NHS London SelfScreen

NHS London SelfScreen Opportunistic HPV Self-Sampling Pathway: Professional Guidance for non-General Practice Providers of Cervical Screening

Contents

Version Control

Version	Author/ Change(s) made by	Date	Summary of Change(s)
V1.0	Dr Luke McGeoch, Public Health Registrar	11th February 2026	N/A – first version

Acronyms

CSMS: Cervical Screening Management System
CSL: Cervical Screening London
CSP: Cervical Screening Programme London
HPV: Human papillomavirus
HSL: Health Services Laboratory
MHRA: Medicines and Healthcare products Regulatory Agency
RIDAC: Research, Innovation and Development Advisory Committee
SQAS: Screening Quality Assurance Service

Introduction

NHS England London received approval from the national NHS Cervical Screening Programme and Research, Innovation and Development Advisory Committee (RIDAC) to implement an opportunistic programme to offer HPV self-sampling, otherwise known as cervical self-screening, for under- or never-screened women and people with a cervix registered at participating primary care and other cervical screening provider sites in London. This followed positive results from the YouScreen research study that found increased uptake of cervical screening among women in London when offered HPV self-sampling. This service improvement is part of the NHS commitment to eliminate cervical cancer by 2040, which is dependent on improving cervical screening coverage rates to 70% (London had 63% coverage in 2023).

Phase one of the programme recruited 97 sites across the region in 2025, which are opportunistically offering self-sampling to 20,000 women and people with a cervix. In phase two of this programme, an additional 50,000 women and people with a cervix will be offered self-sampling opportunistically in participating general practices and other cervical screening providers.

Self-sampling is undertaken in participating general practices and other cervical screening providers, with kit logistics, testing and reporting undertaken by the Cervical Screening London (CSL) laboratory. In order to offer HPV self-sampling, the eligible cohort must be correctly identified by participating sites. A service evaluation will be conducted to assess how effective the initiative is in terms of improved screening attendance across the target population.

This professional guidance outlines the background to the offer, detail on the pathway, testing and results, logistics, and error or harm reporting.

Background

Cervical cancer is highly preventable via screening and HPV vaccination, yet in England there are still over 2,600 cases annually.[1] Over half of cases arise in individuals who are under- or never-screened, providing a strong rationale to ensure high screening participation.[2] Screening coverage in London fell twice as fast as the national decline observed between 2011 and 2022 (-12% vs -6%) and is below 50% in some boroughs. In addition, many cancers are detected at more advanced stages, with this rate being higher in London. With the aim to eliminate cervical cancer by 2040, screening rates must increase.

More than 95% of cervical cancers are caused by Human Papillomavirus (HPV) (70% by HPV types 16 & 18). HPV is one of the most common viral infections, infecting 80% of the population at some point. Cervical cancer is curable if detected early and adequately treated and 99.8% of cervical cancer cases are preventable. Unscreened and under-screened women and people with a cervix are at the highest risk of developing cervical cancer.[3] [4] HPV self-sampling has already been introduced into screening programmes in other countries but is yet to be introduced in the UK. Globally, 17 countries recommend the use of HPV self-sampling.[5] Evidence shows that HPV self-sampling increases uptake in non-attenders (generally across sociodemographic groups), has similar accuracy to clinician-taken samples (conventional cervical screening), and is highly acceptable. HPV self-sampling addresses many screening barriers by enabling women and people with a cervix to take their own vaginal sample, in private. Offering a self-screen has been shown to be acceptable to under-screened women who may face barriers to clinician-collected HPV cervical screening, including those with symptoms of pain and discomfort, those with learning difficulties, and victims of sexual violence.

[1] Cervical Cancer Incidence Statistics | Cancer Research UK," accessed April 7, 2025, https://www.cancerresearchuk.org/health-professional/cancer-statistics/statistics-by-cancer-type/cervical-cancer/incidence#heading-Zero.
[2] Rebecca Landy et al., "Impact of Cervical Screening on Cervical Cancer Mortality: Estimation Using Stage-Specific Results from a Nested Case–Control Study," *British Journal of Cancer 2016 115:9* 115, no. 9 (September 15, 2016): 1140–46, https://doi.org/10.1038/bjc.2016.290.
[3] Marc Arbyn et al., "Detecting Cervical Precancer and Reaching Underscreened Women by Using HPV Testing on Self Samples: Updated Meta-Analyses," *BMJ* 363 (December 5, 2018): 4823, https://doi.org/10.1136/BMJ.K4823.
[4] Tomasz Tatara et al., "The Influence of Vaginal HPV Self-Sampling on the Efficacy of Populational Screening for Cervical Cancer-An Umbrella Review," *Cancers* 14, no. 23 (December 1, 2022), https://doi.org/10.3390/CANCERS14235913.
[5] B. Serrano et al., "Worldwide Use of HPV Self-Sampling for Cervical Cancer Screening," *Preventive Medicine* 154 (January 1, 2022): 106900, https://doi.org/10.1016/J.YPMED.2021.106900.

The YouScreen study was a clinical trial offering HPV self-sampling to non-attenders within the NHS Cervical Screening Programme in North East and North Central London. This investigated an end-to-end pathway for HPV self-sampling within the NHS cervical screening programme in England, providing evidence for how best to implement HPV self-sampling at scale in England. It found:

- HPV self-sampling was highly acceptable to participants and delivery feasible in primary care,
- Self-screens were returned from 65.5% of those who accepted an opportunistic offer in primary care,
- HPV self-sampling resulted in a 22% increase in non-attenders screened per month,
- HPV self-sampling being offered in this way can address inequalities and reach an ethnically diverse population,
- Opportunistic offering of HPV self-sampling to non-attenders is an effective strategy for improving uptake in under-screened individuals.

Evidence, including that from the HPValidate study, also suggests that there is agreement in results between clinician-acquired samples and HPV self-sampling. In addition, the high relative sensitivities in these studies (range 94.2-97% from across several studies) demonstrate that a high proportion of people who truly have HPV are correctly identified by HPV self-sampling compared to clinician-collected samples. The relative specificity range of 91.3–99.3% demonstrates that the vast majority of negative results correctly identify those who do not have the disease.[6] [7] [8]

More details on the national and local background, the YouScreen, and HPValidate studies can be found in Appendix A.

[6] Performance and pre-analytical stability of self-collected samples versus clinician cervical samples for the detection of HPV16, HPV18 and a pool of 12 other HPV types on the Roche Cobas 8800 System - PubMed

[7] Analytical performance of HPV assays on vaginal self-collected vs practitioner-collected cervical samples _ the SCoPE study

[8] qmul.ac.uk/fmd/media/smd/documents/research/hpv-self-collection-test-accuracy-report-hpvalidate-lot1.pdf

Key Principles of the Offer

- This is an offer to under- and never-screened women and people with a cervix to complete an HPV self-sample – full inclusion and exclusion criteria are outlined on page 10.
- The offer is opportunistic.
- Healthcare professionals who make the offer must be trained to do so and be able to digitally complete and print an HMR101 form using the cervical screening management system (CSMS).
- The woman or person with a cervix should be offered the choice between a self-screen and routine clinician sampling of cervical cells using a speculum.
- The trained healthcare professional making the offer is responsible for the entire pathway, including making the offer, ensuring the woman or person with a cervix is able to take a sample, proactive follow up and action of results. The healthcare professional's failsafe responsibilities are covered in Cervical screening: cytology reporting failsafe (primary HPV) - GOV.UK (section 5).

Please note that the offer of HPV self-sampling to your patients does not attract payment and should not be included in the cervical screening activity SLAM data your trust may submit to commissioners for payment verification purposes.

Preparing for the Offer

Healthcare Professional Eligibility and Readiness

Doctors and registered nurses working at participating settings are eligible to make an offer of HPV self-sampling, provided they have completed the HPV self-sampling training, irrespective of whether they are a registered Cervical Screening sample-taker. The following additional healthcare professional groups are also eligible to offer HPV self-sampling, **provided that they are trained Cervical Screening sample takers with a valid PIN recorded in the London Cervical Sample Taker Database** and have completed the HPV self-sampling training:

- Nursing and Midwifery Council (NMC) registered nursing associates*
- NMC registered midwives
- physician associates who are registered on the Physician Associate Managed Voluntary Register (PAMVR) or with the General Medical Council (GMC)
- registered healthcare professionals working in integrated sexual health (ISH) clinics
- registered paramedics working in primary care

Qualified sample takers should ensure that they have completed the required 3 yearly training updates to maintain competency and meet their clinical and professional responsibilities for continuing professional development and revalidation. NHS Cervical Screening Programme – Good practice guidance for sample takers - GOV.UK

* Existing delegation arrangements for registered nursing associates who are cervical sample takers also apply to the HPV self-sampling programme[9,10]. This means that a doctor or registered nurse must be present on-site when a registered nursing associate is making an offer of self-sampling to a patient and when this self-sampling is undertaken, to indirectly supervise their practice.

In order to offer HPV self-sampling, **healthcare professionals must have completed the HPV Self-Sample training and self-assessment**. The certificate of completion must be provided to the site's HPV self-sampling lead.

[9] NHS Cervical Screening Education Pathway
[10] RCN Position Statement on Nursing Associates (NAs) Training in Cervical Screening

Patient eligibility and Exclusion Criteria

The eligibility criteria are as follows:

- Registered with a London GP,
- Any woman and person with a cervix at least 6 months overdue screening:
    - Aged 25.5 years to 64 years or aged 65+ and not screened since age 60; and
    - Not ceased from the cervical screening programme.

Exclusion criteria are:

- No cervix,
- Has had a cervical screening result in the last 3.5 years for those aged 25-49, or 5.5 years in those aged 50-64,*
- Known to be on an early-recall pathway,
- Known to be on a test-of-cure pathway,
- Known to be pregnant,
- Less than three months after giving birth,
- New to cervical screening in England (to be eligible for this pathway it must be at least six months since they became eligible for cervical screening in England),
- Ceased/suspended

*Cervical screening intervals have been extended to five years for individuals aged 2 5 to 49 who test negative for HPV following routine clinician sampling. **Cervical screening intervals for individuals who test negative following HPV self-sampling remain at three years.** This interval will be reviewed in the future.

Making the Opportunistic Offer

When consulting the woman or person with a cervix, an opportunistic offer of HPV self-sampling must be based on an assessment of the patient's screening history using the Cervical Screening Management System (CSMS) to check eligibility against the inclusion criteria.

Once eligibility is confirmed, the healthcare professional should counsel the woman or person with a cervix, including:

- Checking eligibility and exclusion criteria
- Information about the offer
- Any temporary criteria which may preclude the woman or person with a cervix from taking part (e.g., menstruation, recent sexual intercourse)
- Information about the sample collection itself
- Offering the choice between HPV self-sampling and routine clinician sampling of the cervix
- The steps after the sample has been taken, including if the sample is negative, positive, or insufficient
- Risks and benefits
- The use of the collection device being used off-label (as the swab is being transported dry)

To ensure the self-sample is of sufficient quality for testing, please familiarise yourself with the *Patient instructions for collecting self-screen sample* (Appendix D) and encourage patients to follow the guidance given in the instruction sheet.

Detailed guidance on what should be included in this discussion is provided in Appendix B.

Always offer the woman or person with a cervix the choice of:

1. Self-collection
2. Routine clinician sampling of the cervix
3. Assistance in taking the self-sample, should they require it

Implementation Suggestion: If a woman or person with a cervix wants more time to think about the self-collection, offer them an appointment at another time (or in another clinic slot run by a healthcare professional who is trained to make the offer). This allows them to consider the offer and another opportunity to ask questions.

They can also be given an electronic or hard copy version of the 'HPV Self-Screening for Cervical Screening' leaflet developed by NHS England.

If your site uses SNOMED coding, the following SNOMED codes should be used:

If the woman or person with a cervix is offered HPV self-sampling, the following SNOMED code should be logged: "Human papillomavirus self-sample screening offered" (code: 1091941000000105).

If the woman or person with a cervix accepts and the self-sample will be completed during the same attendance in which the offer was made, the following SNOMED code should be logged: "Human papillomavirus test consent given" (code: 391144006).

If the woman or person with a cervix declines, the SNOMED code should be recorded that they have declined the offer – "Human papillomavirus self-sample screening declined" (code: 1091931000000101).

A full list of SNOMED codes can be found in Appendix C. Sites that do not use SNOMED coding should nevertheless record the self-sampling offer, and the acceptance or decline of the offer, in the patient's clinical record.

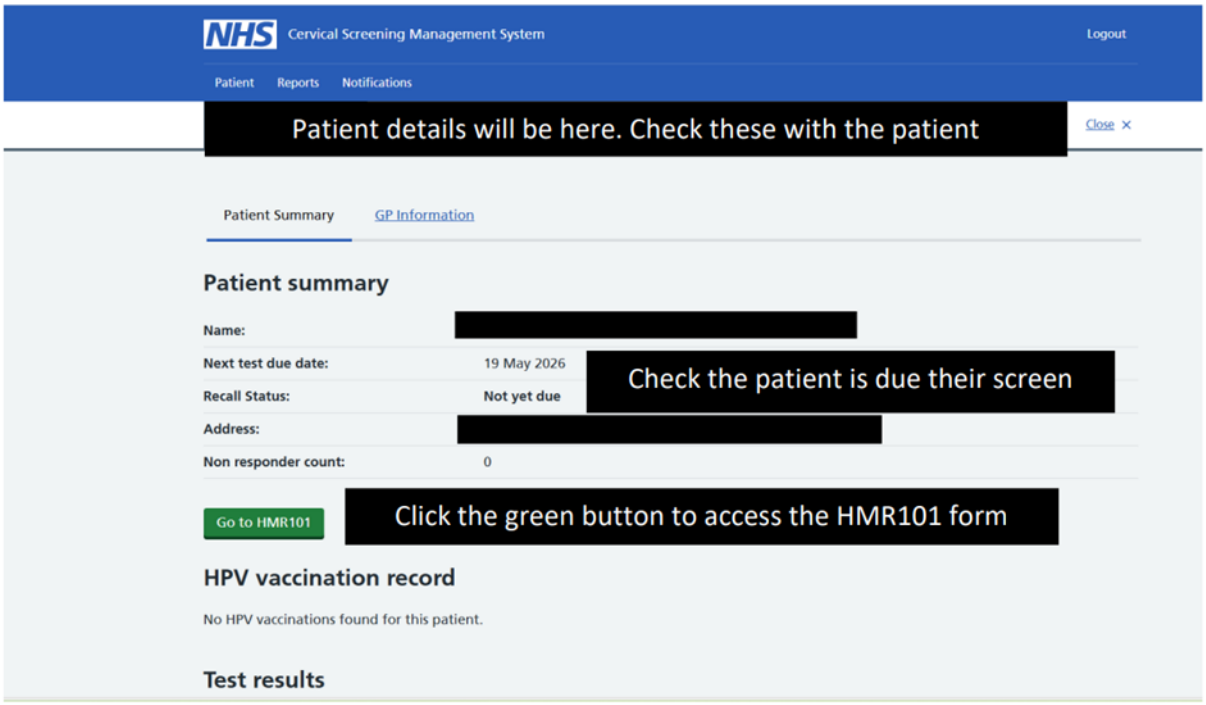
Requesting HPV self-sample testing

If the woman or person with a cervix accepts the self-sample offer, the healthcare professional should then complete an HMR101 sample testing request form on the Cervical Screening Management System (CSMS). This should be completed digitally and then printed. The minimum information needed on the request form is:

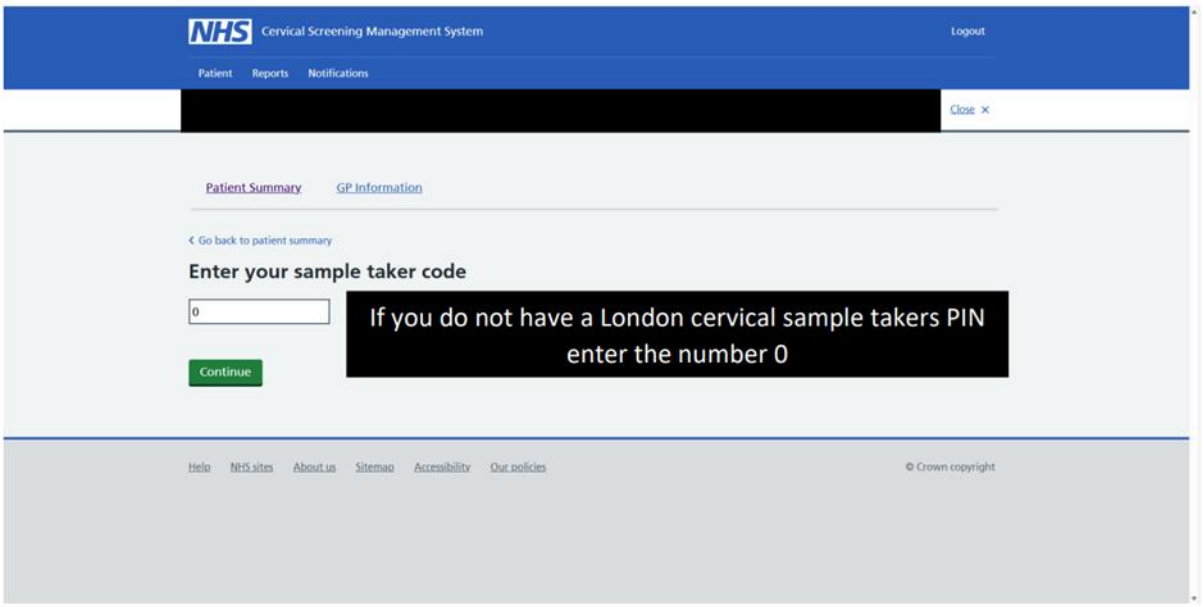
- NHS number
- Full name (first and last name)
- Date of birth
- Address
- Name and address of sender organisation
- Date of sample collection

Instructions on how to access and complete the HMR101 form are as follows:

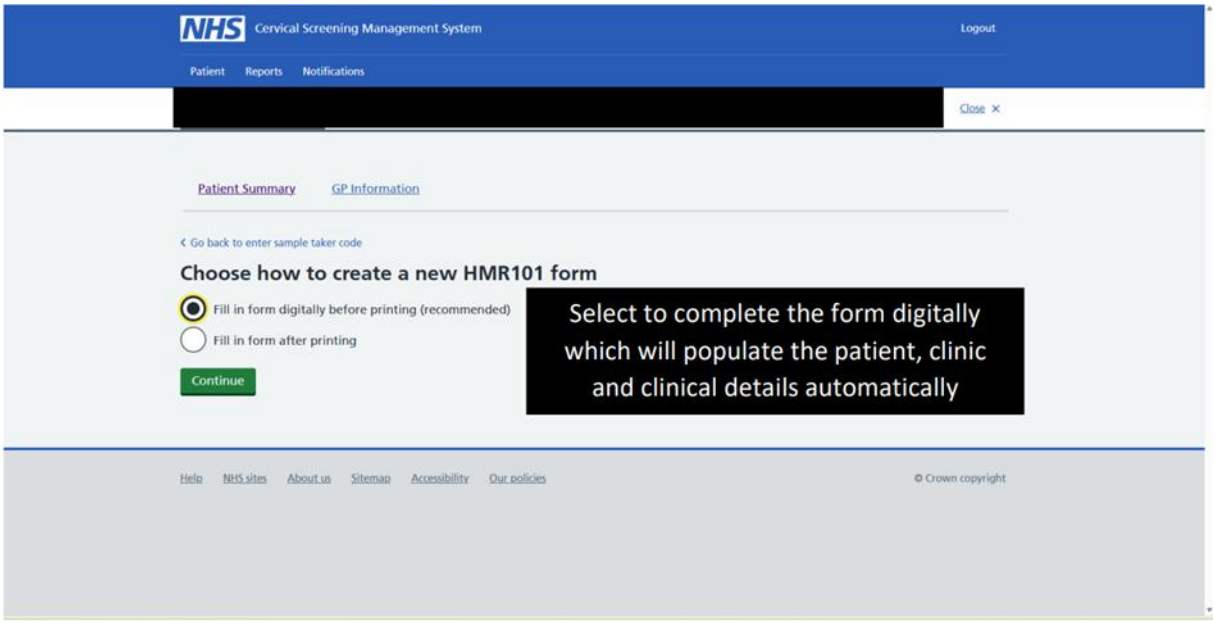
The HMR101 cervical screening sample request form can be launched on the Cervical Screening Management System, as shown below.



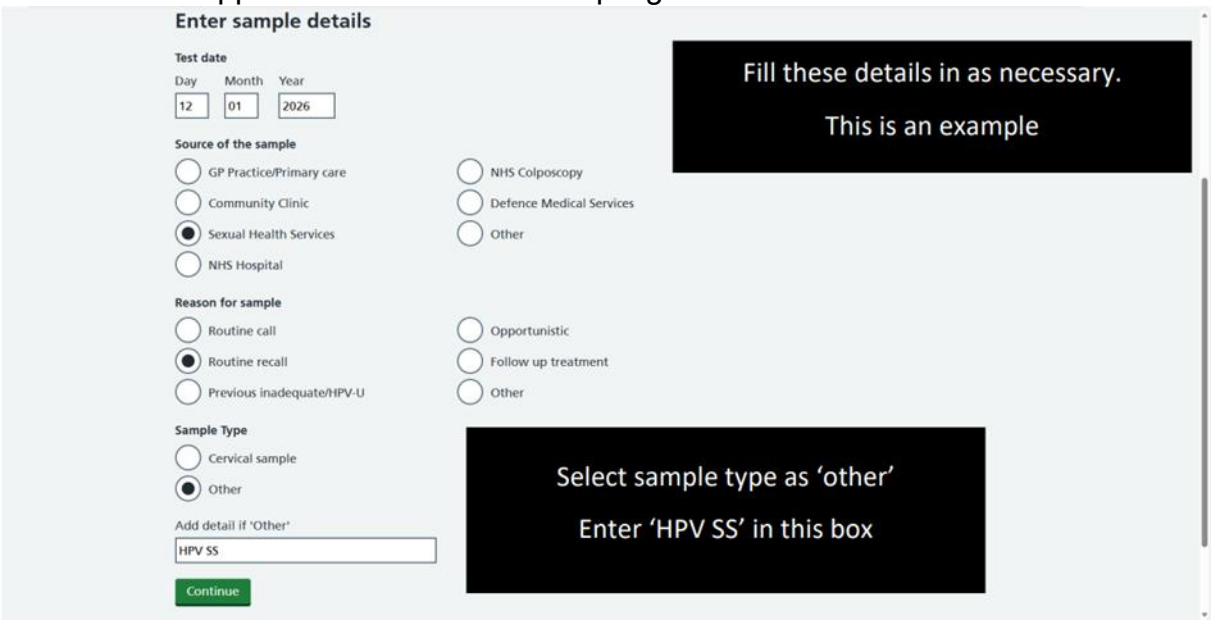
To access the form, you will be asked to enter your sample taker PIN. If you do not have a valid London cervical sample taker PIN but are a doctor or registered nurse and therefore still eligible to offer HPV self-sampling, enter the digit '0' and press continue – this does not apply to any other professional groups.



Select the option to fill in the form digitally before printing.

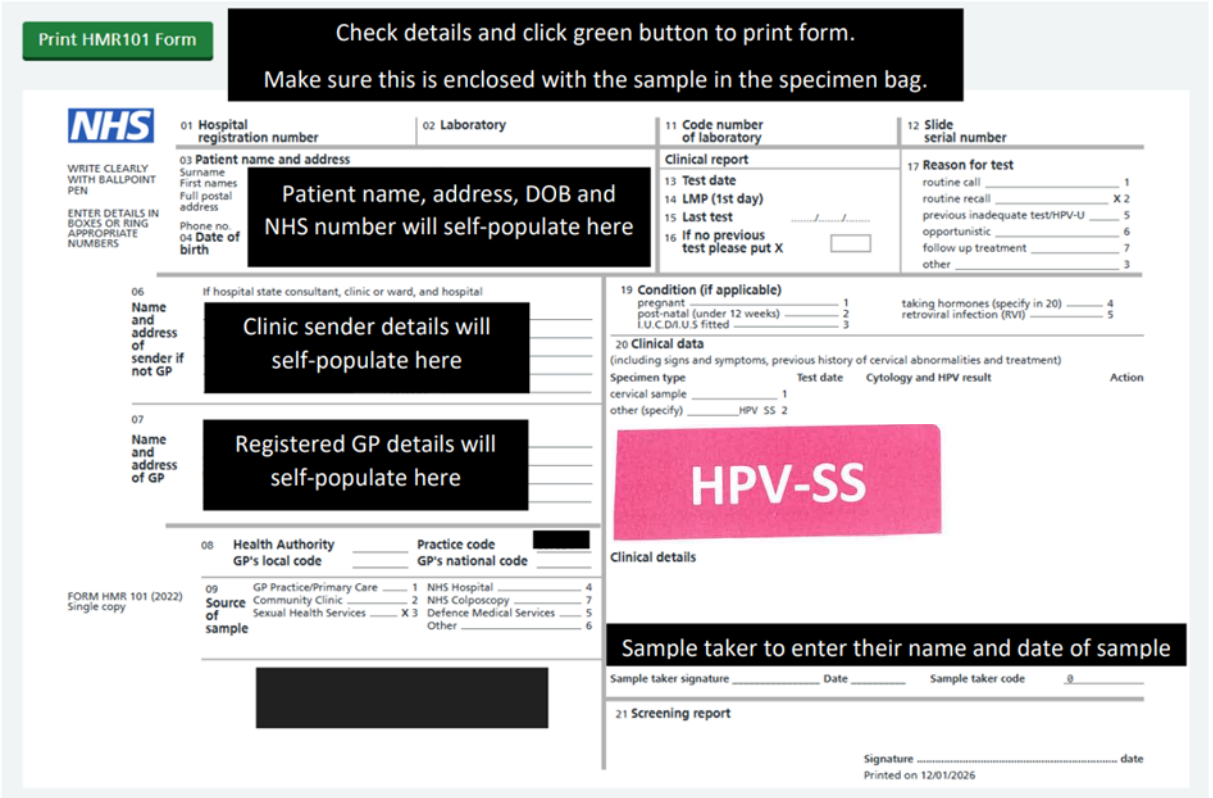


You will then be asked to fill in the sample details. It is very important that you select the ‘Other’ option for sample type, and enter the text ‘HPV SS’ in the Add detail box below. This will let the cervical screening laboratory know that this is a self-sample specimen. Once you have entered these sample details, click continue.



You will now see the completed HMR101 form. Please check that the details are correct, then click the green print button.

Once you have printed the form, you will need to attach the **pink HPV self-sampling sticker** provided by the cervical screening laboratory, as shown on this image, which enables the laboratory to easily identify that this as an HPVSS self-sample test request.



The Sample

The ‘grab bag’ of consumables will contain the instruction leaflet, the vaginal self-screen swab, a plastic sample collection tube, and a sticky label for the healthcare professional to complete (if applicable, please see below). The swab is the breakable FLOQswab 5E160N01, which is CE marked for HPV self-sampling. This bag should be stored at 2-30^{O}C to ensure the swab can meet the intended specification. The bag in which the consumables arrive will also act as the transport bag.

The self-screen swab is only licensed to be performed in-clinic by the patient. We hope this offer can be expanded to at-home use in due course.

Some key information about the swab:

- It does not contain any animal products
- Use with caution if allergic to nylon fibre and ABS (Acrylonitrile butadiene styrene) material
- The swab 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
- This is for HPV ONLY and not suitable for collecting cells for cervical cytology (microscopic) assessment.

The instruction leaflet will have a website link as well as a QR code that allows the text to be read in multiple languages. This is found in Appendix D. Participating sites will also be given several laminated copies of the leaflet in the available languages.

Once the offer of HPV self-sampling has been accepted, the healthcare worker will need to hand-write the following information on the sticky label that is in the grab bag, then attach it to the collection tube:

- The patient’s name (first and last name)
- Date of birth on the tube
- Date of sample on the tube

The HMR101 form should be kept by the healthcare professional when the individual is completing their self-sample.

The woman or person with a cervix will then complete the self-sample. **The woman or person with a cervix does not need to be in the same room as you to**

complete the sample – please provide them with a private space to take the sample. This can be the consultation room, a toilet, or other private space.

Once the sample is completed, the individual will hand this back to the healthcare professional in the 'grab bag.' The printed HMR101 form **must** then be inserted into the document pouch on the 'grab bag' to ensure this is sent to the lab with the sample.

Ensure the details on the HMR101 form match the details on the tube. Ensure the swab is in the correct, labelled container and none of the waste (e.g., the snapped off part of the swab, the search which contained the swab) is in the Grab Bag.

This is a dry swab therefore there is no need for the healthcare professional to suspend the sample in cell preserving liquid.

Transport to the Lab

'Grab bags' with:

- The labelled sample container, including patients name, date of birth, date of sample (either printed or handwritten – see information above),
- The HMR101 request form

should be placed into the same purple bags as samples from the Cervical Screening Programme (picture below). Details can be found here: Cervical screening samples | Health Services Laboratories.

Please ensure a CSL barcode is placed on the purple bag before it is transported to the lab.

It is <u>essential</u> the sample goes into the purple collection bag – not doing so may result in the sample not being tested.

Samples should arrive at the lab within 14 days of the sample being taken to allow effective resuspension and to ensure results are valid.

Implementation Suggestion: Place a purple collection bag in the room of each healthcare professional who is making this offer. This ensures the sample goes into the correct bag straight away. At the end of each day or when collection takes place, combine these into one bag.

Results

Details of how healthcare providers and patients receive results can be found here: Cervical screening results | Health Services Laboratories.

Women and people with a cervix will receive self-screen results via the routes used by the national Cervical Screening Programme, as will participating cervical screening provider sites.

It is the responsibility of the healthcare professional making the offer to ensure that results are received and proactively review results to ensure follow-up of those with an HPV positive or unavailable/insufficient results. The full responsibilities of the offer-maker are outlined in Section 5 of Cervical screening: cytology reporting failsafe (primary HPV) - GOV.UK.

Where SNOMED coding is in use, the correct SNOMED code should be included in the patient's clinical record:

- For hrHPV Not Detected - Human papillomavirus self-sample test negative - 1091741000000108
- For hrHPV Detected - Human papillomavirus self-sample test positive - 1091911000000109
- For hrHPV Unavailable or Unreliable - Human papillomavirus self-sample insufficient – 1094051000000107

A full list of SNOMED codes can be found in Appendix C. Sites that do not use SNOMED coding should nevertheless record the test result in the patient's clinical record.

Women and people with a cervix who have a **hrHPV Detected** result on a self-screen will be advised in their results letter to book a follow-up appointment at their general practice or other location where self-sampling was completed to have a standard screening test taken by healthcare professional (HPV primary screening test), as cells from the cervix are not exfoliated in self-screen collection. The follow-up test (standard cervical screening test) should be taken as soon as possible with proactive follow-up of results. There is no need to wait for three months before the

standard screening test. **It is good practice that this follow up routine screening test is performed at the same location as the self-sampling test offer.**

The genotyping will **not** be provided to the healthcare professional or the NHS Cervical Screening Administration Service (CSAS).

A **hrHPV Not Detected** result will lead to a change in next test due date in the Cervical Screening Programme.

Participants aged 25.5-49 years old and who are HPV negative on the self-sample will **remain on a 3-year recall interval** until routine intervals in relation to self-sampling for this age group are reviewed by the NHSCSP.

If the self-sample returns a result of **hrHPV Unavailable or Unreliable**, the individual is advised to return to the general practice or other location where self-sampling was completed to repeat the self-sample. This can be done at any time – there is no need to wait. Please note that all invalid HPV samples are HPV tested again. An unavailable/unreliable test result is only issued if two invalid HPV results are obtained on the same sample.

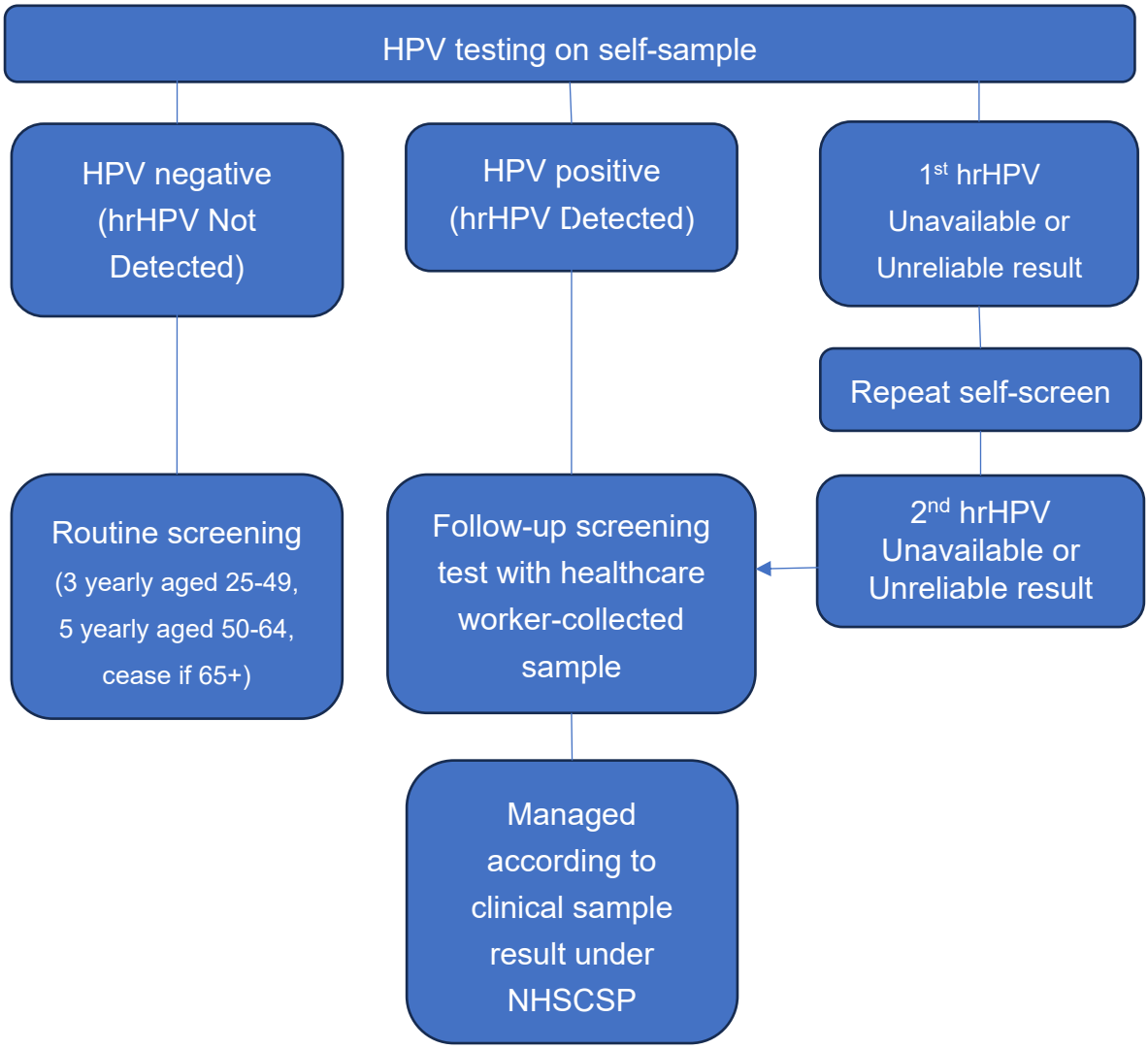
If there is a second HPV unavailable or insufficient result (following a second self-sample), the individual will be advised by letter, to schedule a routine cervical screening appointment at their general practice or location where self-sampling was completed. This routine cervical screening can be done at any time – there is no need to wait 12 weeks or three months .

Women and people with a cervix will be informed via postal letter or NHS App notification and asked to contact the practice in the following scenarios:

- repeat HPV self-sampling after a first insufficient/unavailable result
- book a standard clinician screening appointment after a second insufficient/unavailable result
- book a standard clinician screening appointment following an HPV self-sampling positive results

It is, however, **the responsibility of the healthcare professional who made the offer to proactively follow-up these patients to ensure that the subsequent screening test is completed if the patient so chooses.** The healthcare professional's failsafe responsibilities are outlined in Section 5 of Cervical screening: cytology reporting failsafe (primary HPV) - GOV.UK.

It is advisable that healthcare professionals make a record of all self-sampling tests to ensure that results are returned and actioned.



Cervical Screening Management System (CSMS)

To facilitate this offer, changes have been made to the Cervical Screening Management System (CSMS) to allow self-screening results to be recorded on the system. Appendix E outlines the standard result and action codes used on CSMS.

Ordering Grab Bags

Participating settings can order supplies (ThinPrep vials, brooms, supply bags and bar code labels) via the online order page at:
https://pathologyforms.formstack.com/workflows/hpv_surgery_supplies
Please do not try to order supplies via telephone or email.

Supplies will be delivered by ParcelForce; please allow 5 days for delivery.
For queries about sample taker supplies, please contact:
ls.helpdesk@hslpathology.com or phone 020 7307 9440.

Rejected Samples

CSL operate strict sample acceptance criteria in line with National Guidance: Guidance for acceptance of cervical screening samples in laboratories and pathways, roles and responsibilities - GOV.UK

The error codes used alongside the outcomes (e.g., whether a result is issued or not) by the lab are in Appendix F.

The laboratory will inform the requesting healthcare professional, outlining the reason(s) for rejecting the sample (including error code) and next steps necessary. **Women and people with a cervix will not be directly informed that the sample has been rejected, and they should be proactively followed up by the healthcare professional who made the offer.** They should also be invited to book a standard screening test if they prefer.

Reporting Harm or Safety Issues

HPV self-sampling harms, safety issues and incidents should be managed and reported in the same way as the national NHS cervical screening programme. Please see national screening incident guidance.

As per the guidance, ensure NHS England (england.londonscreening-incidents@nhs.net) and the screening quality assurance service (SQAS) are informed (england.cervicalqa@nhs.net), as well as the relevant ICB patient safety or quality team.

Please report any device-related adverse events, incidents or concerns to the MHRA via the Yellow card scheme. Please see guidance Yellow Card | Making medicines and medical devices safer

Resources

The following resources are available to deliver the pathway (please click on the links to access):

Patient Information Leaflet (information about the pathway, in Multiple Languages)

Patient Swab Instruction Sheet (English)

Patient Swab Instruction Sheet (Multiple Languages)

Patient Instruction Video (Multiple Languages)

Queries

General queries related to the London HVPV self-sampling pathway should be directed to the NHS London commissioning team england.ypa@nhs.net.

Appendices

Appendix A: Further background to HPV self-sampling

In England, cervical screening currently prevents around 70% of cervical cancer deaths, but approximately 3 in 10 people do not take up the offer of screening. It could prevent many more deaths if everyone invited was able to attend screening regularly. Data indicate that screening coverage in London fell twice as fast as the national decline between 2011 and 2022 (-12% vs -6%) and is below 50% in some boroughs. The proportion of cervical cancers diagnosed via the Programme and those diagnosed at stage 1 (when prognosis is significantly more favourable) is declining at rates faster than national levels. London consistently has the lowest cervical screening coverage nationally (65.6% versus 72.6% across England in 2018/2019) with declining coverage since 2012. In 2023, London had the lowest cervical screening coverage in the country (63% in 2023). In 2023, the NHS committed to the elimination of cervical cancer by 2040 through achieving:

- Cervical screening rates of 70%
- HPV vaccination rates of 90%

To meet this target in London, an additional 65,000 people would need to be screened every year, resulting in an annual increase in coverage of 2%.

YouScreen

The YouScreen study was a clinical trial offering HPV self-sampling to non-attenders within the NHS Cervical Screening Programme in North East and North Central London. This investigated an end-to-end pathway for HPV self-sampling within the NHS cervical screening programme in England providing evidence for how best to implement HPV self-sampling at scale in England. The study had 2 aims:

- Test a new pathway for the implementation of HPV self-sampling for non-attenders within the NHS cervical screening programme in England.
- Provide the evidence-base that HPV self-sampling can improve cervical screening coverage in England and can increase detection and treatment of high grade CIN (CIN2+).

The target population was women aged 25-64 years who are at least 6 months overdue cervical screening, and all GP practices in Barnet, Camden, Islington,

Newham and Tower Hamlets were invited to participate (these boroughs had the lowest screening coverage across NCL and NEL). Eligible women were identified via an opportunistic offer as well as direct mail-out. Samples were collected vaginally using a flocked swab (Copan FLOQSwab®) and tested for HPV by the Cervical Screening Laboratory for London (CSL). Samples were transported dry at room temperature.

YouScreen found that HPV self-sampling was highly acceptable to participants and primary care, and that screening being offered in this way can address inequalities and reach an ethnically diverse population. There is a social gradient in both cervical screening coverage and (in the opposite direction) in cervical cancer mortality. Similarly, Black women are less likely to participate in screening and more likely to die from cervical cancer than White women.

- Self-samples were returned from 65.5% of those who accepted an opportunistic offer and was much more efficient than direct mail out of kits.
- HPV self-sampling was highly acceptable and managed to capture underserved populations (e.g. transmen, women with a history of mental illness, abuse, or learning difficulties). Responders were representative of the ethnically diverse and deprived underlying non-attendee population.
- HPV self-sampling resulted in a 22% increase in non-attenders screened per month.
- Coverage increased by 1.6% at participating versus non-participating practices equating to 7.4% over a 3 year screening round.

Results showed that opportunistic offering of HPV self-sampling to non-attenders is an effective strategy for improving uptake in under-screened individuals.

HPValidate

HPValidate was a national study that set out to investigate if vaginal self-samples were as accurate at identifying HPV as clinician taken screening tests in the NHS Cervical Screening Programme in England.

The study recruited >6000 eligible people from General practices and colposcopy clinics. People who participated were invited to take a self-sample using a vaginal swab or brush. Those recruited in General practices also had their standard clinician sample taken when they attended their routine appointment. The laboratories tested both samples (self-taken and clinician-taken) so the results could be compared. The

study used 3 different collection devices (Evalyn Brush (Rovers Medical), Self-Vaginal Floqswabs (Copan) and Aptima Multitest (Hologic)) and 2 HPV tests used by laboratories in the UK for testing cervical screening samples at the time (Cobas HPV Test (Roche) and the Aptima HPV Assay (Hologic)).

The study found that 4 combinations of self-collection device and HPV tests worked well. These were

- Evalyn Brush and Cobas
- FLOQswabs and Cobas
- FLOQswabs and Aptima
- Aptima Multitest and Aptima

The findings of this study can inform the choice of HPV self-sampling kits and testing platforms to use if HPV self-sampling is offered to ‘under-screened’ people (who have never or rarely attended cervical screening). The results can also be evaluated further in future scientific studies to help determine if HPV self-sampling could be introduced effectively as a future option to all screening participants.

A substudy assessed individuals’ experience of HPV self-sampling and their attitudes towards this in the future. It found that the experience of people completing a self-sample in a primary care setting was overwhelmingly positive. Most participants said the overall experience of using a self-sample was excellent (75%) or good (23%). If offered a choice, 69% said they would choose HPV self-sampling while 19% would prefer to have the test done by a clinician. All 3 devices used in HPValidate were deemed as valid consideration for future use from an acceptability perspective

Appendix B: Suggested guidelines for counselling patients

The following points need to be covered when counselling a patient on the HPV self-sampling offer.

- Eligibility check:
  - Registered with a London GP,
  - Any woman and person with a cervix aged 25.5 years to 64 years; aged 65+ and not screened since age 60; or who have yet to meet the criteria to be ceased from the programme,
  - At least 6 months overdue screening,
  - Has NOT had a cervical screening result in the last 3.5 years for those aged 25-49, and 5.5 years in those aged 50-64,
  - NOT on an early-recall pathway,
  - NOT on a test-of-cure pathway,
  - NOT known to be pregnant and less than three months after giving birth,
  - NOT new to cervical screening in England (to be eligible for this pathway it must be at least six months since they became eligible for cervical screening in England),
  - NOT Ceased/suspended.
- Explain the offer:
  - Explain that the person is overdue their cervical screening.
  - This setting is offering people who are overdue their cervical screening by at least 6 months the opportunity to do the screening themselves.
  - This would be in place of the usual screening test done by a healthcare professional.
- Ascertain the following – if any of these are present, then suggest another time to complete the self-sample:
  - Recent gynaecological operation.
  - Currently menstruating.
  - Use of vaginal ovules, creams or washes, vaginal contraceptives or condoms in the 3 days prior to self collection.
  - Sexual intercourse, ultrasound scans or gynaecological examinations in the 2 days prior to self collection.
- If the person is experiencing unusual vaginal bleeding or pelvic pain, they should be reviewed clinically and the cause of their symptoms investigated as appropriate.
- Explain the test:
  - The test is taken themselves in private.
  - It should be done here in the clinic.
  - It should be a painless test and easy to do.
  - There are full instructions in the pack, as well as the container to insert the swab into once completed.
  - Once collected, the patient gives it back to us.

- Once we have sent the sample to the laboratory, they will look for the 14 high-risk human papillomavirus (HPV) types on the sample, which are known causes of cervical cancer.
- **Reiterating that healthcare professional collected screening is most effective, but this offer is a very good alternative if women and people with a cervix do not wish to have a healthcare professional collected sample.**
- **They can also choose to have a healthcare professional collected sample today – explain the choice is theirs.**

- Explain the next steps:
  - The results will be issued to the patient in the same way as the Cervical Screening Programme.
  - If HPV is found on the self-collected sample, the individual will need to have a "usual" screening test undertaken by a healthcare professional. This sample will be tested again for HPV. If HPV is found, the sample will be checked for abnormal cells. If this test finds cell changes, they will be invited for a colposcopy.
  - If the test by the healthcare professional finds no cell changes, they will be invited to have another HPV screening test in one year to make sure no cell changes have occurred.
  - If no HPV is found on the self-collected sample, the individual will return to routine recall and be invited again for screening in 3 or 5 years, depending on their age.
  - It's important to note that extended intervals will not apply to people aged 25-49 years of age who test HPV negative on HPV self-sampling. They will be recalled after three years.
- Explains benefits and risks:
  - Benefits
    - Ensures the individual has screening (HPV self-sampling is better than no screening)
    - Can detect an entirely preventable cancer
    - No need for a healthcare professional to be in the room with you
    - Can be done quickly now
  - Risks
    - Healthcare professional collected screening is most effective, but this offer is a very good alternative for people who do not wish to have the usual screening test which is undertaken by a healthcare professional. Evidence shows no difference in outcomes and self-sampling is being used widely in other countries.
    - Swab breaking, however this is very unlikely unless excessive force applied.
- Explain the off-label use – for example, "I just need to make you aware - usually these swabs are sent to the lab in a liquid but we will be sending the swab without a liquid. However, as long as the swab gets to the lab within 14 days, evidence suggests the sample will remain stable. Therefore, once you have finished collecting your sample, please put it in the empty tube."

- Do you have any questions?
- Are you happy to take up the HPV self-sampling offer?

Appendix C: SNOMED codes for HPV self-sampling

Scenario	Code Name	Code Number
Individual offered HPV self-sampling	Human papillomavirus self-sample screening offered	1091941000000105
Individual accepts the HPV self-sampling offer and it will be completed during the same attendance in which the offer was made	Human papillomavirus test consent given	391144006
Individual declines the HPV self-sampling offer	Human papillomavirus self-sample screening declined	1091931000000101
Result is HPV positive (hrHPV Detected)	Human papillomavirus self-sample test positive	1091911000000109
Result is HPV negative (hrHPV Not Detected)	Human papillomavirus self-sample test negative	1091741000000108
Insufficient or inadequate sample, so no result available (hrHPV Unavailable or Unreliable)	Human papillomavirus self-sample insufficient	1094051000000107

Appendix D: Patient instructions for collecting self-screen sample

Long version provided in Grab Bag

Cervical Screening London

NHS England London

HPV SELF-COLLECTION PACK

This pack contains the materials required for sample self-collection.

Important information

- Please read these instructions carefully and completely before attempting to collect your sample.
- If the instructions are followed you should experience minimal discomfort and no pain.
- Sample collection should not be performed: during menstruation (your period), during pregnancy, in the three months after giving birth, if you recently had a gynaecological operation, or in case of unusual bleeding or pelvic pain.
- Sample collection should not be performed if you have used vaginal ovules, creams or washes, vaginal contraceptives or condoms in the 3 days before.
- Sample collection should not be performed if you have had sexual intercourse, ultrasound scans or gynaecological examinations in the 2 days before.
- If you have problems, feel unwell/lightheaded, please pause or consult with your healthcare professional.
- The swab does not contain material of animal origin.

Sample pack contents

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

Vaginal swab and collection tube

Sample return bag

Sample label

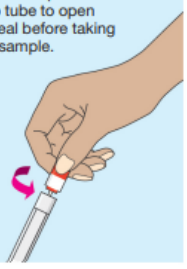
PATIENT INSTRUCTIONS – SWAB SAMPLE

1 Wash your hands in warm soapy water. Open the pack containing the swab and collection tube.

Take the cap off the collection tube and leave it to one side.

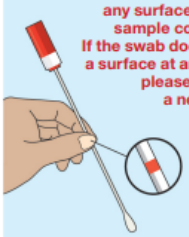
2 It is important to maintain a comfortable balance during sample collection. You can take your sample in a standing position.

Twist the cap of the swab tube to open the seal before taking your sample.



3 Take the swab out of the tube and hold it in your fingers at the red mark in the middle of the stick to take your sample. **Do not hold it by the red end cap.**

Please do not let the white swab tip touch any surfaces during sample collection. If the swab does touch a surface at any point, please request a new pack.



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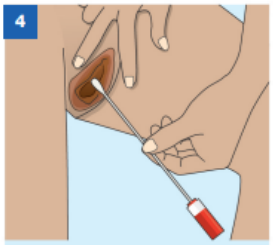
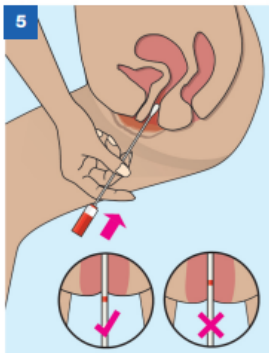


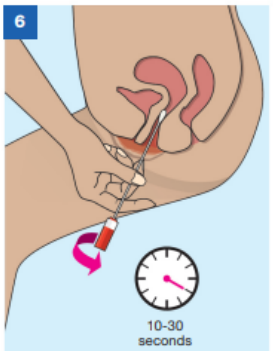
Hold the swab straight when inserting into or removing the swab from your vagina. With your other hand, gently spread the skin outside the vagina. Insert the tip of the swab into the vagina opening. Point the tip towards your lower back and relax your muscles.

5



Insert the swab into your vagina as shown. If the swab does not slide easily, gently rotate it as you put it in. Your fingers on the red line will stop you going in too far. If it is too difficult, do not attempt to continue.

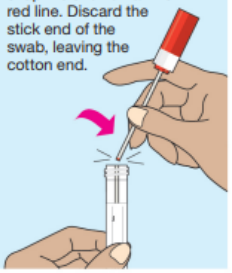
6



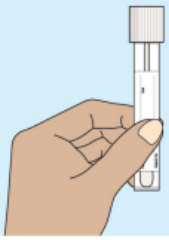
Rotate the swab for 10-30 seconds, making sure it touches the walls of your vagina, then carefully remove the swab.

7 Carefully put the swab into the collection tube.

Holding the tube steady, snap the stick off at the red line. Discard the stick end of the swab, leaving the cotton end.



8 Screw the cap back onto the collection tube tightly.



Now you are ready to hand the swab back to your healthcare professional. They will complete the procedure required for your sample before it is sent for testing.

Hand the swab collection tube, clear sample bag, sample label and this instruction sheet to your healthcare professional.

To view these instructions in other languages please visit: www.hslpathology.com/cervical-screening-self-collection

HEALTHCARE PROFESSIONAL INSTRUCTIONS

- Please make sure that the details on the request form and the swab collection tube match correctly.
- The swab collection tube should only contain the swab end.
- Swab samples should only be returned through the cervical screening pathway, not with general pathology.

Please produce a T-Quest label for the sample tube if you have access, otherwise complete the sample label included in the pack. Apply the label along the length of the tube as shown.

Please check that the details on the request form and sample lable match.

IMPORTANT CHECKLIST

Before you return the sample please do the following:

- ☐ Place the completed request form into the outer sleeve of the sample return bag
- ☐ Make sure that the swab collection tube is labelled and place it into the sample return bag
- ☐ Seal the sample return bag and place it in the purple transport envelope with your cervical screening samples for collection

Warnings and precautions

- This pack is designed for use by persons aged 25 and over and upon request of a healthcare professional or healthcare organisation.
- The pack should not be used by individuals lacking the physical or mental capacity to correctly follow the self-collection instructions.
- Sample collection should not be performed during menstruation (your period), during pregnancy, in the three months after giving birth, if the patient recently had a gynaecological operation, or in case of unusual bleeding or pelvic pain.
- Sample collection should not be performed if vaginal ovules, creams or washes, vaginal contraceptives or condoms have been used in the 3 days before.
- Sample collection should not be performed if sexual intercourse, ultrasound scans or gynaecological examinations have occurred in the 2 days before.
- This pack 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:
  - 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 14 days of sample taking may not be tested.
- This collection pack 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.

Laboratory Tests

- The tests and procedures undertaken by Health Services Laboratories 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 Health Services Laboratories and the patients designated healthcare professional or healthcare organisation.

Assembled by Cervical Screening London (CSL)

TAP5696/15-07-25/V8

Cervical Screening London

NHS England London

HPV SELF-COLLECTION PACK

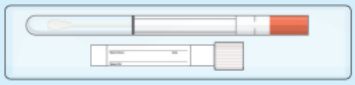
This pack contains the materials required for sample self-collection.

Important information

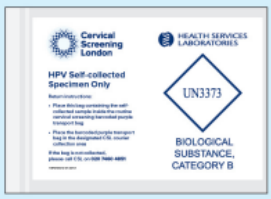
- Please read these instructions carefully and completely before attempting to collect your sample.
- If the instructions are followed you should experience minimal discomfort and no pain.
- Sample collection should not be performed: during menstruation (your period), during pregnancy, in the three months after giving birth, if you recently had a gynaecological operation, or in case of unusual bleeding or pelvic pain.
- Sample collection should not be performed if you have used vaginal ovules, creams or washes, vaginal contraceptives or condoms in the 3 days before.
- Sample collection should not be performed if you have had sexual intercourse, ultrasound scans or gynaecological examinations in the 2 days before.
- If you have problems, feel unwell/lightheaded, please pause or consult with your healthcare professional.
- The swab does not contain material of animal origin.

Sample pack contents

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



Vaginal swab and collection tube



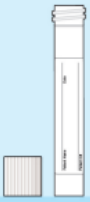
Sample return bag

Sample label

PATIENT INSTRUCTIONS – SWAB SAMPLE

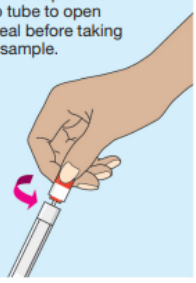
1 Wash your hands in warm soapy water. Open the pack containing the swab and collection tube.

Take the cap off the collection tube and leave it to one side.



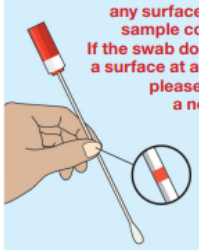
2 It is important to maintain a comfortable balance during sample collection. You can take your sample in a standing position.

Twist the cap of the swab tube to open the seal before taking your sample.



3 Take the swab out of the tube and hold it in your fingers at the red mark in the middle of the stick to take your sample. **Do not hold it by the red end cap.**

Please do not let the white swab tip touch any surfaces during sample collection. If the swab does touch a surface at any point, please request a new pack.



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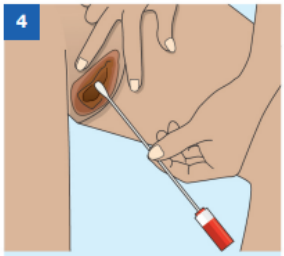

Hold the swab straight when inserting into or removing the swab from your vagina. With your other hand, gently spread the skin outside the vagina. Insert the tip of the swab into the vagina opening. Point the tip towards your lower back and relax your muscles.

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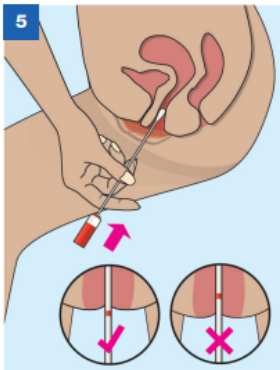
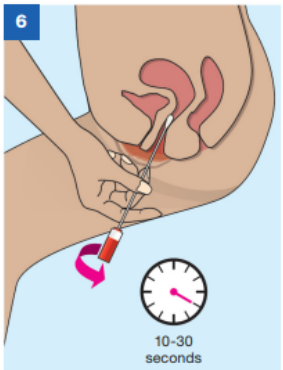


Insert the swab into your vagina as shown. If the swab does not slide easily, gently rotate it as you put it in. Your fingers on the red line will stop you going in too far. If it is too difficult, do not attempt to continue.

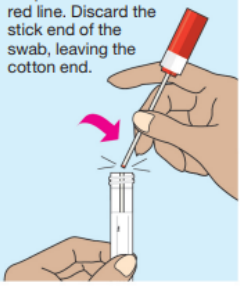
6



Rotate the swab for 10-30 seconds, making sure it touches the walls of your vagina, then carefully remove the swab.

7 Carefully put the swab into the collection tube.

Holding the tube steady, snap the stick off at the red line. Discard the stick end of the swab, leaving the cotton end.



8 Screw the cap back onto the collection tube tightly.

Now you are ready to hand the swab back to your healthcare professional. They will complete the procedure required for your sample before it is sent for testing.

Hand the swab collection tube, clear sample bag, sample label and this instruction sheet to your healthcare professional.

To view these instructions in other languages please visit:
www.hslpathology.com/cervical-screening-self-collection

TAP5692/17-07-25/V8

Appendix E: Result and action codes

Self-Sample Result Code	Result/Action
X0A	No cytology result. HPV not detected. Action: Routine Recall
X9R	No cytology Result. HPV detected Action: Early Recall
XUH	No cytology result. HPV unavailable. No change to recall

Appendix F: CSL error codes for rejected samples

The table below has been amended from the '*NHS Cervical Screening Programme Guidance for acceptance of cervical screening samples in laboratories and pathways, roles and responsibilities, September 2024'*.

Error code	Action
S1 Self- sample received without form	Contact sender and ask for form. If no form received reject the sample and request repeat test to be taken. **No test result.**
S2 Form received without self-sample	Contact sender and check a sample was taken. If not request repeat test to be taken. **No test result.**
S3 Self-sample is unlabelled	Inform sender. Reject sample and request new sample to be taken. **No test result.**
S4 Patient details on form and self-sample do not match	Device only partially labelled but unacceptable: Significant data inconsistencies require a repeat sample. Inform sender. Reject sample and request new sample to be taken. **No test result.** Device only partially labelled but acceptable Follow guidance for minor labelling: A minor discrepancy may be a: • minimal spelling difference • specimen or form labelled with the person's maiden or previous name while the corresponding form/specimen is labelled with her current surname • single digit error in date of birth with all other identifiers matching In these circumstances, the laboratory is confident of the patient's identity despite the discrepancy. The laboratory will book in and report such samples. Check details via the

	CSMS application. Record the discrepancy and remedial action taken in the laboratory error log and inform the sender of the discrepancy. Explain any discrepancy in the report. **Result issued.** **Multiple minor discrepancies constitute a major discrepancy and are dealt with accordingly.**
S5 Self-sample device is damaged	Process sample. If hrHPV DETECTED report and advise clinician-based sample to be taken. **Test result issued.** Process sample. If hrHPV NOT DETECTED / Invalid. Reject sample and inform sample taker. **No test result**
S6 Out of date device	Reject sample. Inform sender. Ask sender to check stock and return any out-of-date devices to the laboratory for safe disposal. **No test result.**
S7 Out of programme – too young to old.	Inform sender and reject sample. **No test result.**
S8 Already had an LBC test in programme	Inform sender and reject sample. **No test result.**
S9 Self-sample issue – other	Inform sample taker request repeat sample. **No test result.**
S10 Patient details differ from past records	Contact sender and ask for correct information to be confirmed in writing. If correct information not received reject the sample and request repeat test to be taken. **No test result.**
S11 Sample received >14 days after self-collection	Process sample. If hrHPV DETECTED report and advise clinician-based sample to be taken. **Test result issued.**

	Process sample. If hrHPV NOT DETECTED / Invalid. Reject sample and inform sample taker. **No test result**