THE DOCTORS LABORATORY

SEXUAL HEALTH COLLECTION KIT

A lesion sample collection kit used for the collection and transportation of samples for the laboratory analysis of lesion and vesicular rash causing viruses 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 KT405

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

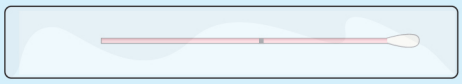
18+ For use by persons aged 18 and over

Sample collection instructions (Steps 1–14)

- **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.**

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.

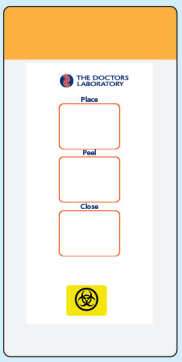


Sample collection swab, CE STERILE EO

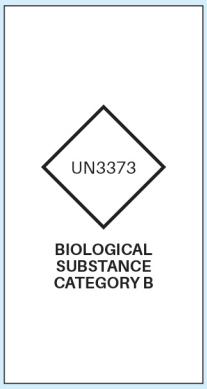
Swab specimen transport tube, IVD

Return security label

Sample label

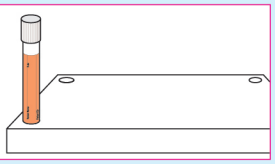


Transport pouch with absorbent pad



Return postal box

IMPORTANT!
The kit contents are supplied in a tray, please empty the tray contents and push through the holes in the base. Then turn the tray upside down and place your tube into one of the larger holes as shown when collecting your sample.



Herpes is a common viral infection caused by herpes simplex virus (HSV). The virus exists as two main types, HSV-1 and HSV-2, both are contagious and can affect the oral or genital areas. HSV testing identifies the presence of the virus in a sample taken from a blister, sore (lesion) or fluid. When first infected, there may be obvious and painful blisters at the site of infection. These usually appear within two weeks after the virus is transmitted. These lesions generally heal within two to four weeks. The blisters can appear in the vaginal area, on the penis, around the anus, or on the buttocks or thighs. Blisters are not always apparent and in mild cases they may appear similar in appearance to insect bites or a rash. Blisters may not appear from weeks to even years after being infected, but once infected the virus remains in a latent (dormant) form and may reactivate from time to time.

Importantly, other viruses may produce similar lesions on other parts of the body. Monkeypox rash usually appears 1 to 5 days after the first symptoms. The rash often begins on the face, then spreads to other parts of the body. This can include the genitals. The rash is sometimes confused with chickenpox. It starts as raised spots, which turn into small blisters filled with fluid. These blisters eventually form scabs which later fall off.

Please collect your sample from the blister or lesion site using the collection methodology described in collection points 10 and 11.

GENITAL LESION SWAB COLLECTION

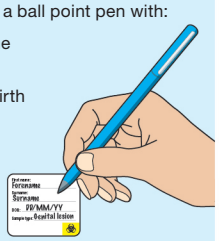
Important sample taking detail

- If there are no visible blisters or sores the swab sample should not be taken.
- Ideally samples should be collected within the first three days of the blister(s) developing.
- Once crusting and healing have begun, the quality of the sample becomes reduced.
- Do not collect a sample from multiple blister sites, please limit swab sample collection to one part of the body only. Indicate sample type on the collection tube label.

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: Genital lesion

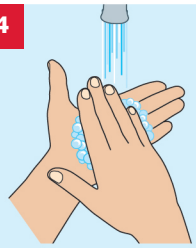


3 **IMPORTANT SAMPLE TRACKING INFORMATION!**

The return postal box has a postal tracking label applied. 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

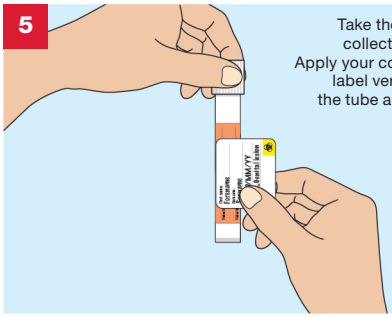
Write your tracking number here for reference – keep this safe.

4

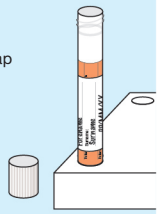


Wash hands using soap and water and dry them.

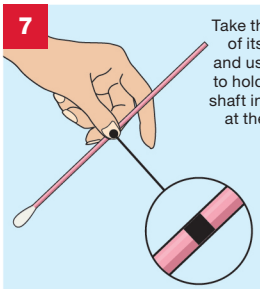
5 Take the sample collection tube. Apply your completed label vertically to the tube as shown.



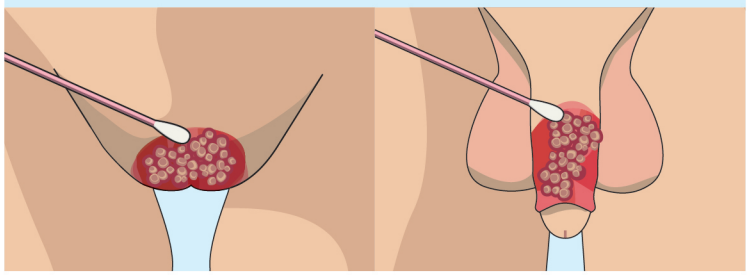
6 Place the tube upright in one of the larger holes, as shown. Remove the cap and put it foil side up, to one side, whilst you take your sample. Take care not to spill any of the liquid the tube contains. **Do not touch or pierce the foil top of the lid.**



7 Take the swab out of its packaging and use one hand to hold the plastic shaft in the middle at the black line.

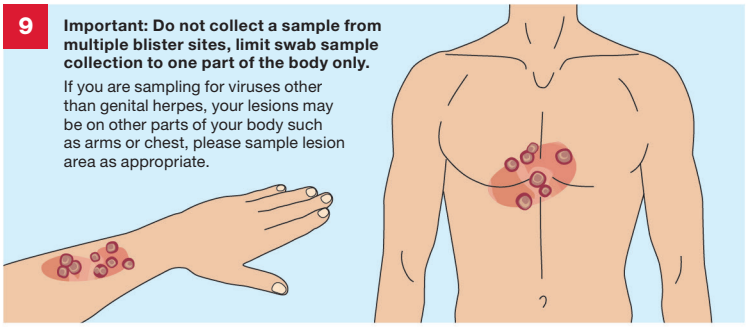


8 Using the swab tip, apply/scrape gently from a blister or sore.

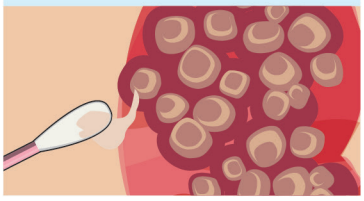


9 **Important: Do not collect a sample from multiple blister sites, limit swab sample collection to one part of the body only.**

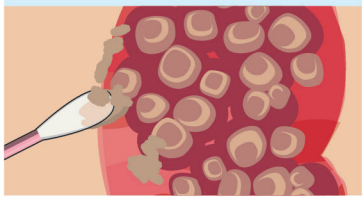
If you are sampling for viruses other than genital herpes, your lesions may be on other parts of your body such as arms or chest, please sample lesion area as appropriate.



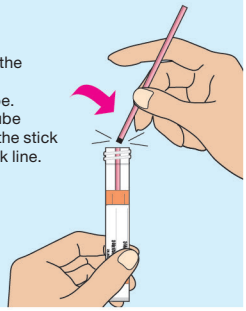
10 If possible, use the swab tip to collect fluid, if present, from the blister.



11 If there is crusting, and the scab can be lifted, use the swab tip to collect from the base of the opened lesion(s).

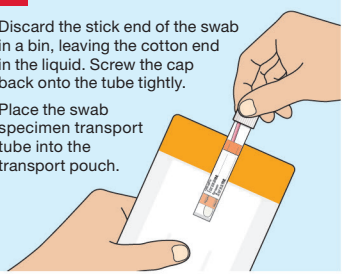


12 Carefully put the swab into the collection tube. Holding the tube steady, snap the stick off at the black line.



13 Discard the stick end of the swab in a bin, leaving the cotton end in the liquid. Screw the cap back onto the tube tightly.

Place the swab specimen transport tube into the transport pouch.



14 IMPORTANT CHECKLIST

Before you return your sample please do the following:

- ☐ **Place your completed request form supplied by your doctor/clinic into the kit tray**
- ☐ **Make sure the swab specimen tube is labelled**
- ☐ **Make sure that swab specimen tube is in the transport pouch and this is firmly sealed**
- ☐ **Place the transport pouch into the kit tray**
- ☐ **Slide the kit tray back into the return postal box**
- ☐ **Close the return postal box and apply the return security label to seal the end of the box**
- ☐ **Check that you have taken note of your postal tracking number**

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/aPmyrFPDZF

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

EC REP 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, 2025. Illustrations: © Jag Matharu/Thin Air Productions

RDI-IFU-068, TAP5027E/13-03-25/V22. Issue No. 3; Date 13/03/25.

Revision/Date		Change summary
1	02/2023	Initial RDi product for UK market
2	02/2024	RDi IVD product CE registration
3	03/2025	Componentry change: secondary and outer packaging.

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.

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.
- The Hologic transport buffer contains no substances which at their given concentration, are considered to be hazardous to health. In the case of contact with eyes, skin or mouth please and rinse thoroughly with clean water, if ingested please drink plenty of water and if any symptoms occur please consult a medical professional. In the case of spillages please wipe with absorbent paper and dispose in normal household waste. For further information please refer to safety datasheets which can be found at www.hologic.com or contact MolecularSupport@hologic.com.
- Samples arriving at the laboratory which show evidence of the below may not be tested:
  - Leaking sample/no liquid present in collection tube
  - No swab inside the collection tube
  - Two or more swabs inside the collection tube
  - Swab placed upside down in the collection tube
  - More than 1 collection tube per return box
  - Different swab type/brand to the one supplied
  - General damage
- The sample collection swab has a score line, which after sampling helps the swab break at the correct position when pressure is applied to allow it to fit in the collection tube. If this score line is broken, appears damaged or the swab arrives in two broken parts, do not use and request another kit from your healthcare organisation.
- 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 30 days (Aptima swab) of sample taking may not be tested.

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