

COVID-19

Sample Collection Kit

Instructions for Use

Please read all instructions carefully before collecting your sample

Intended Use: The COVID-19 Sample Collection Kit is intended to be used for the collection, preservation and transport of cellular and/or other material collected via a nasal swab, for investigation by in vitro diagnostic procedures. This is a single-use device.

The test is suitable for the following people:

- Adults aged 18 and over: self-test (unless unable to do so)
- Teenagers aged 12 to 17: self-test with adult supervision
- Children 11 and under: adult to test, following the instructions in this document

1. Activate your Test

Activate your test online at www.myhealthchecked.com/activate-kit before sample collection. Your sample should be collected on the same day as you post it.

Note: if you are helping someone else to collect a swab for testing, please ensure the details completed are for the person whose sample is being returned to the Laboratory.

2. Check the contents

Check that your sample collection kit contains the following:

 	 1x sterile CE marked flocked swab	 1x essential checklist card	Do not proceed with the sample collection if any of the components listed are damaged or missing. Refer to section 8 for instructions on how to check the PrimeStore® MTM tube for damage.
 1x UN3373 posting bag	 1x pre-paid return postage label	 1x Instructions for Use	

3. Complete your details

Complete your name and date of birth on the biohazard ShuttlePouch™ and tube of PrimeStore® MTM inactivation media. By recording these details, we will be able to locate your sample using a 2-factor authentication in case of any queries.

Note: Please ensure the details provided match the details registered online (as defined in step 1).

4. Be ready to post your sample straight away

Ensure you post the sample back to the laboratory on the same day as sample collection. To find your nearest Priority Postbox and collection times, visit www.royalmail.com/services-near-you. If you are using an alternative courier service, please check their instructions for sample delivery/collection.

5. Read the Instructions for Use

Ensure you have read and understood the Instructions for Use before collecting your sample.



6. Wash your hands

Wash your hands with soap and warm water for 20 seconds. If you do not have access to soap and water, please use hand sanitiser and apply thoroughly.



7. Clear your nostrils

Check your nose and gently remove any visible mucus with a tissue.



8. Inspect and remove the PrimeStore® MTM tube from the ShuttlePouch™

Hold the ShuttlePouch™ so that you have a clear view of the PrimeStore® MTM tube inside, visually check the white pad behind the tube for any signs of leakage such as discolouration or crystallisation. If there are signs of leakage do not remove the tube from the ShuttlePouch™, seal the ShuttlePouch™ and do not proceed with the sample collection. Place the ShuttlePouch™ back inside the box, and dispose in your household waste.

Please contact care@myhealthchecked.com immediately and advise them of the barcode number on the damaged tube.

If there are no signs of leakage, remove the tube of PrimeStore® MTM, place on a clean surface and proceed to section 9.



9. Open the swab package

Carefully remove the flocked swab from the packaging ensuring the tip of the swab does not touch any external surfaces.



10. Insert swab into nostril and collect sample

Gently insert the tip of the swab into your nostril until you feel gentle resistance. Hold the shaft of the swab and rotate 5 times for approximately 10 seconds, ensuring the tip of the swab is always in contact with the nasal wall. Carefully withdraw the swab and repeat this process with the other nostril. Do not force the swab any further up into your nose whilst you are swabbing.



11. Un-cap the tube of PrimeStore® MTM

Immediately uncap the tube of PrimeStore® MTM taking care not to spill the contents or touch any external surfaces with the tip of the swab. In the case of a spillage refer to the 'Warning' section for guidance.



12. Insert the sample swab into the tube of PrimeStore® MTM

Insert the swab into the PrimeStore® MTM tube ensuring the tip of the swab is submerged into the solution, then snap the shaft of the swab at the breakpoint.



13. Re-cap the tube of PrimeStore® MTM

Re-cap the tube of PrimeStore® MTM and gently invert the tube for 3-5 seconds.



14. Wash your hands

Wash your hands with soap and warm water for 20 seconds. If you do not have access to soap and water, please use hand sanitiser and apply thoroughly.



15. Seal the tube of PrimeStore® MTM in the ShuttlePouch™ and place into the box

Place the tube of PrimeStore® MTM back into the ShuttlePouch™ following the instructions shown on the front of the pouch. Place the sealed ShuttlePouch™ back inside the box and close the box.



16. Label the posting envelope and seal the box inside

Adhere the pre-paid postage label to the UN3373 posting bag, place the closed box inside and seal the bag. If you are using an alternative courier service, please follow their instructions for labelling the envelope.



17. Post your sample for testing

Return your pre-paid UN3373 posting bag to your nearest Royal Mail Priority Postbox on the same day as taking your sample (find your nearest Priority Postbox and collection times by visiting: www.royalmail.com/services-near-you). Please ensure you write down the tracking number on your pre-paid envelope to track online at www.royalmail.com. If you are using an alternative courier service, please follow their instructions for sample delivery/collection.

Please note that your sample will not be viable unless it is received at the laboratory within 7 days of sample collection.

For more information visit www.myhealthchecked.com

Warning:

Do not use the sample collection kit if any components listed in section 2 are missing or damaged, contact us at: care@myhealthchecked.com

- Do not allow the PrimeStore® MTM media to come into contact with skin, eyes or any external surface.
- Do not ingest PrimeStore® MTM.
- If PrimeStore® MTM comes into contact with skin, wash the affected area with soap and water for several minutes, seek medical attention if required.
- If PrimeStore® MTM comes into contact with eyes, rinse the eye thoroughly with running water whilst protecting the unaffected eye for at least 15 minutes – Seek immediate ophthalmic treatment.
- If PrimeStore® MTM is ingested, do not induce vomiting, never give anything by mouth to an unconscious person, rinse out mouth and give plenty of water to drink – seek immediate medical attention.
- If you experience any symptoms after coming into contact with PrimeStore® MTM, seek immediate medical attention.



T100005 V3



Stanbio Laboratory, An EKF Diagnostics Company
1261 North Main St, Boerne, TX USA 78006

+44 (0)29 20710570

info@ekfdiagnostics.com

www.ekfdiagnostics.com



EKF-diagnostic GmbH, Ebendorfer Chaussee 3, 39179 Barleben, Germany

+49 39293 511 0

support@ekf-diagnostic.de

www.ekfdiagnostics.com

Distributed by:

Concepta Diagnostics, The Maltings, East Tyndall Street, Cardiff, CF24 5EA, UK.

+44 (0)29 2035 1454

care@myhealthchecked.com

www.myhealthchecked.com