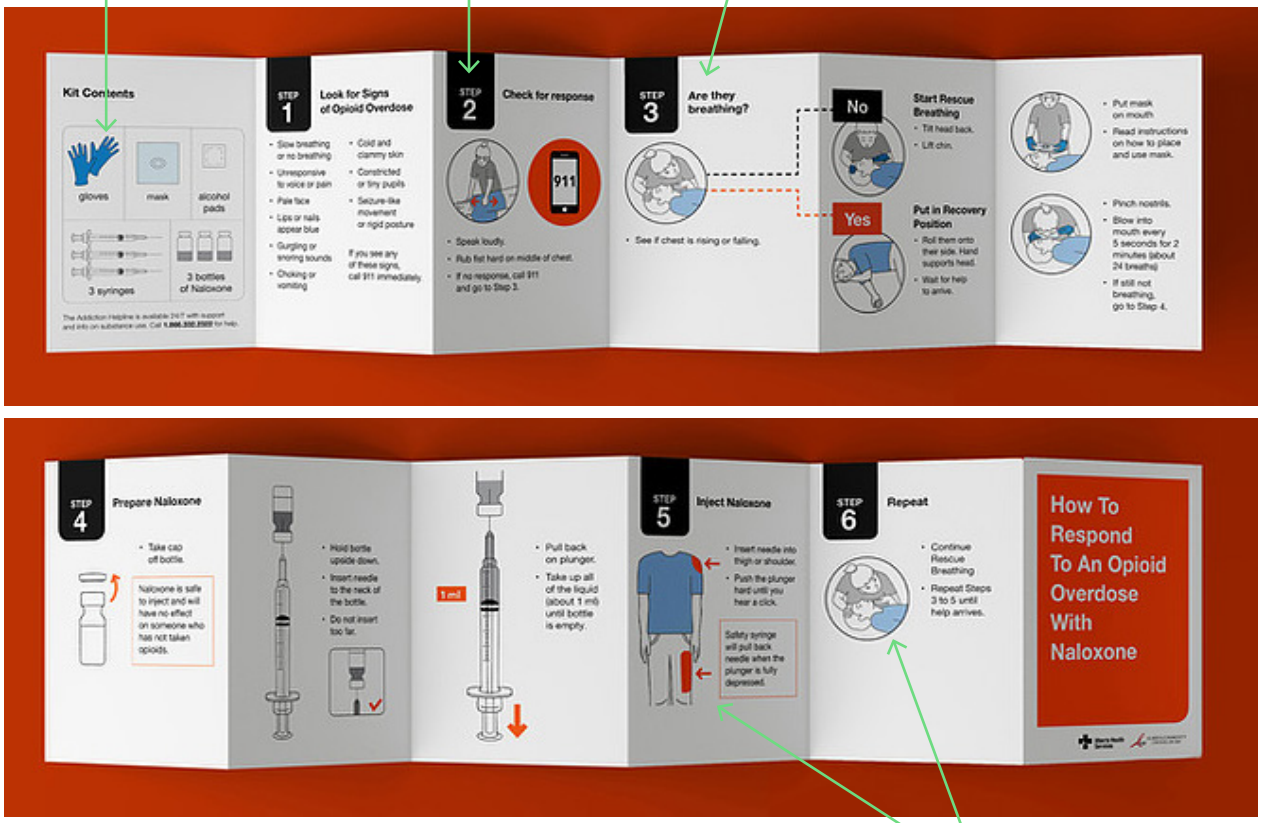
What we like about this example:

- The instructions are small in size and short, so they can be used at the time of need.
- Each page presents a different step, and typography and layout provide a clear structure.
- The text that describes the actions is concise and written in clear language.
- The illustrations are large, describe important details and colour has been used to highlight actions all the way through.

Kit components are depicted in sufficient detail to help the reader to identify and handle them.

The steps are clearly identified by a number reversed out of a black box.

The heading for each step is set in bold type and arranged at the top of the page to differentiate it from the main text.



Colour is used consistently to signal actions (orange), and in illustrations to indicate items of clothing (blue).

Instructions for beer brewing kit

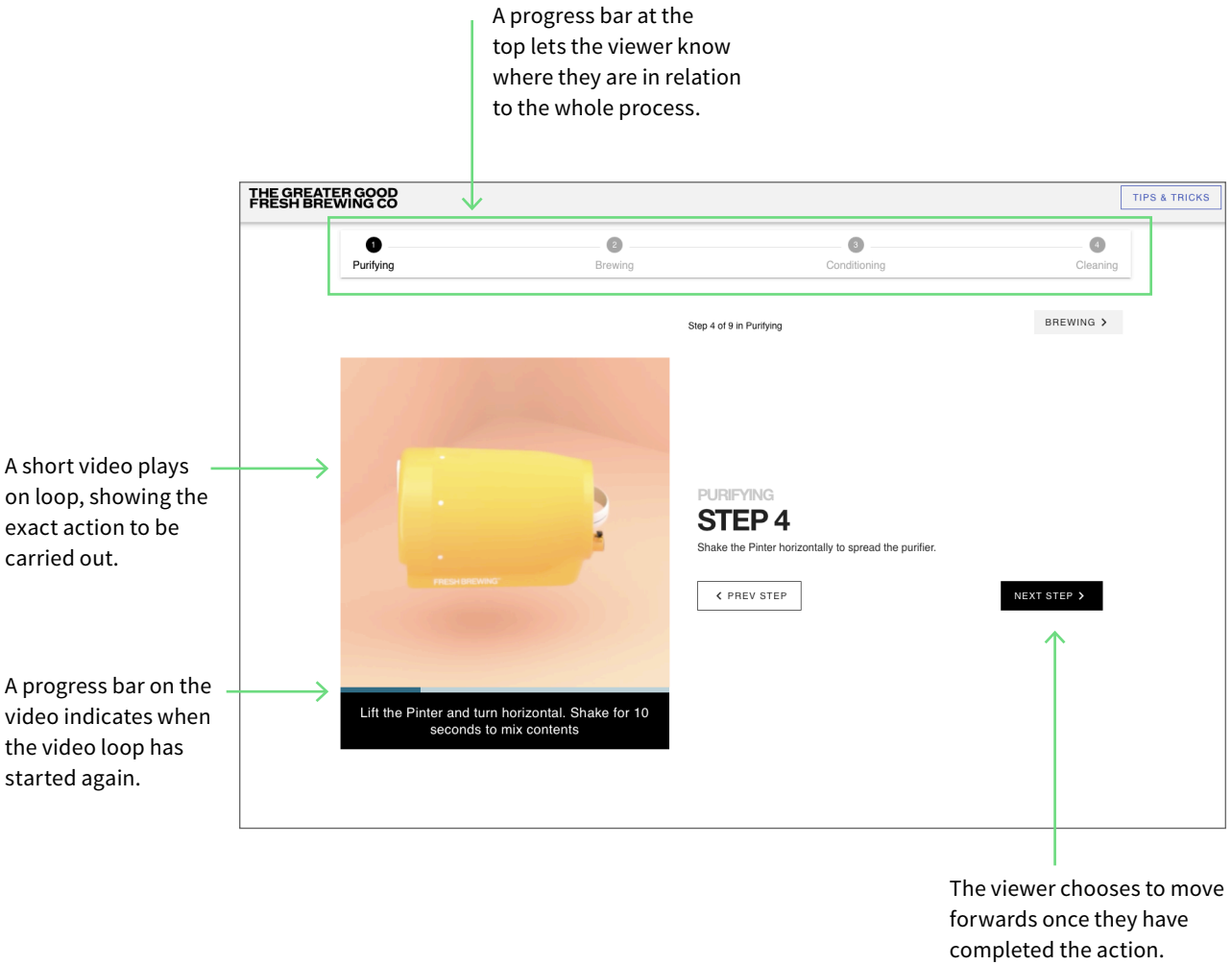
The Greater Good Brewery
https://instructions.thegreatergood.co.uk

In this example, we are interested in how interactive formats may support users to:

- get a general view of the procedure they are attempting to do
- focus on the detail of every action

What we like about this example:

- Clear navigation supports the viewer so that they know where they are at all times.
- Elements that are clearly labelled.
- Each step is clearly described and demonstrated.
- The viewer controls the pace.



How to do a COVID-19 Self Test (Rapid Antigen Test)

Instructional video by DHSC

https://www.youtube.com/watch?v=S9XR8RZxKNo

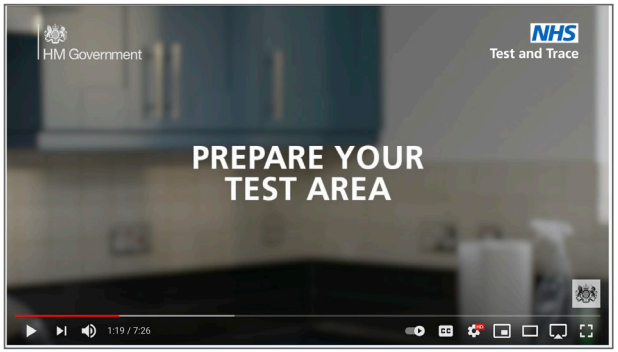
Instructional videos help to give a general idea of the procedure and demonstrate how the actions are done.

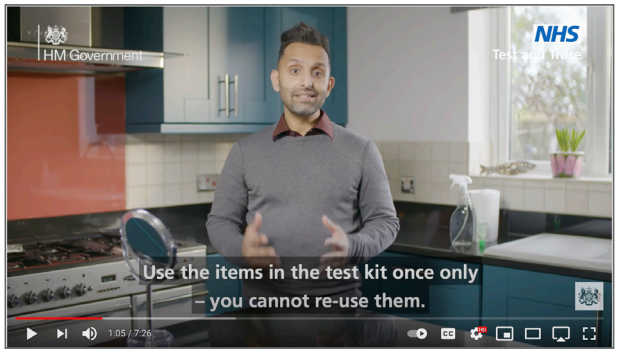
What we like about this example:

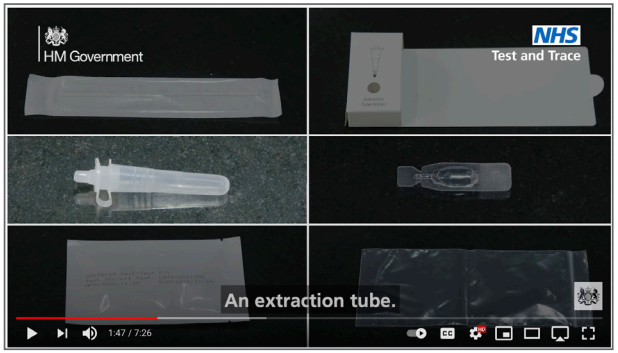
- It is comprehensive, covering the information needed before the test, how to prepare to take the test, the components of the kit and the action steps to follow.
- The language is informal but clear.
- The actions are demonstrated with a useful level of detail.

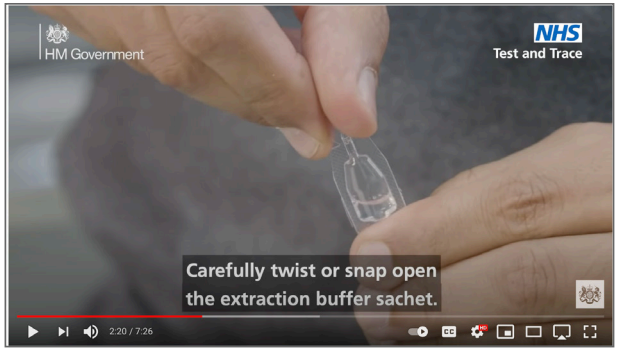
Legible intertitle at the beginning of each section of the video, combined with pause in voice over.

The person is looking to the camera as they speak and uses expression to emphasise important information.









When showing the test kit contents, care has been taken to signal each one as they are named, and to arrange the items on screen to aid identification.

Medium, close and extremely close shots are combined to show the actions in the most informative way possible.

User-friendly point-of-use instructions for home use diagnostic tests: guidance and tools

How to cite this publication:

Walker, Sue, Bravo, Josefina and Edwards, Al (2022): User-friendly point-of-use instructions for home use diagnostic tests. University of Reading. Other. https://doi.org/10.17864/1947.000419