

HPV COLLECTION KIT


A vaginal swab sample collection kit used for the collection and transportation of samples for laboratory analysis of Human Papilloma Virus (HPV) by nucleic acid technique (NAT)


This kit contains the materials required for either sample self-collection or collection by a health/social care professional.


IVD For *in vitro* diagnostic use, sample self-collection

REF KT364



 Carefully read the enclosed instruction leaflet before use

 Important: Do not use kit if security seal is broken. Keep out of reach of children

 Do not re-use

 For use by persons aged 18 and over

Sample collection instructions (Steps 1–12)

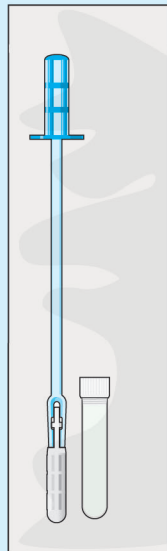
- Please ensure the kit is within expiry date and read these instructions carefully and completely before attempting to collect the sample.
- If your kit requires online activation, please follow the instructions provided by your healthcare organisation. If you need assistance please contact the healthcare organisation who arranged the test.
- The white tip of the wand must be in place and not be bent or removed before self-sampling.
- Ensure the wand is held straight when inserting it in and taking it out of your vagina. You can take your test in a standing or lying position.
- Do not collect a sample during menstruation (your period). Sampling can be carried out during the first three months of pregnancy.

Your sample collection kit contents

Please check that the kit contains all of the items outlined below. Do not proceed with sample taking if any items are missing or damaged, contact the healthcare organisation who arranged your test for assistance.

First name: _____
Surname: _____
DOB: _____
Sample type: _____
TAP488820-10-CLV7

Security Seal
To Open Box - Tear Seal & Lift Flap
McKwest.com



Qvintip® self-sampling wand and sample tube ©



Collection kit outer box




Return postal envelope



Protective packing case

SELF-COLLECTION HPV SAMPLE

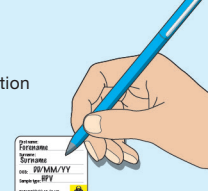
1 If not already pre-populated please complete the test request form, provided by your doctor/clinic, separate to this kit. **Make sure the sample date is completed.**



2 Clearly complete the sample collection tube label using a ball point pen with:

- Your First name
- Your Surname
- Your Date of birth
- Sample type: HPV

Do not affix it to the tube at this stage.



3

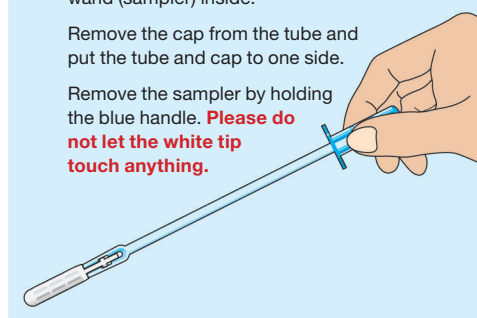


Wash your hands in warm soapy water.

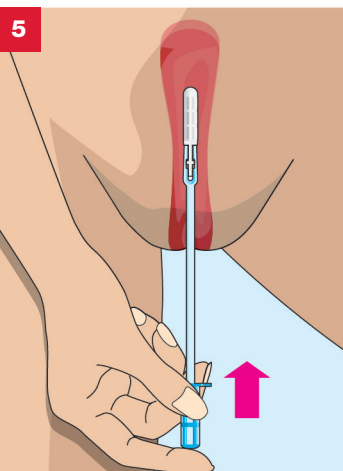
4 Open the package where indicated and remove the tube, leaving the self-sampling wand (sampler) inside.

Remove the cap from the tube and put the tube and cap to one side.

Remove the sampler by holding the blue handle. **Please do not let the white tip touch anything.**

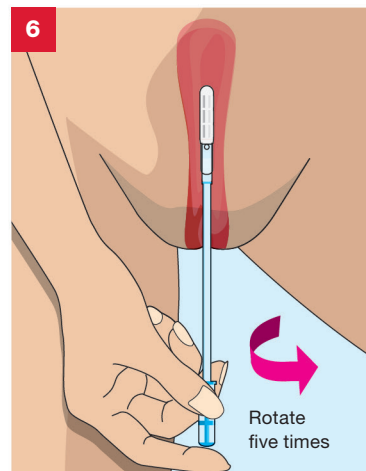


5



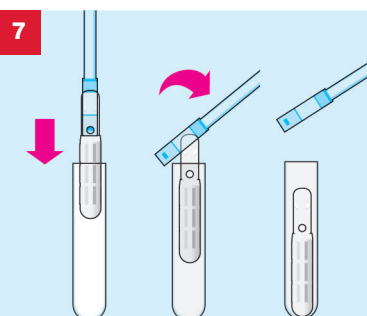
Keep the wand straight while collecting your sample. Insert the wand into your vagina as shown.

6



Rotate the self-sampling wand five times. Take the wand out (keeping it straight).

7

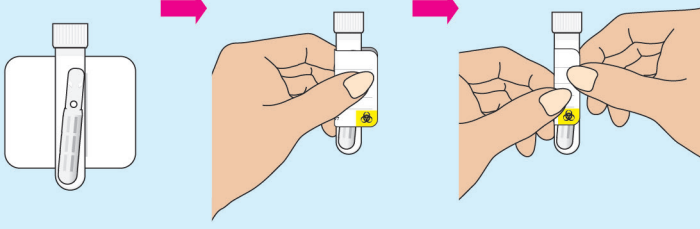


Place the white tip portion of the sampler into the tube, stop when the blue part is in line with the rim.

Bend the sampler until the blue part touches the rim of the tube. Slowly pull the blue handle away from the tube so that the white tip breaks off and falls into the tube.

Screw the lid back onto the sample tube and dispose of the blue portion of the wand.

8 Affix the label by placing the sample tube in the middle of the label and wrapping the label around the shaft as shown below.



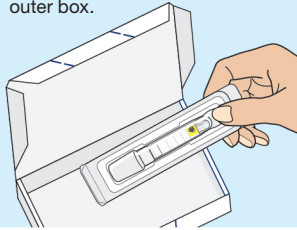
9

Place the labelled sample tube into the protective packing case.



10

Place the protective packing case into the collection kit outer box.



11

Please make a note of the unique tracking number displayed under the barcode on the postal tracking label, as shown below. Keep this in a safe place for future reference. **You can track delivery of your Royal Mail parcel by entering this number using the following link: <http://www.royalmail.com/track-your-item>**



Write your tracking number here for reference – keep this safe.

12 IMPORTANT CHECKLIST

Before you return your sample please do the following:

- Place your completed request form supplied by your doctor/clinic into the postal envelope
- Make sure that the sample tube is labelled and has been placed inside the protective packing case
- Place the packing case into the collection kit outer box
- Close the collection kit outer box firmly and apply the return security label to seal it
- Place the collection kit outer box into the return postal envelope
- Check that you have taken note of your postal tracking number

You are now ready to seal the postal envelope. Please store at room temperature until posted.

Please post your sample to **The Doctors Laboratory** as soon as possible (ideally on same day or within 24 hours of sample collection) from **ANY** Royal Mail post box in the UK. No stamp is required within the UK.

If you need assistance please contact The Doctors Laboratory on 020 7307 7373 or email samples@tdlpathology.com.



We would welcome feedback on your experience of using this self-collection kit to help us improve our services. To complete a short online survey please scan the code or visit:

<https://forms.office.com/r/nriHyUX6kj>

Warnings and precautions

- This kit is designed for use by persons aged 18 and over and upon request of a healthcare professional or healthcare organisation.
- Please consult with a healthcare professional for guidance on sample collection processes for adolescent and younger children.
- The kit should not be used by individuals lacking the physical or mental capacity to correctly follow the self-collection instructions. If you have problems or feel unwell or lightheaded during the collection process, please pause and if necessary, consult with your advising healthcare professional.
- Do not collect a sample during menstruation (your period).
- Sampling can be carried out during the first three months of pregnancy.
- It is advisable to refrain from intercourse and the use of vaginal creams, gels and tablets for 48 hours prior to sampling.
- This kit is not suitable for collecting alternative sample types or for the collection and transport of viruses or other microorganisms, other than those which have been verified by the testing laboratory.
- Samples arriving at the laboratory which show evidence of the below may not be tested:
 - No white wand end inside the collection tube
 - Different swab type/brand to the one supplied
 - General damage
- Use with caution if allergic to nylon fibre and ABS (Acrylonitrile butadiene styrene) material. If any problems arise during the sample collection process please contact your healthcare organisation.
- The accuracy of your results may be compromised if you do not read and follow the instructions in full.
- Samples arriving at the laboratory which show signs of degradation or general damage or arrive after 6 days of sample taking may not be tested.
- This collection kit is for HPV ONLY and not suitable for collecting cells for cervical cytology (microscopic) assessment.

Materials required but not provided

- **Test request form.** This will be provided by your healthcare professional or healthcare organisation. **Please complete the request form with your details as instructed.**

Laboratory Tests

- The tests and procedures undertaken by The Doctors Laboratory Limited are verified and performed in line with supplier product instructions for use and supported by additional validation data for use with self-collection procedures.
- Test results are provided in line with clinically approved results pathways, agreed between The Doctors Laboratory Limited and the patients designated healthcare professional or healthcare organisation.

KEY TO SYMBOLS

IVD	For <i>in vitro</i> diagnostic use	Use by end of year-month	UK CA	UK Conformity Assessed
REF	Catalogue number	Manufacturer	CE	EU Conformity Assessed
LOT	Batch code	EC REP		EU Authorised Representative
	Biological risk. Biological sample, treat as potentially infectious	Temperature limits: 4°–25°C		Do not re-use
	Do not use if package is damaged	Keep away from sunlight		Consult instructions for use
	Caution, consult accompanying documents			For use by persons aged 18 and over
				Keep dry



REAL Digital International Limited, 2 Queensway, Croydon, Surrey, CR0 4BD, UK
Website: www.real-digital.co.uk



Casus Europe BV, Lange Viestraat 2 B, 3511BK Utrecht, The Netherlands.



The Doctors Laboratory Limited

Distribution is restricted to regions in which the product is registered by the manufacturer.

© The Doctors Laboratory Limited, 2024. Illustrations: © Jag Matharu/Thin Air Productions
RDI-IFU-024, TAP4874C/18-01-24/V26. Issue No. 2; Date 18/01/24.

Revision/Date Change summary

1	02/2023	Initial RDI product for UK market
2	01/2024	RDI IVD product CE registration

If any serious incident occurs in relation to the use of this kit, it should be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.