

IFU version 0.9.2	Step	Instruction	Usability observation	Recommendation	Recommendations incorporated into IFU version 1.1.4
Page 0 and 1		General introduction about the test	Participants were skipping over the general introductory information and focusing on the numbered steps of use	Add a clear message at the start of the IFU to ask users to read the entire guide before performing a test	Read this whole guide carefully before you start your test added to the front cover
Page 1		Testing is suitable for the following people		Advise that the adolescents test can be carried out by an adult if necessary	Copy added "The adult may conduct the test as necessary" Page 3
Page 1		Covid-19 guidance and help	Participant found it difficult to find specific types of information	Separate out the guidance and help section into 3 clear headings. Use improved language and structure.	Guidance now under three headings. Page 3 Covid-19 guidance If your symptoms get worse In case of medical emergency
Page 3		Avoid eating and drinking for at least 30 minutes before doing the test to reduce the risk of spoiling the test	One participant commented that they had drunk a coffee just before the interview started this resulted in an invalid test (which may or may not have been the cause)	Highlight the need to avoid eating or drinking	Additional highlighted note added to Page 6
Page 4		Read the instruction guide carefully	Participants did not attach much importance to steps without numbers	Number as a step	Step number added Step 1 page 6
Page 4		Clear, clean and dry a flat surface to place the home test kit on.	Participants either performed the step or commented that they had already cleaned the surface before starting the interview. Those that did neither commented that as it was not numbered it looked less like a sequential step to follow.	Number as a step	Step numbers added Step 2 Page 6 Spray bottle included into the illustration to indicate cleaning a surface and wiping cloth shaded for prominence. Wording changed to <i>Clear, clean and dry a flat surface immediately before starting the test.</i>
Page 4		Wash your hands thoroughly for 20 seconds, using soap and warm water, or hand sanitiser.	A sequential step	Number as a step	Step number added Step 3 page 6
Page 4		Take the test kit out of the foil packaging and place it onto the cleaned flat surface.	Participants did not perform this step as intended. For a number of reasons.		
			1 Not clear that the pack contained the test strip	Change wording in IFU from test kit to test strip	Wording changed. Step 5 Page 8
			2 The pack containing the test strip is opaque. Participants were unsure what was inside.	Show test strip and pack together	Illustration created showing test strip being removed from the pack. Step 5 Page 8
			3 The instruction to take out the test strip appears before the check your contents section. The relevance and importance of this step was missed, as was the instruction to start the test within 30 minutes	Reposition instruction at the start of the test set up	Instruction and revised illustration relocated as the first step in the Set up your test section. Step 5 page 8.
			4 Printing on the foil pack containing the test strip refers to test cartridge	Change printing on the outside of the foil pack to state test strip	
Page 5		Check your contents	Participants did not clearly identify the test strip as this was inside the opaque pack	Refer to the foil pack with test strip inside.	New illustration of pack, indicating component inside Page 7
			Some participants were confused by the presence of a desiccant bag in the pouch.	Refer to the desiccant in the foil pack and need to dispose of it.	Desiccant note added and how to dispose of it. Step 5 page 8.
			The need to gather other items to perform the test i.e. watch, cup etc were overlooked leading to disruption during the test when participants realised that they were needed	Make the need for these items more prominent and reposition information	Items clearly stated within a warning box on Page 8
			Participants commented that the colour of the sachet was grey in the illustration, but was actually a clear component	Change colour of sachet	Sachet grey tone removed from the illustration Step 4 page 7 and throughout the IFU where the sachet appears
			Participants need clearer guidance when not to use the test kit	Make the instruction do not use the test kit if it is damaged, broken or something missing clearer.	Wording repositioned and contained within a warning box Page 7
Set up your test					
Page 6	1	Carefully twist or snap open the sachet. Being careful not to spill any of the fluid			
Page 6	2	Pour all of the fluid from the sachet into the extraction tube. Avoid touching the sachet against the tube	Instruction calls to pour liquid from extraction buffer sachet when a squeezing action is actually needed.	Change wording to squeeze instead of pour.	Change of wording to squeeze. Step 7 page 8.
			The majority of participants rested the end of the sachet against the end of the extraction tube. This in many cases was to keep the hand steady to dispense the liquid into the tube without spilling any.	Assess risk of touching the components together vs steadying the hand to dispense the liquid. Word "avoid" makes it sound optional change to "Do not". This is only recommended if the action of touching the two components creates a higher risk that the test will be invalid.	
Page 6	3	Place the filled tube in a cup or container to avoid spilling it while you use the swab	The majority of participants had not noticed the need for a small container to place the extraction tube in while performing swabbing and to keep the tube upright. This led to participants leaving the testing area to search to a container. Often they would return to realise that the container they had found was too large in diameter and unable to keep the extraction tube upright. This led to further excursions to find a more suitable container.	Make the instruction for the need for a small cup more prominent and at the beginning of the guide before testing is underway and/or Provide an extraction tube holder with test kit	An extraction tube holding feature has been incorporated into the test kit box and a note that a small cup can also be used as part of the instruction Step 8 page 8.
Page 6	4	Check the swab in the sealed wrapper in front of you	Participants were able to identify the soft fabric end. However it was noted that this step was out of logical sequence	Make this step directly before the removal of the swab	Repositioned to Step 11 page 9.
Page 7	5	Gently blow your nose into a tissue.	Participants taking the test blew their noses, although one caregiver blew their nose and didn't ask the dependent to blow their nose.		
Page 7	6	Wash and dry your hands again (or use sanitiser if this is available).	Most participants washed their hands with sanitiser and a few washed with soap and water. On one occasion a caregiver thought that the person being tested needed to clean their hands and not them.	Make it clear that washing hands must be undertaken by the person performing the test	Wording added - If you are performing this test on another person, both people should rewash or sanitise their hands Step 10 page 9
Page 7	7	Open the swab package and gently take out the swab.	Participants had difficulty opening the pack to take out the swab. This was due to the pack design making it difficult to separate the ends to peel apart. This action was difficult for two reasons:		
			1 The illustration shows the top of the pack being ripped away. Several participants noted this and thought that this was the intended action	Change illustration to show a peeling action	Illustration changed to show peeling action. Step 12 page 9.
			2 The word peel here is on the back of the pack, which participants fail to see	Make peel here and arrow stand out more on pack	
Take your swab sample					
Page 8		Take your swab sample	Participants were missing the instruction that if the swab touches tongue, cheek or teeth that the test is invalid	Make more prominent and reposition away from the introductory text	Instruction repositioned and highlighted Page 10
Page 8	8	Holding the swab between your fingers, open your mouth wide and rub the fabric tip of the swab over both tonsils (or where they would have been). Do this with firm contact 4 times on each side (use a mirror to help you do this). Carefully remove the swab from the back of your throat	Participants found this challenging for a number of reasons:		
			1 Locating the tonsil	Emphasise the need for a mirror when self testing	Highlighted on Page 6
			2 Swabbing both tonsils the required number of times	Reposition illustration x4 bubble	Repositioned Step 13 Page 10
Page 8	9	Put the same swab gently into one nostril until you feel a slight resistance (about 2.5cm up your nose). Roll the swab firmly around the inside of the nostril, making 10 complete circles.	Participants twizzled the swab in their fingers keeping the swab at the same place in the nostril. In addition participants in general did not make 10 complete rotating actions	Encourage participants to rotate the swab around the whole of the nostril and for the required number of rotations	The instruction to roll swab for 10 rotations has been made more prominent and x10 bubble repositioned Step 14 page 10.
Testing a child or dependent					
Page 9	8	Ask the child to open their mouth wide, then rub the fabric tip of the swab over both tonsils (or where they would have been). Do this with firm contact 4 times on each side. Carefully remove the swab. If you cannot swab the tonsils, you can swab both nostrils.	Participants found this challenging to perform on their child due to the child being reluctant to comply	Highlight that if the tonsils cannot be swabbed to swab the tonsils	Highlighted note before throat swab instruction that both nostrils can be used instead. Step 13 page 11
		Avoiding touching the tongue	Keeping the tongue away from the swabbing area proved difficult	Participant who performed this step on others suggested that a tongue depressor could be useful to keep the tongue flat while swabbing	Evaluate in a further usability study whether a tongue depressor improve swabbing technique

Page 9	9	Put the fabric tip of the same swab gently into one of their nostrils until you feel some resistance. Roll the swab firmly around the inside of the nostril, making 10 complete circles and slowly remove it. If you could not swab their throat repeat in their other nostril.	Participants twizzled the swab in their fingers keeping the swab in the same place in the nostril. In addition participants in general did not make 10 complete rotating actions	Encourage participants to rotate the swab around the whole nostril. Stress the need to rotate the swab for 10 complete circles	The instruction to roll swab for 10 rotations has been made more prominent on the page and x10 bubble repositioned Step 14 page 11.
Process the sample					
Page 10	10	Remove the extraction tube from the cup and place the fabric tip of the swab into the extraction tube so it is in the fluid. Press the tip against the edge of the extraction tube with force, while rotating it around the tube for 15 seconds.	Participants missed the importance of the rotating the swab for 15 seconds	Emphasise the need to rotate for 15 seconds	Highlighted text and repositioning x15 bubble. Step 15 Page 12
Page 10	11	Pinch the tube as you remove the swab to make sure that all the fluid is removed from the soft tip of the swab. Place the swab in the plastic waste bag provided.	Participants were confused how to extract the fluid from the swab using the tube.	Illustrate to show pinching of tube over the swab. Reword to make instruction clearer	Illustration updated and instruction reworded Step 16 page 12
Page 10	12	Press the nozzle cap lightly on to the extraction tube to avoid any leaks			
Page 10	13	Gently squeeze the extraction tube to place 2 drops of liquid onto the specimen well on the test strip.	Participants performed this step although the location of sample well on the test strip and number of drops to dispense could be made clearer as some errors occurred	Reposition magnified image of drops entering the sample well to emphasise the position of the well. Make 2 drops bubble more prominent	Illustration layout changed and 2 drop bubble repositioned Step 18 Page 12
Page 11	14	Place the test strip on a flat and level surface Check the time or set a timer if you have one. Wait 30 minutes to read your result.			