



## HPVvalidate

# A study to compare cervical screening results using a self-sample and a clinician-taken sample

Public Health England (PHE) is sponsoring a study about self-sampling tests for use in the NHS Cervical Screening Programme. You are invited to take part.

Self-sampling is a new method being considered for cervical screening. It can be done at home, and if it is included in the programme, this could increase access to screening.

However, before we can offer self-sampling as part of routine screening, we need to be sure that a self-test is as accurate as a sample taken by a doctor or nurse. To do this, we need to undertake a clinical validation. This means comparing self-taken samples with samples taken by a doctor or nurse. This is a really important study and the results will help the cervical screening programme decide how it may use HPV self-sampling in the future.

## Who we are inviting to take part

We are inviting women and people with a cervix who are attending:

- cervical screening appointments
- appointments at colposcopy clinics after their screening showed abnormal cells

You are still able to take part in the study if you have been vaccinated for HPV.

## If you decide to take part in the study

At your cervical screening or colposcopy appointment, the nurse or doctor will give you a self-sample test and ask you to do the following.

### 1. **Take a sample from your vagina (not the cervix).**

The doctor or nurse will explain how to do this and will give you written and verbal instructions. You can ask to see the self-test before deciding to take part in the study. You take the sample in private and the process should not take longer than a couple minutes.

The self-test sample will be sent for processing to look for human papillomavirus (HPV). HPV is very common. It can sometimes cause abnormal cells in the cervix which, if left untreated, can turn into cervical cancer over time.

## 2. Have your cervical screening (smear test) or colposcopy - depending on which appointment you are attending

If you are attending your GP practice, your doctor or nurse will then take a regular cervical screening test (taking a sample of cells from your cervix). We then compare the results from both samples to look for HPV.

If you are attending a colposcopy appointment, you will have the colposcopy examination after taking the self-sample test. We will compare the result of the self-taken sample with your last cervical screening result. As part of the study we will also request information from the clinic on the outcome of your colposcopy appointment.

The results of your cervical screening or colposcopy will be posted to you as usual.

## 3. Complete a short questionnaire about using the self-sample test

The doctor or nurse will ask you to complete the survey before you leave your appointment. They will show you what you need to do. It will take about 5 minutes.

You do not have to complete the survey. You can decide to use the self-sample test but not complete the questionnaire.

If you are attending a colposcopy appointment, you will not be asked to do a questionnaire.

## 4. Decide if you agree to PHE storing your self-test sample for future use.

You do not have to agree to this, but it will help us to carry out studies like this more quickly in the future. Access to a collection of existing samples helps us to quickly assess new tests as they are developed.

We would like to keep your sample for a minimum of 10 years. If you choose not to let PHE store your sample, we will process them just for this study and then destroy it. Your sample will not be shared with any other organisations.

## How will we use information about you?

All information collected about you during the study will be kept strictly confidential. People working on the study data will not be able to see your name or contact details. Your data will be linked by a unique code instead of any identifying details. The unique identifier will not contain your name or contact details

For those asked to complete the questionnaire via Survey Monkey, this is anonymous information and not linked to your results. It will not have your name on it or the unique code. The Survey Monkey website does collect some information such as IP address, which is stored temporarily in the company's servers in the USA. Learn more about how Survey Monkey manages this data at:

**(<https://www.surveymonkey.co.uk/mp/legal/survey-research-privacy-notice/>)**

## Use of your health records/information in the study

We need to use information from your screening records for this study. The information we use will include:

- your age and previous screening history
- the results of the HPV tests for both the self-collected sample and the clinician-taken sample (if you had cervical screening)
- the results of the colposcopy examination (if you had a colposcopy)

We will keep all information about you safe and secure.

Once we have finished the study, we will keep some of the data so we can check results. We will write our reports in a way that no-one can work out that you took part in the study. The study reports will not show any personal data, and you will not be able to be identified.

## Your choices about how your information is used

You can:

- stop being part of the study at any time, without giving a reason - this will not affect any future cervical screening or colposcopy appointments
- refuse to allow PHE to keep your samples - this will not affect the study, as we will process your samples and then destroy them

- change your mind and withdraw from the study – if you do please contact us at: [PHE.screeninghelpdesk@nhs.net](mailto:PHE.screeninghelpdesk@nhs.net) (with 'HPVvalidate study' in the subject of your email) or call 020 3682 0890 to let us know
- decide not to complete the questionnaire part of the study or withdraw at any time while you are completing it (if you are having cervical screening at your GP practice) - the questionnaire is anonymous so we will not be able to identify you and this means that your data cannot be changed or deleted afterwards

You can ask the doctor or nurse at your appointment if you have any questions.

Please note - we need to manage your records in certain ways for the study data to be reliable. This means that we are **not** able to let you see or change the data we hold about you.

## Find out more about how the study information is used

You can find out more about how we use your information:

- at [www.hra.nhs.uk/information-about-patients/](http://www.hra.nhs.uk/information-about-patients/)
- at [www.gov.uk/government/organisations/public-health-england/about/personal-information-charter](http://www.gov.uk/government/organisations/public-health-england/about/personal-information-charter)
- by sending an email to [PHE.screeninghelpdesk@nhs.net](mailto:PHE.screeninghelpdesk@nhs.net) (with 'HPVvalidate study' in the subject of your email) or calling 020 3682 0890
- by sending an email to either [dataprotectionofficer@phe.gov.uk](mailto:dataprotectionofficer@phe.gov.uk) or [FOI@phe.gov.uk](mailto:FOI@phe.gov.uk) or calling 020 7654 8000 and asking for the Data Protection team.
- by writing to:

Public Accountability Unit  
Public Health England  
7th Floor North, Wellington House  
133-155 Waterloo Road  
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The London-Stanmore Research Ethics Committee has approved the ethics of the study (REC reference: 20/LO/1009).