

Saliva Sample Collection Pack

INSTRUCTIONS FOR USE

A collection of non-sterile devices and materials for the collection and mailing of human saliva samples for *in vitro* diagnostic testing.

Store at 15-25°C. DO NOT FREEZE.

For *in vitro* diagnostic use only.



INTENDED USE

This sample collection pack is intended to be used for the collection and mailing of human saliva samples and to be used with saliva immunoassays.

The pack can be used by lay persons. Product is not intended for infants. Paediatric patients (up to and including age 16) shall have their samples collected by a healthcare practitioner or adult.

INDICATIONS FOR USE

Do not use this sample collection pack if you are taking steroids, steroid asthma inhalers, steroid containing creams, are undergoing cancer therapy or taking supplements containing DHEA, pregnenolone or progesterone.

Children who have not yet reached puberty will not get a DHEA result as low levels are normal at this key stage. Cortisol levels are not affected.

PACK STORAGE

Before use, store pack at 15-25°C. Do not freeze.

Keep dry and away from direct sunlight.

⚠️ KEEP OUT OF REACH OF CHILDREN.

Once you open any of the components, use them immediately.

SAMPLE TYPE

Saliva

1.5mL (millilitres) sample volume

No other sample types may be used as these have not been validated.

The saliva must be collected into the supplied saliva collection tubes. The saliva samples should be stored in the fridge at 2-8°C and posted the next day.

WARNINGS

Read the instructions carefully before performing the sample collection. Failure to follow the instructions may lead to inaccurate test results.

Use of any other components except those supplied with the pack will invalidate the results.

The components are intended for single use only.

Do not use the pack beyond the expiry date.

Do not use if any pack components are damaged.

Do not use if the product has been exposed to excessive heat or humidity.

Do not use any other specimen type than the saliva sample.

Clean up spills immediately and thoroughly using an appropriate disinfectant.

⚠️ KEEP OUT OF REACH OF CHILDREN.

CONTENTS OF THE SAMPLE COLLECTION PACK

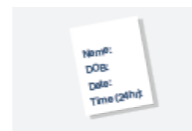
Before proceeding, check that all the contents required to perform the saliva collection are present in the pack. Materials provided (inside plastic clam-pack):



Plastic clam-pack container



5 saliva collection tubes



5 sample ID labels (numbered S1 to S5)



1 sample information form



1 instructions for use



1 self-seal plastic pre-paid return envelope



1 self-seal plastic pouch, containing absorbent pad (do not remove)



1 sample collection timing & labelling insert

Also provided:

If any items are missing or you require additional support, please contact the provider of the sample collection pack.

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SYMBOL LEGEND

The following symbols have been used within the labelling of this product.



This product fulfils the applicable requirements of Medical Device Regulations 2002 (SI 2002 No. 618, as amended) (UK MDR 2002) for UKCA Marking.



This product fulfils the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices.



Batch code



Catalogue number



Caution



Consult instructions for use



Contains sufficient for "n" tests



Do not re-use



In vitro diagnostics medical device



Keep dry



Manufacturer



Keep away from sunlight



Temperature limit

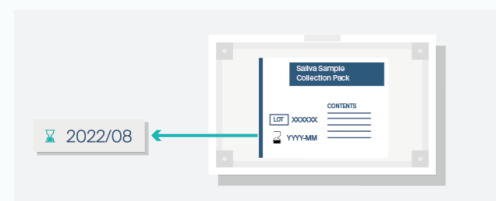


Use-by date

⚠️ Do not dispose. Sample to be shipped back using the container

SAMPLE COLLECTION

IMPORTANT INFORMATION - PLEASE READ BEFORE STARTING



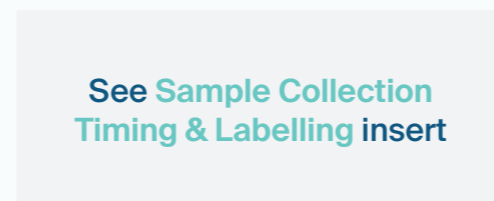
1. Check expiry date on front of pack to ensure pack is valid.



2. Avoid brushing your teeth, eating, drinking, chewing gum, exercise or smoking 30 minutes prior to each sample collection.

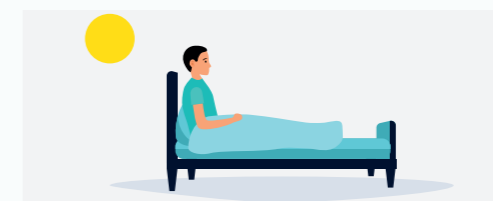


3. Remove contents from pack. Read procedure carefully and check all contents are present.



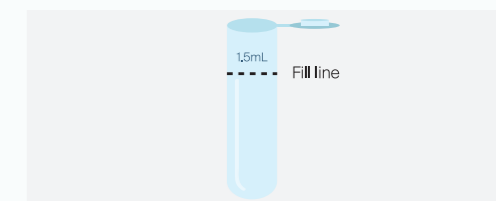
4. It is essential saliva collection should be taken at the right time.

⚠ This step is really important.



5. The first sample must be collected on waking.

⚠ This step is really important.



6. You will need to provide enough saliva (without foam) to fill saliva tube to the line 1.5mL (3/4 full). Once started, sample must be taken immediately.

Preparing for the sample collection

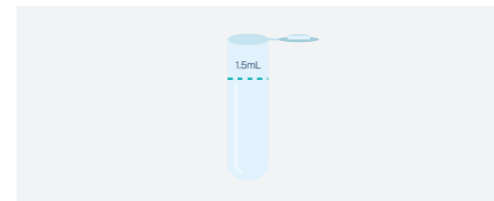
⚠ Failure to provide the information requested, or unclear handwriting, means the sample will be rejected and testing delayed.



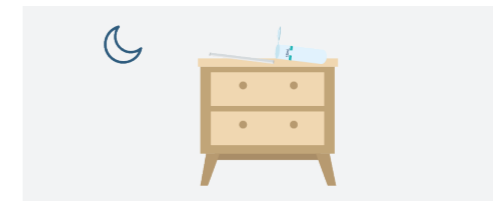
7. Fill in your personal information on all the labels with a biro or waterproof pen, leaving the date and collection time blank.



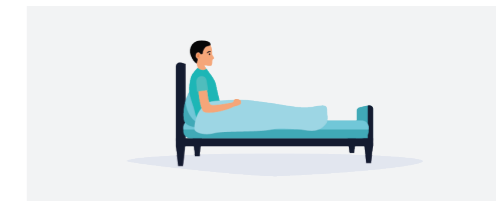
8. Fill out all requested details on sample information form using CAPITAL LETTERS.



9. Before each sample collection, remove one saliva collection tube from the grip-seal plastic bag and keep the remainder in the clam-pack for safekeeping.



10. Before you go to bed, put one saliva collection tube by your bed, ready for the first collection on waking.

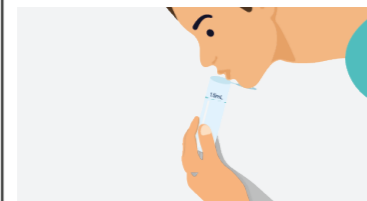


11. To collect your sample relax by sitting quietly for a few minutes, move your tongue around your mouth and let the saliva accumulate.

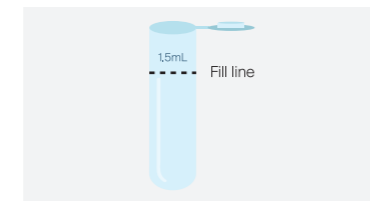
Sample collection



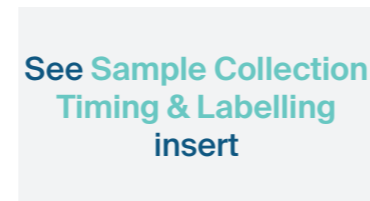
12. Take the first sample (S1) as soon as you wake up, while still in bed. Then follow steps 13 to 19.



13. Let the collected saliva drool/drip into the collection tube. DO NOT spit.



14. Fill the collection tube to the line 1.5 mL (3/4 full), excluding any foam from the measurement. **Firmly close the lid.**



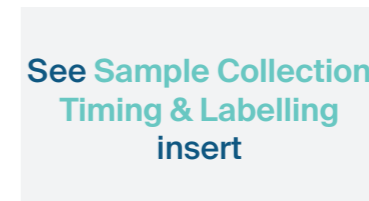
15. Use the correct label for each sample, for example, for sample one use label S1 and sample two use label S2, and so on.



16. Write the date and time of collection on the label. **Use the 24-hour clock.**



17. Once the label is filled in, apply to saliva collection tube, lengthways, as shown in the image.



18. Ensure the correct label is applied to the saliva collection tube.

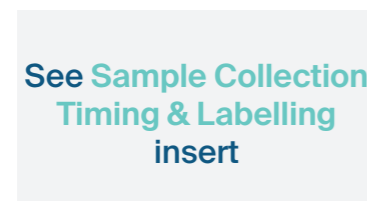


19. Store in the fridge inside the grip-seal plastic bag until all remaining samples have been collected and are ready to post.

Step 13 to 19 will need to be repeated throughout the day



20. Repeat steps 13 to 19 using a fresh saliva collection tube for all remaining samples.



21. For the four remaining samples collect within the above timeframe.



22. Double check all lids of the saliva collection tubes are firmly closed.

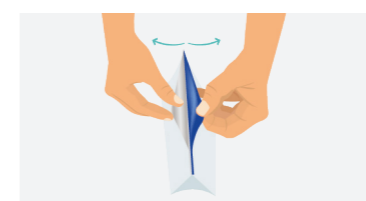


23. Place the grip-seal plastic bag containing the five saliva collection tubes within the self-seal plastic pouch.



24. **Do not remove absorbent pad from self-seal plastic pouch.**

⚠ This step is really important.



25. **Seal the pouch by removing the metallic silver strip and press the blue adhesive strips and the pouch tightly together.**



26. Ensure the self-seal plastic pouch is tightly sealed.

Sending the sample to the lab



27. Place following items into clam-pack:
 ● self-sealed plastic pouch containing five saliva collection tubes
 ● completed sample information form



28. Securely close clam-pack and pack into the pre-paid return envelope.



29. Please return your sample as soon as possible and not more than 48 hours after collection. Store in fridge until posted.

If you find it hard to obtain a saliva sample, please contact the provider of the sample collection pack.

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IMPORTANT CHECKLIST

- Have you filled in your sample information form?
- Have you completed labels for all saliva collection tubes?
- Have you collected all your samples at the specified time?
- Have you put all 5 saliva collection tubes into the self-sealed plastic pouch?
- Have you put the self-sealed plastic pouch with completed sample information form inside clam-pack?
- Have you put the clam-pack inside the pre-paid envelope?

You're now ready to post