THE DOCTORS LABORATORY

Cervical Screening

The Cytology Laboratory provides a rapid service for liquid based cervical samples. Urine cytology is performed in house while other non-gynaecological cytology samples are referred to a UKAS accredited laboratory for reporting.

Human papilloma virus (HPV), Chlamydia and Gonorrhoea testing is carried out routinely from ThinPrep vials and can be requested at the time the cervical sample is taken.

Laboratory hours

The laboratory department is open between 9.00am and 6.00pm.
Out of hours results available on 020 7307 7373.

Urgent samples

It is helpful if requests for urgent samples can be discussed with the Cytology Manager. Please telephone 020 7307 7323.

Use of service/Information required

Request forms must include **3 identifiers** (this can be patient's full name = 2, date of birth, hospital number or reference number) and need to accompany each sample.

Appropriate clinical information providing previous treatment/histological diagnosis is essential to ensure correct management recommendations can be given in the patient report. Tick boxes are provided to assist you.

The specimen container must be clearly labelled with patient details. Forms and samples which are mismatched will result in the sample being returned to the sender for correction and will delay the report turn around time.

Clinical advice

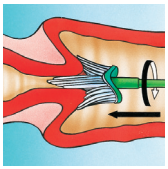
The Consultant Cytopathologists and the Advanced Practitioner work together to provide clinical and technical advice, including recommendations for follow-up, HPV testing and management of complex cases. To contact the department directly, please telephone 020 7307 7323.

Cervical Screening

RECORD…

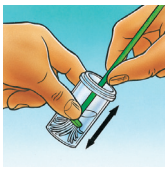
…the patient's 3 identifiers to include date of birth on the vial.

…the patient information and medical history on the cytology requisition form.



OBTAIN…

…an adequate sample from the cervix using a Cervex Brush (broom-like device). Insert the central bristles of the brush into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently and rotate the brush in a clockwise direction five times.



RINSE…

…the Cervex Brush immediately into the PreservCyt Solution vial by pushing it into the bottom of the vial 10 times, forcing the bristles apart. As a final step, swirl the brush vigorously to further release material. Visually inspect the Cervex Brush to ensure that no material remains attached. Discard the brush.

Do not leave the head of the Cervex Brush in the vial. Check the vial is in date before use.

TIGHTEN…

…the cap so that the black torque line on the cap passes the black torque line on the vial. Do not over-tighten.

PLACE…

…the vial and request form in a specimen bag for transportation to TDL.

Cervical Screening

ThinPrep® PAP Test Cervex Brush Protocol

PREPARE ALL EQUIPMENT BEFORE STARTING THE PROCEDURE

- Note expiry date on sample collection vial. Do not use expired vials.
- Ensure the entire plastic seal is removed from the lid of the vial and discarded.
- Complete patient details on both the request form and the vial. Specimens may be returned or discarded if details are missing from the vial.
- Remove the lid from the vial before taking the sample.
- **Use of lubricant is NOT recommended**.

DO

- If excessive mucus is present, this should be gently removed before sampling.
- Use either the Cervex Brush (broom-like device) on its own or a Plastic spatula and endocervical brush combination.
- The Cervex Brush should be rotated 5 times in a clockwise direction. The Plastic spatula should be rotated through 360 degrees and the endocervical brush rotated through one quarter to one half turn.
- Immediately rinse the collected material into the vial.
- Replace the lid and tighten so that the black torque line on the cap passes the black torque line on the vial to avoid leakage.
- Keep the unlabelled portion of the sample vial free of labels so that the contents can be seen.
- If barcoded labels are used these must be applied horizontally around the vial.
- Samples should be sent to the laboratory without delay.

DON'T

- DO NOT leave the head of the Cervex Brush in the vial.
- DO NOT routinely clean the cervix or take a cervical swab before taking a cervical sample.
- An endocervical brush should never be used in isolation.
- DO NOT under any circumstances use a wooden spatula.
- DO NOT leave the collection device sitting in the vial whilst dealing with the patient.
- DO NOT over-tighten the lid on the vial.
- DO NOT place multiple labels on the outside of the vial.
- DO NOT apply barcoded labels vertically on the vial.
- DO NOT use expired vials.
- DO NOT delay the sending of vials to the laboratory. The sample needs to be processed within 3 weeks of collection.
- DO NOT use excessive lubricant – please AVOID if possible.

Cervical Screening

Gynaecological Samples

The Cytology department processes cervical samples directly referred from all sectors of practice – Health Screening, Occupational Health, GP's, Consultants, Colposcopy Units, Clinics, Hospitals and other Laboratories.

Liquid Based Cytology (LBC) is processed using the Hologic ThinPrep system.
The Doctors Laboratory uses the Hologic Imaging system as an enhanced Quality Control.

Information for Sample Takers is available by contacting the department. **Important: the head of the cervical broom must NOT be left in the vial**. The use of lubricant interferes with LBC sampling and may result in an inadequate sample. Use of lubricant is NOT recommended as it can affect the processing quality of the sample. Supplies of Thin prep vials are available from TDL.

STI Screening from Hologic Thin Prep Vial (HPV – see page 6)

Tests are priced individually. Please request tests individually. Thin Prep Vials are kept for 21 days after receipt of sample. Requests for additional tests from the vial already received in the laboratory can be made by contacting the Cytology Department.

Infection by PCR (singles)

TEST	CODE	SAMPLE REQS	TAT
Chlamydia trachomatis	TPCR	**TPV**	2 days
N. gonorrhoea	TGON	**TPV**	2 days
Chlamydia/Gonorrhoea	TCG	**TPV**	5 days
Mycoplasma genitalium	MGEN	**TPV**	2 days
Ureaplasma urealyticum	UGEN	**TPV**	2 days
Trichomonas vaginalis	TVPC	**TPV**	2 days
Gardnerella vaginalis	GVPC	**TPV**	2 days
Herpes Simplex I/II	HERD	**TPV**	5 days

7 STI PROFILE BY PCR FROM THIN PREP VIAL

Chlamydia trachomatis
N. gonorrhoea
Mycoplasma genitalium
Macrolide Resistance Test (M.gen)*
Ureaplasma
Trichomonas vaginalis
Gardnerella vaginalis
Herpes Simplex I/II

All tests can be requested individually
**included if POSITIVE M.gen is detected from the same sample.*

TAT 2 DAYS

PP12

TPV

Cervical Screening

Human papillomavirus (HPV) is a common virus transmitted through sexual contact. High Risk sub-types of HPV (HR-HPV) are linked to the development of abnormal cells and can cause cervical cancer. HPV is a necessary cause of invasive cervical cancer. Evidence shows HPV testing is a more effective way to identify women at risk of cervical cancer than by testing microscopically for abnormal cells from a PAP smear.

HR-HPV testing has been used in the UK since 2011 to identify women with low grade cytology abnormalities and as a follow up test of cure in women who have received treatment. In 2017 the UK NHSCSP recommended that **testing for HPV should replace cytology as the first (primary test) in cervical screening**. Primary HR-HPV testing has higher sensitivity for high grade CIN than primary cytology. HR-HPV testing also has a lower false negative rate than cytology. Primary HR-HPV testing was fully implemented in the UK during 2020. Sample taking remains unchanged: HR-HPV testing is carried out from Thin Prep samples. Cytology will be undertaken as a triage if HPV is DETECTED.

WHAT DOES THIS CHANGE MEAN?

It means that HPV testing is the **FIRST LINE TEST**. It will be carried out as a single test, with a single result reported as DETECTED/NOT DETECTED.

- If HR-HPV is NEGATIVE (NOT DETECTED) – this means no further testing is needed for your patient: she returns to Routine Recall
- If HR-HPV is POSITIVE (DETECTED) – this means that **CYTOLOGY** will be processed from the same Thin Prep Vial. **A further specimen is not required**.
- **If the CYTOLOGY result from this sample is HR-HPV NOT DETECTED** – the patient Recall will be determined by the screening history and will either be a repeat HR-HPV test in 12 months' time or, if HR-HPV remains persistent, a referral to colposcopy will be recommended.
- **If the CYTOLOGY result from this sample is ABNORMAL** the recommendation is to refer this patient for COLPOSCOPY.

https://www.gov.uk/government/publications/cervical-screening-primary-hpv-screening-implementation/cervical-screening-implementation-guide-for-primary-hpv-screening

Since 1st January 2019 all TDL requests for HPV have been processed as follows:

- **If HPV is requested as a single test, and the result is NEGATIVE/NOT DETECTED, cervical cytology (PAPT) will only be processed if specifically requested. The PAPT would be charged as an additional test.**
- **If HPV result is DETECTED, cervical cytology (PAPT) will be processed, even if not requested. The PAPT cervical sample will NOT be charged additionally.**
- **If cervical cytology (PAPT) is requested, HPV will always be processed with the PAPT. The PAPT will be charged.**

Cervical Screening

UNDERSTANDING THE SIGNIFICANCE OF HPV TESTING

The benefit of a negative HPV result is its negative predictive value – meaning that a negative HPV result indicates that a patient is at very low risk of developing cervical disease. The negative predictive value of both DNA and mRNA testing is the same. DNA tests detect presence of virus only. A mRNA test detects the presence of viral oncogenic expression.

Requests for Cervical Cytology (PAPT) only will no longer be processed without HPV. HPV testing will be charged.

Requests for PAPT

TEST	CODE	SAMPLE REQS	TAT
Cervical Cytology	PAPT will include HPVH	**TPV**	2-3 days

If PAPT is requested as a single test, HR-HPV will be undertaken additionally, and a combined report will be issued. **PAPT and HPVH will be charged**.

Requests for PAPT with selected HPV (HPVH or HP20 or HPVT)

TEST	CODE	SAMPLE REQS	TAT
PAPT and HPVH	PAPT + HPVH	**TPV**	2-3 days

If PAPT and HPVH are requested together, results will be given as a combined report, **PAPT and selected HPVH test will be charged**.

Requests for HPV as the PRIMARY TEST will reflex to PAPT if HPV is DETECTED/POSITIVE. PAPT will NOT be charged.

TEST	CODE	SAMPLE REQS	TAT
HPV mRNA (All High Risk Subtypes)	HPVH	**TPV**	2-3 days

If HPV is DETECTED/POSITIVE, cervical cytology (PAPT) will be processed **without charge**. The PAPT will be processed from the same vial.

Requests for HP20 as a single test

TEST	CODE	SAMPLE REQS	TAT
HPV Typed DNA	HP20	**TPV/PCR Swab**	2-3 days

HPV low and high risk DNA subtypes will be reported individually (5 low and 14 high risk). If HPV is DETECTED/POSITIVE, cervical cytology (PAPT) will be processed **without charge**. The PAPT will be processed from the same vial.

Requests for HPVT as a single test

TEST	CODE	SAMPLE REQS	TAT
HPV Typed DNA	HPVT	**TPV**	3 days

If one or more of DNA types 16, 18, 31, 33, 45 are DETECTED/POSITIVE, reflex testing for expression of E6/E7 oncoproteins will be undertaken and cervical cytology (PAPT) will be processed **without charge**. The PAPT will be processed from the same vial.

HPV/PAPT Combined Report

Where HPV result is reported with Cervical Cytology, a recommendation for patient management will be given, based on the combined findings.

Self-collection HPV samples

TDL Self-Collection HPV Test

Human Papillomavirus (HPV) is the primary cause of nearly all cervical cancer. In most cases, the HPV virus is harmless and causes no symptoms. Most women who acquire HPV are able to clear the infection through their own immune systems. Persistent presence of high-risk types of HPV can cause cervical lesions which over time may develop into cancer if untreated. Testing for HPV determines the presence, or absence, of HPV and will determine whether the HPV type present is high risk for CIN and cervical cancer.

The **Self Collection HPV Test** provides women with the option to self-collect a vaginal specimen that is then sent to the laboratory for testing. There is well documented high level of concordance between the HPV DNA results from self-collected and clinician-collected specimens.

The **Self-Collection HPV Test** is validated, using a CE marked sample collection device for vaginal cell collection. This sample is then sent to the laboratory for processing for 14 high risk HPV DNA subtypes. A negative result means that these high-risk subtypes HPV were not detected and the patient is at extremely low risk of developing high-grade cervical disease/CIN2+ before their next routine visit.

A positive HPV result might indicate an increased risk of developing CIN/cervical cancer, and the report from the laboratory will provide a clear recommendation for follow-up/colposcopy.

The value of HPV DNA testing in cervical cancer screening and disease detection has been proven over and over again. Self-collection of specimens for HPV testing is not intended to replace existing patient management pathways but allows for:

- Those who wish to test following a change of sexual partner
- Option for identifying individual high risk DNA subtypes
- Personal preference to self-collect vaginal samples
- An acceptable option for women who avoid having regular cervical smears
- Self-collection for HPV increases acceptability and coverage rate of cervical cancer prevention

Results will always be sent to the requesting clinician, clinic or healthcare organisation.

HPVY Self-Collected HPV DNA with reporting of high risk subtypes (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68).

HPVZ Self-Collected HPV DNA with **individual** reporting of all subtypes 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, 68.

For more information, or to order Self-Collection HPV Test Packs, please contact Annette Wilkinson on 020 7307 7373 or annette.wilkinson@tdlpathology.com

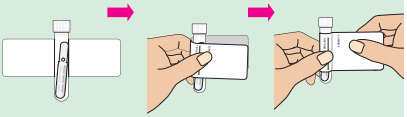
TEST	CODE	SAMPLE REQS	TAT
HPV mRNA (All High Risk Subtypes)	HPVY	**Self-collection kit**	3 days
HPV Individually Typed High Risk DNA Subtypes	HPVZ	**Self-collection kit**	10 days

Self-collection HPV samples

7

Make sure your sample is labelled with your details using the label supplied in your pack. This is very important as unlabelled samples cannot be processed.

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



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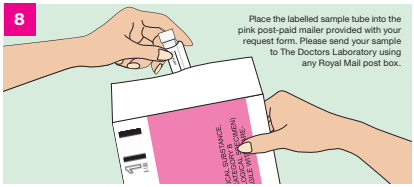


Place the labelled sample tube into the pink post-paid mailer provided with your request form. Please send your sample to The Doctors Laboratory using any Royal Mail post box.

The Doctors Laboratory
The Halo Building, 1 Mabledon Place, London WC1H 9AX
Tel: 020 7307 7373 Fax: 020 7307 7374 E-mail: tdl@tdlpathology.com
Website: www.tdlpathology.com

TAP2893/16-09-15/V4

THE DOCTORS LABORATORY

SELF-COLLECTION HPV SAMPLE

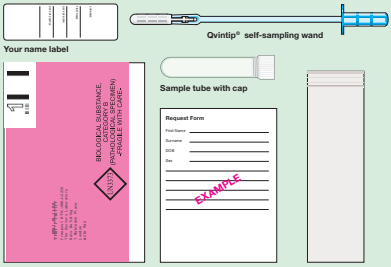
Sample Collection Instructions

Please read these instructions the whole way through before attempting to collect your sample.

Clearly complete the Name Label using a ball point pen with:

- **Your surname**
- **Your first name**
- **Your date of birth**
- **Date of sample collection**

Your sample collection pack contents



Self addressed, post paid mailer | **Request form** | **Plastic sample bag**

Self-sampling step-by-step

Before use, check that the product is intact (blue and white self-sampling wand, sample tube with cap, pink post-paid mailer). The self-sampling wand should be handled with care and only according to these instructions. Hold the wand straight when taking it in and out of your vagina. You can take your test in a standing or lying position. Don't collect a sample during your period. Sampling can be carried out during the first three months of pregnancy.

General Information

An infection with human papilloma virus (HPV) could potentially lead to cervical cancer. Your sample will be tested for prevalence of high-risk HPV. Your request will be handled confidentially. The results of the analysis will be posted to you.

Negative results

If the results are negative and the test shows no high-risk HPV, it means there is currently very little risk of cervical cancer. Please note that you might be infected at a later stage. HPV is sexually transmitted.

Positive results

If the results are positive, it means you have an infection with high risk subtypes. Please contact your gynaecologist for follow-up counselling. Women with persistent infection run an increased risk of cell changes which may lead to cervical cancer. Detecting an infection at an early stage allows for treatment.

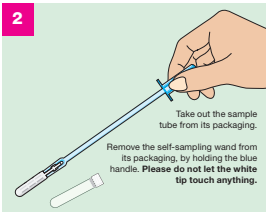
PLEASE NOTE – FOR EASY SELF SAMPLING

- Please note that the self-sampling wand is intended for **single use only**. The self-sampling wand should be handled with care and **only according to these instructions**.
- The white tip of the wand **must not be bent or removed** before self-sampling.
- To ensure correct results, the sample must **immediately be sent in by post** after taking.

1

Wash your hands in warm soapy water.

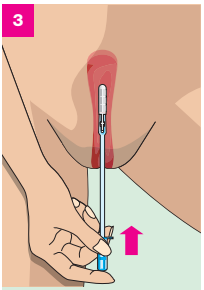
2



Take out the sample tube from its packaging.

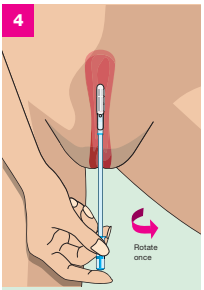
Remove the self-sampling wand from its packaging, by holding the blue handle. **Please do not let the white tip touch anything.**

3



Keep the wand straight while collecting your sample. Insert the wand into your vagina (see diagram).

4

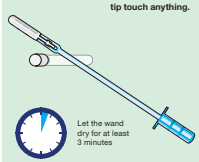


Rotate the self-sampling wand once. Take the wand out (keeping it straight).

5

Let the wand dry for at least 3 minutes, by resting in against the sample tube with the white tip in the air.

Make sure not to let the white tip touch anything.



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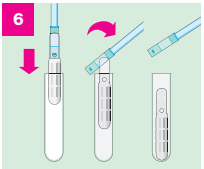

Unscrew the lid of the sample tube. Put the white portion of the wand into the sample tube. Bend the wand so that the white section falls into the sample tube. Screw the lid back onto the sample tube and dispose of the blue portion of the wand.