

NHS London SelfScreen Opportunistic HPV Self-Sampling Pathway: Primary Care Professional Guidance



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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 has received approval by the national NHS Cervical Screening Programme and Research, Innovation and Development Advisory Committee (RIDAC) to implement Phase 1 of an opportunistic programme to offer HPV self-sampling, otherwise known as cervical self-screening, to 20,000 under- or never-screened women and people with a cervix registered at participating GP practices in London. This is following 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). Self-testing will be undertaken in general practice, with kit logistics, testing and reporting to be undertaken by the Cervical Screening London (CSL) laboratory. In order to offer HPV self-sampling, the eligible cohort need to be correctly identified by the participating GP practices. 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, 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 strong rationale to ensure high screening participation.² Recent data indicate that screening coverage in London has been falling twice as fast as the national decline 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), and 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 most screening barriers by enabling women and people with a cervix to take their own vaginal sample, in private and at a time and place of their choosing. Offering a self-screen has shown to be acceptable to under-screened women who may face barriers to taking the clinician-collected HPV cervical screening test including symptoms of pain and discomfort, those with learning difficulties, or 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,
- 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 HPVValidate 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 HPVValidate 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 gmul.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 a HPV self-sample – full inclusion and exclusion criteria are outlined on page 10.
- The offer is largely opportunistic, but participating GP practices are also able to identify and invite eligible women and people with a cervix. This should be arranged locally.
- Doctors and nurses who make the offer must be trained to do so and have access to tQuest for requesting the self-screen sample.
- The woman or person with a cervix should be offered the choice between a self-screen and a healthcare professional speculum collected screen (i.e. the regular Cervical Screening Programme).
- The trained doctor or nurse 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, and proactive follow up and action of results. The failsafe responsibilities of the offer-maker are covered in [Cervical screening: cytology reporting failsafe \(primary HPV\) - GOV.UK](#) (section 5).

Preparing for the Offer

Healthcare Professional Readiness

This opportunistic offer can be made by a doctor or nurse (referred to as healthcare professionals from this point forward) within a participating GP practice that has access to tQuest.

You do not need to be a Cervical Screening Programme sample-taker, **but you must have completed the HPV Self-Sample training**. Your practice manager will provide the link to the training and ensure you are competent to make the offer.

You can only make the offer if you have completed this training.

To access the training, please ask your practice manager for the link. The link is also available on the resources section of the HPV self-sampling clinical template on EMIS/SystemOne.

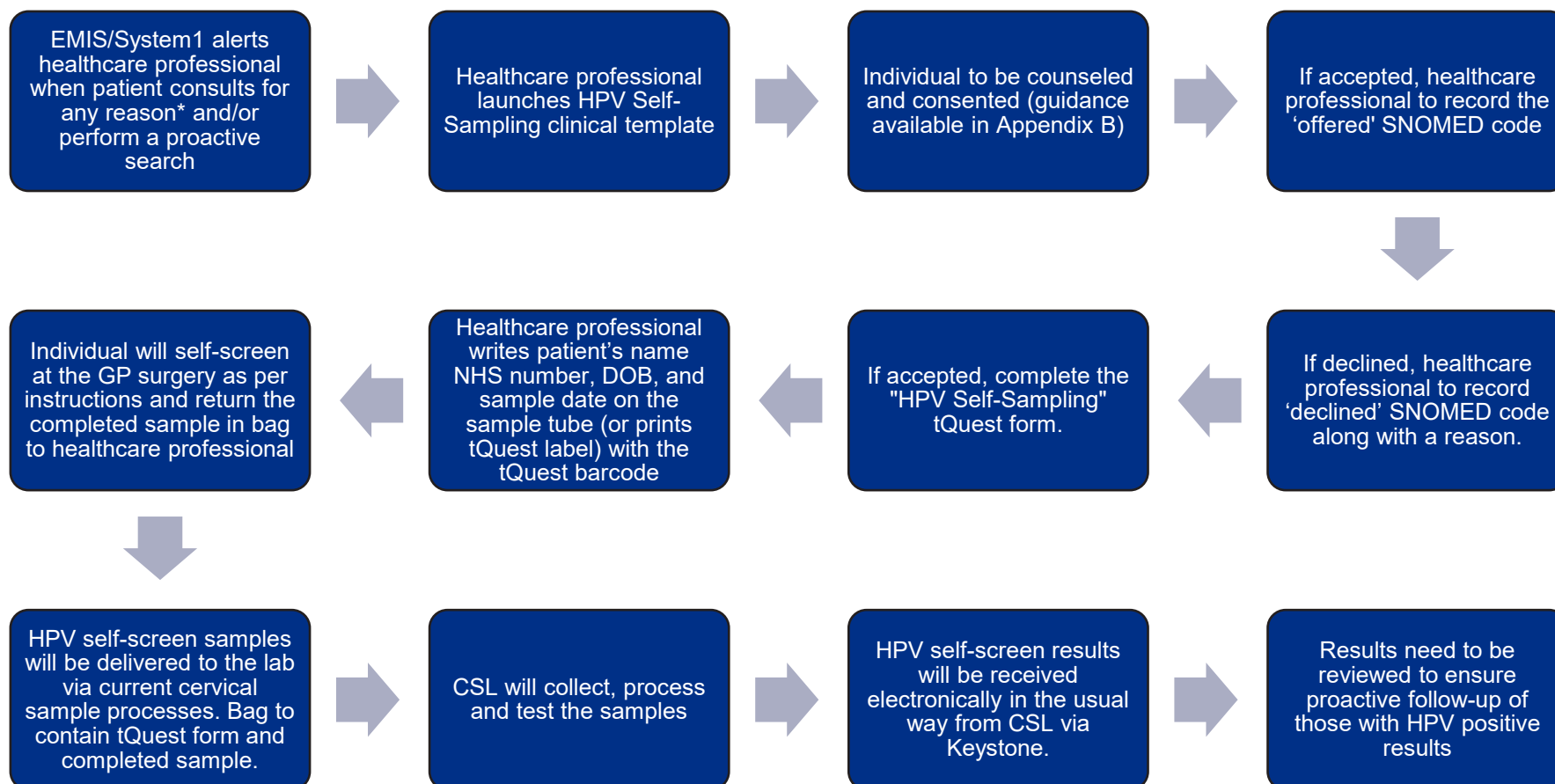
When you have completed the training, please provide the certificate to your practice manager.

IT System Readiness

The offer must **only be made in response to a pop-up alert on EMIS/SystemOne that informs the healthcare professional the woman or person with a cervix is eligible (opportunistic offer) or based on a pre-defined list of identified women or people with a cervix.** It should not be offered in any other way.

If you are working at a GP practice that uses EMIS, the pop-up alert and clinical template for HPV self-sampling will need to be uploaded to your system. Appendix B explains this process.

HPV Self-Sampling Pathway



* The Cervical Screening Management System (CSMS) should be checked to ensure the woman or person with a cervix is eligible for the HPV self-sampling offer. * If you do not have access to CSMS, please ask a colleague to check this

Eligibility and Exclusion Criteria

The eligibility criteria are as follows:

- Registered with a London GP participating in the HPVSS,
- Any woman and person with a cervix at least 6 months overdue screening who are:
 - Aged 24.5 years to 64 years or aged 65+ and not screened since age 60; and
 - Who have yet to meet the criteria to be ceased from the programme.

Exclusion criteria are:

- No cervix,
- Has 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,*
- 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

* Following the introduction of extended intervals to 5-years for people 25-49 years in the NHSCSP in July 2025, the exclusion from HPVSS of 25-49-year-olds with a screening result within the last 3.5 years remains in place. This is because the interval extension will only apply to people who have a primary HPV negative result from routine clinician screening as of July 2025. This exclusion criterion will be reviewed in the coming years as the programme continues.

Making the Opportunistic Offer

When consulting the woman or person with a cervix, a pop-up will appear on EMIS or SystmOne informing the healthcare professional that the patient is eligible to complete a HPV self-sample. They can then be opportunistically offered to self-screen.

Whilst the system aims to accurately identify women and people with a cervix who are eligible, it is up to the healthcare profession to ensure the eligibility criteria are met. It is best practice to check the patient's screening history on CSMS to ensure

eligibility for the HPV self-sampling offer. If you do not have access to CSMS, please ask a colleague to check this.

Once eligibility is confirmed, the healthcare professional should launch the clinical template “HPV Self-Sampling (NHSE London).” This will include guidelines on how to 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
- That the woman or person with a cervix has a choice between HPV self-sampling and healthcare professional speculum collected sampling
- 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)

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

The clinical template will also have links to several documents, including this guidance, the training webinar, the patient instruction leaflet, and the patient information leaflet.

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

1. Self-collection
2. A healthcare professional speculum collected-sample
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 in a cervical screening clinic 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 the woman or person with a cervix accepts, the following SNOMED code should be logged: "Human papillomavirus self-sample screening offered" (code: 1091941000000105).

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 D.

If the woman accepts, the healthcare professional should then complete the tQuest form entitled "HPV Self-Sample." Information is electronically sent to the lab, in the same way as healthcare professional taken samples in the Cervical Screening Programme.

Healthcare professionals will complete the tQuest request form and **print off the form (and label if your practice is able to print tQuest labels)**. The minimum information needed on the request form are:

- NHS Number
- Full name (first and last name)
- Date of birth
- Address
- Name and address of GP
- Date of sample collection

Screenshots of the form are provided in Appendix E. The sample-taker PIN will not be required, as this is a self-collected sample.

Making the Proactive Offer

To enable the proactive offer, a search on the Cervical Screening Management System (CSMS) can be carried out, using the non-responder list. A new bespoke report (Non-Responder List V3.0) has been developed that practices can run to identify all non-responders eligible for HPV self-sampling. The non-responders report contains individuals who:

- Have not responded to their most recent cervical screening invitation and are now more than 6 months overdue
- Have been ceased due to age but were non-responders at the time of ceasing and are still under 65 years old and so remain eligible for their last screening test.

Details on the report and how it is run can be found in the [CSMS user guide](#). For support with CSMS please go to [CSMS help](#).

Otherwise, the same principles as the opportunistic offer apply. However, the offer will be made to women and people with a cervix on a pre-defined list, based on the eligibility criteria.

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°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 F. Practices will also be given several laminated copies of the leaflet in the available languages.

Once the offer of HPV self-sampling has been accepted, depending on the practice, the healthcare worker will need to either:

1. Attach the tQuest label to the collection tube, or
2. 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 tQuest 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 and give this back to the healthcare professional.

The printed tQuest 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 tQuest form match those with 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.

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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 tQuest 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 essential 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 primary care 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.

HPV self-screen results will be received electronically by the GP practice in the same way as the Cervical Screening Programme via Keystone.

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](#).

Once the healthcare professional has the result, the correct SNOMED code should be included in the patient's GP 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 D.

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

GP practice 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. **This follow up screening test should be performed at the same location as the self-screening 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 24.5-49 years old and are HPV negative on this self-sample will **remain on a 3-year recall interval** until routine intervals in relation to self-sampling as part of the NHS Cervical Screening Programme are agreed.

If the self-screen sample is **hrHPV Unavailable or Unreliable**, the individual is advised to return to the GP practice to repeat the self-screen 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.

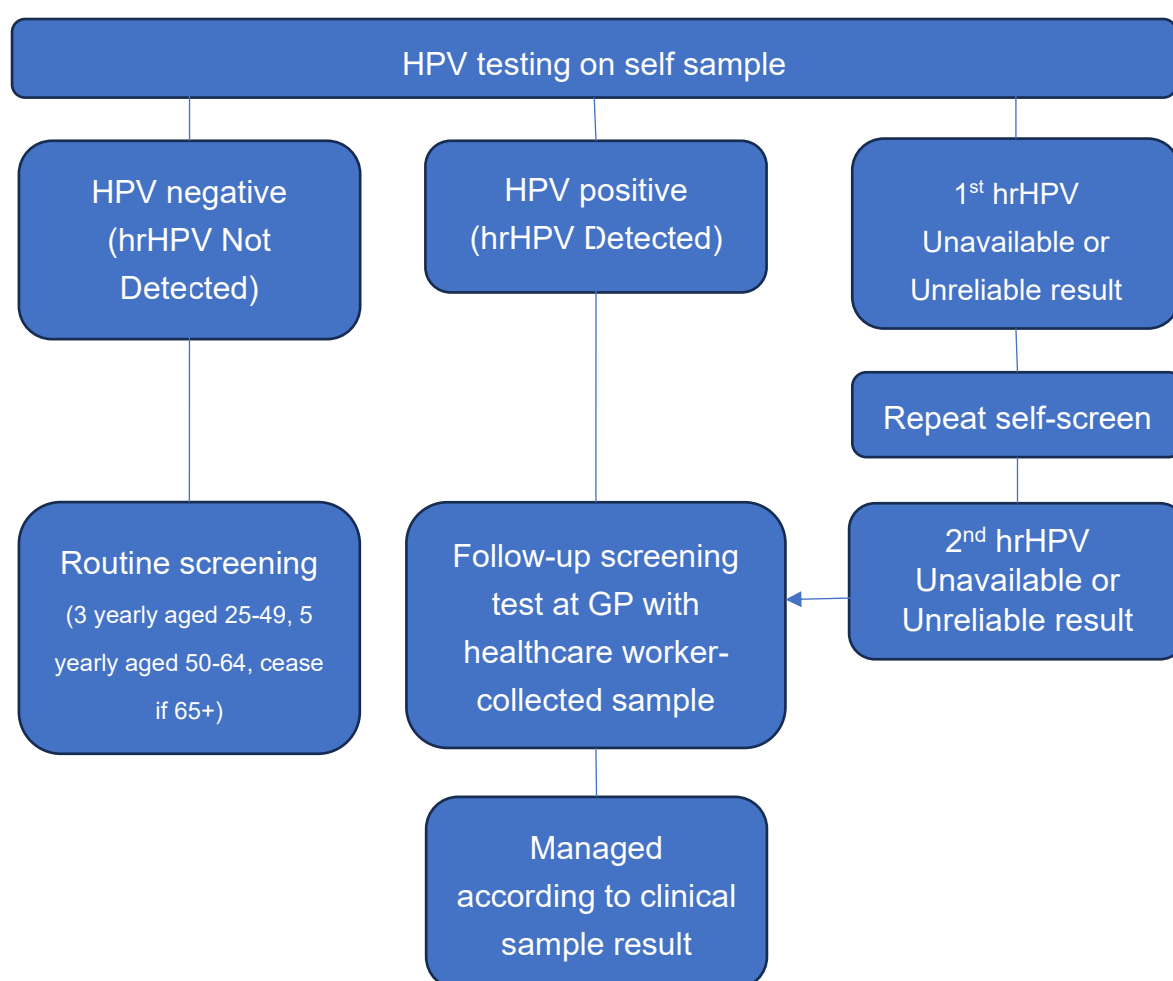
If there is a second HPV unavailable or insufficient result, the individual receives a letter inviting them to attend for the usual/routine healthcare worker taken sample. This can be done at any time – there is no need to wait.

Women and people with a cervix will be informed via post or NHSApp 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 failsafe responsibilities of the offer-maker are outlined in Section 5 of [Cervical screening: cytology reporting failsafe \(primary HPV\) - GOV.UK](#).

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



Cervical Screening Management System (CSMS)

In order to facilitate this offer, changes have been made to the Cervical Screening Management System (CSMS) by NHS Digital to allow self-screening results to be recorded on the system.

Appendix G outlines the standard codes used to report to CSMS.

Ordering Grab Bags

Practices and clinics 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 H.

The laboratory will inform the requesting healthcare professional via the electronic reporting system for the practice, outlining the reason(s) for rejecting the sample (including error code) and next steps necessary. Women and people with a cervix will be informed via post and asked to repeat the HPV self-sampling, however **they should be proactively followed up by the healthcare professional who made the offer**. They will also be invited to book a standard screening test if they prefer.

Reporting Harm or Safety Issues

Reporting harm or safety issues should be done via the usual pathway. HPV self-sampling will use the same process for safety incidents as the cervical screening programme, using the Managing safety incidents in NHS 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).

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)

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. Recent data indicate that screening coverage in London has been falling 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 in London, we would need to screen an additional 65,000 people every year in London, 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,



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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-attender 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.

GP Practices were able to easily make the offer without unduly prolonging the consultation, using embedded software in their IT systems to identify the correct cohort, process the offer according to CSP guidelines and ensure high compliance to clinical follow-up. GP practices expressed a strong desire to:

- allow administrative staff to offer HPV self-sampling kits.
- allow dedicated practice staff who already call lists of women overdue screening to be able to offer kits during these calls.

HPVValidate

HPVValidate 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 GP practices and colposcopy clinics. People who participated were invited to take a self-sample using a vaginal swab or brush. Those recruited in GP 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 HPVValidate were deemed as valid consideration for future use from an acceptability perspective.

Appendix B: EMIS user resources

'HPV Self-Sampling (NHSE London) vX.X' = EMIS template

'HPVSS 25-49 eligible vX' = EMIS Pop-up Protocol for 25-49 cohort

'HPVSS 50-64 eligible vX' = EMIS Pop-up Protocol for 50-64 cohort

You will need to

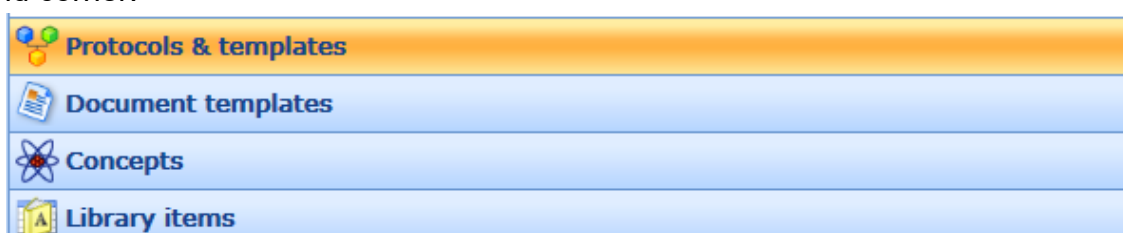
- Create folders for the resources.
- Import the protocols & template
- Set the triggers for the protocols
- Activate the protocols & template for them to be active & available.

1. How to import an EMIS protocol (the HPVSS protocols produces a pop-up in the bottom right hand corner of the EMIS screen for eligible patients).

1.1. **Download the protocols.** To import an EMIS protocol first download each of the protocols (there are 2 protocols one for each age group) onto your desktop.

1.2. **Create a Protocol folder** to save them into. Before you start you need to decide which folder you want to import the protocols into in case you need to create a special dedicated 'HPVSS' folder – we suggest you do this & call it '**HPVSS-London Pilot 2025**'.

1.2.1. In resource publisher select Protocols & template in the bottom left-hand corner.

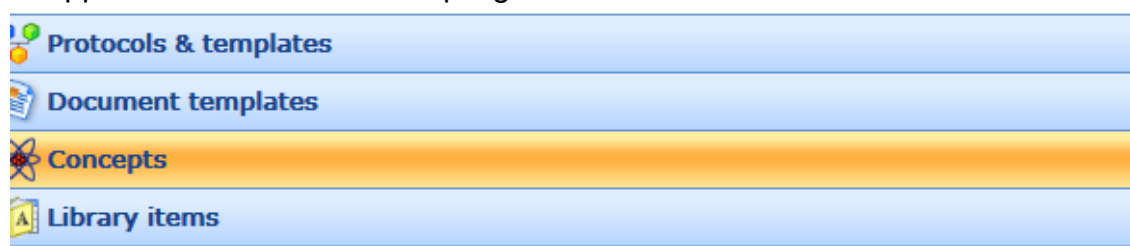


1.2.2. Navigate to where you want your folder. Right click select 'New' & Select 'Folder'.

1.2.3. Name your folder.

1.3. **Create a Concepts folder** for the Concepts associated with the Protocol.

1.3.1. When you import a protocol there are a list of 'concepts' associated with each protocol. You need to decide which folder in the 'concepts' module you are going to save these concepts to. We suggest a dedicated folder named '**HPVSS-London Pilot 2025**'



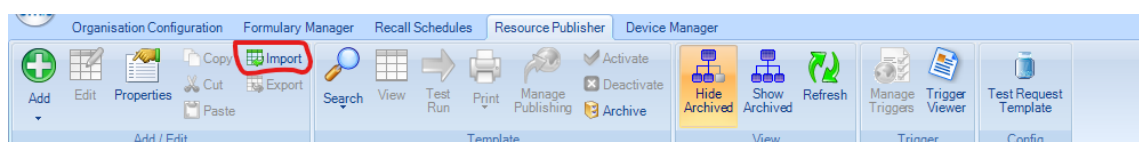
1.3.2. Navigate to where you want your folder. Right click select 'New' & Select 'Folder'.

1.3.3. Name your folder

1.4.Import the Protocol(s).

1.4.1. To import the HPVSS 24-49 protocol. Open the Protocol folder you want to import the protocol into (HPVSS-London Pilot 2025).

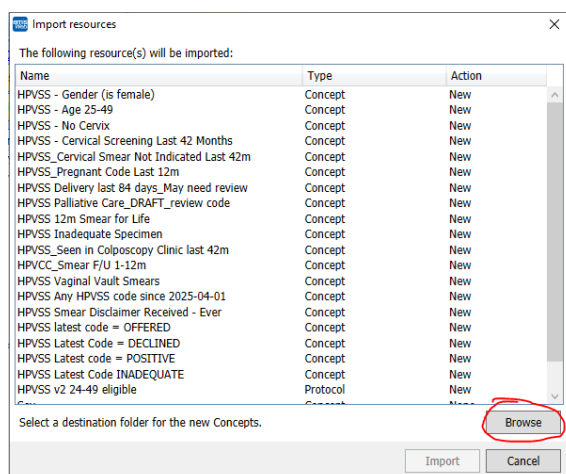
1.4.2. Click import on the top ribbon



1.4.3. The windows navigation box opens.

1.4.4. Navigate to the HPVSS 24-49 protocol on your desktop or download folder & select it.

1.4.4.1. You will receive a message box holding the protocol concepts saying you are importing concepts and asking where to save these. Use the 'Browse' button to navigate to the folder where you want to save them.



1.4.4.2. Navigate to where you want to save the concepts HPVSS-London Pilot 2025 to and select the folder & select 'import'.

NHS London Opportunistic HPV Self-Sampling: Professional Guidance

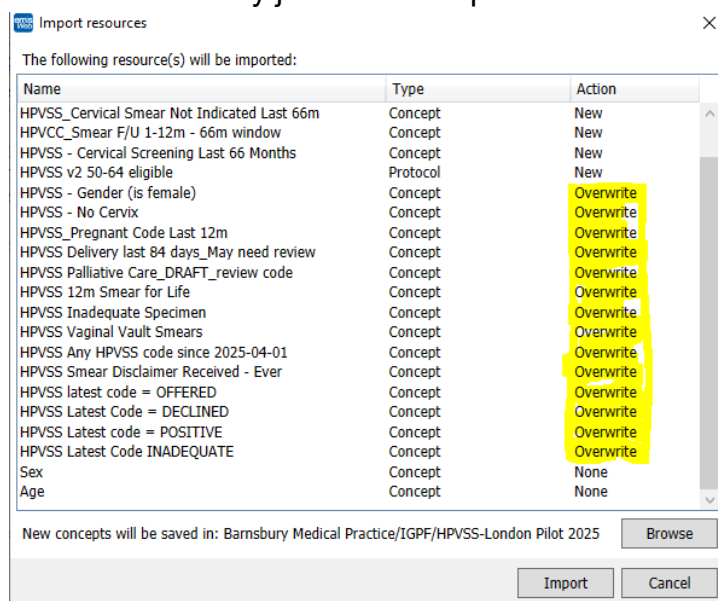
You will get a message saying importing a number of new concepts then 'Import complete. Refreshing...please wait'. This might take a little while.

Import complete. Refreshing... please wait.

When complete you can import the other protocol.

1.4.5. Navigate to the HPV 50-64 protocol on your desktop or download folder & select it and t

- 1.4.5.1. You will get a message box holding the protocol concepts saying you are importing concepts and asking where to save them. Use the 'Browse' button to navigate to the *HPVSS-London Pilot 2025 concept* folder. Note that some of the concepts will be 'new' and some will say they are going to 'over-write' some concepts (see below). This is because the two eligibility protocols share the majority of their concepts with only the age & interval periods being different. Do no worry just select 'Import'.

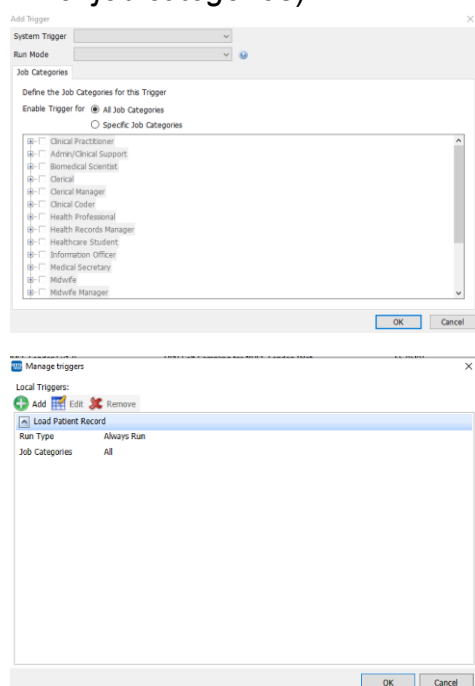


- 1.4.6. **Set Protocol Triggers for Both Protocols** to make the pop-up run automatically you need to set the triggers defining what action activates it & when & for whom.

- 1.4.6.1. Right click the protocol and Select 'Protocol' then select 'Manage Triggers'.
- 1.4.6.2. Select 'Add'
- 1.4.6.3. Set the action for the 'System Trigger' as 'Load Patient Record'
- 1.4.6.4. Set the 'Run mode' as 'Always Run'.
- 1.4.6.5. Set the 'Job Category' as 'All Job Categories'

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1.4.6.6. Click OK. (You may choose to select slightly different settings for job categories)

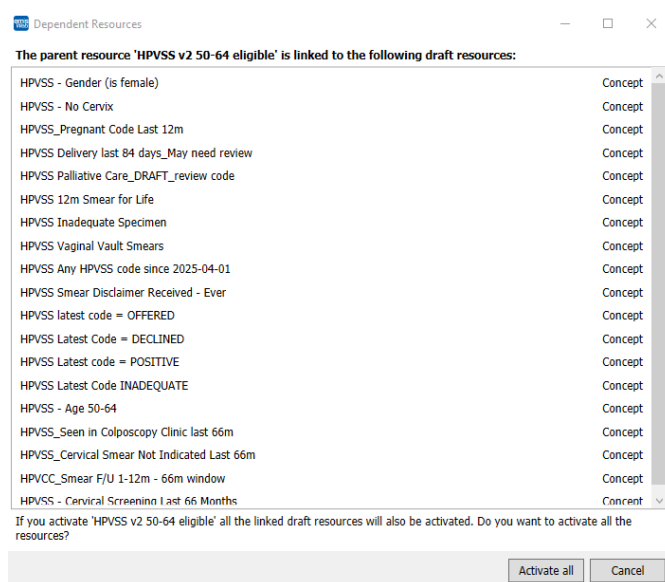


1.4.7. Activate the Protocols

1.4.7.1. Activate the Protocol by right clicking selecting 'Status' and selecting 'Activate'

1.4.7.1.1. It will ask if you want to activate all the linked resources.

1.4.7.1.2. Select 'Activate All'



1.4.7.2. You may need to wait awhile for this to process. You may also need to 're-fresh' using the icon on the toolbar.

1.4.8. Check a known eligible patient from each age category to see if the pop-up appears. (**Remember the protocol must be Active & have correct triggers to display**)

2. EMIS HPV SS alerts – bottom right-hand of screen

Status	Alert displayed text	Detailed text if hover over alert	Alert
Eligible, 6m overdue & No offer	"Offer HPV Self-Sampling"	"Patient is due for Cervical Screening and is eligible for HPV Self-Sampling"	
Offer coded but no outcome ie either declined or result	"HPVSS Was Offered"	"Cervical HPV self sampling has been offered but no outcome coded"	
Offer declined coded not subsequent code	"HPVSS Was offered and Declined"	"HPVSS Latest code entry was Declined"	
Latest result code is HPVSS positive	"HPVSS result was POSITIVE"	"HPVSS Positive Result - Requires screening by clinician"	
Latest result code is HPVSS inadequate	"HPVSS test result was INADEQUATE"	"HPV Self-sampling result was inadequate - if 1st HPVSS inadequate repeat self sampling. If 2nd screen by clinician."	

There is no pop-up for negative as this does not need opportunistic action.

3. How to import an EMIS template

For those with Template Manager see

<https://www.youtube.com/watch?v=sGWIDfHoY08>

3.1. **Download the template** onto your desktop.

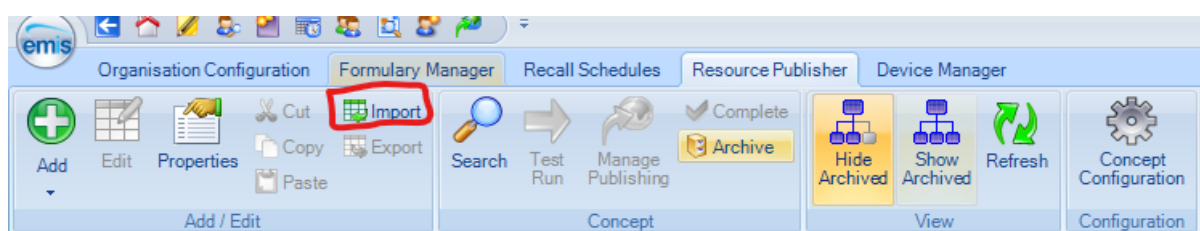
3.2. **Decide which folder** in Resource Publisher 'Protocol & template' hierarchy you wish to save your template. **We suggest you save it in the same subfolder where you saved your HPVSS protocols ie 'HPVSS – London Pilot 2025'**



3.3. To import the template

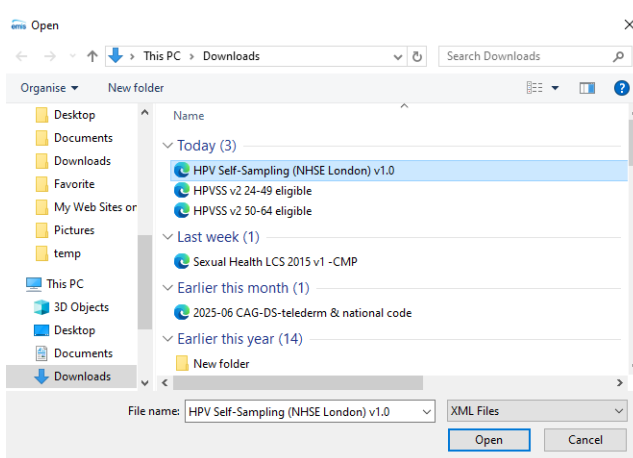
3.3.1. Highlight the destination folder

3.3.2. Click import on the top ribbon



3.3.3. The windows navigation box opens

3.3.4. Navigate to the template on your desktop or download folder & select it.



3.3.5. Select 'Open'. (If you have previously imported the template of the same name – even if it is archived it will ask you if you want to over-write. Select Yes).

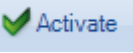
3.3.6. It may not immediately appear if you have Resource Publisher you will

need to 'refresh' your folders using the  icon on the toolbar. If it still does not appear you may need to exit EMIS and re-load.



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3.4. **Activate the template.** Once successfully imported test run and if all running

well activate using the  icon on the toolbar.

4. Screenshots of EMIS Template

HPV Self-Sampling (NHS London) v1.0 - Template Runner

MOUSE, Minnie (Ms) Born 01-Jan-1999 (26y) Gender Female
EMIS No. 516899 Usual GP SEYMOUR, Craig (Dr)

Template Runner

Pages « HPVSS Process

Main Page - Assessment & Offer

Optional - Health Data Entry

Eligibility Criteria - Info

Risks and Benefits - Info

Offer and Test - Info

Results - Pathway & Data entry

Resources

HPVSS Process

Please ensure you have completed the HPV self-screening training before making this offer - see the link to the training in the "Resources" tab

To offer the cervical screening kit:

1. Check eligibility (please see 'Eligibility Criteria' page)
2. Ascertain the following - if any of these are present, then suggest another time to complete the self-sample:
 - a) Recent gynaecological operation or in the case of unusual bleeding or pelvic pains.
 - b) In the 3 days prior to self-collection, was there use of vaginal ovules, creams or washes, vaginal contraceptives or condoms
 - c) In the 2 days prior to self-collection, was there sexual intercourse or ultrasound scans or gynaecological examinations
3. Briefly explain the self-sampling pathway.
 - a) Explaining the offer and test (please see 'Offer and Test' page)
 - b) Explaining the steps after the test (please see the 'Results' page)
 - c) Explaining the risks and benefits and off-label use (Please see the 'Risks and Benefits' page)
 - d) Offering the opportunity to ask questions.

4.1 Main Page – Assessment & Offer

Main Page - Assessment & Offer

HPVSS Process

Please ensure you have completed the HPV self-screening training before making this offer - see the link to the training in the "Resources" tab

To offer the cervical screening kit:

1. Check eligibility (please see 'Eligibility Criteria' page)
2. Ascertain the following - if any of these are present, then suggest another time to complete the self-sample:
 - a) Recent gynaecological operation or in the case of unusual bleeding or pelvic pains.
 - b) In the 3 days prior to self-collection, was there use of vaginal ovules, creams or washes, vaginal contraceptives or condoms
 - c) In the 2 days prior to self-collection, was there sexual intercourse or ultrasound scans or gynaecological examinations
3. Briefly explain the self-sampling pathway.
 - a) Explaining the offer and test (please see 'Offer and Test' page)
 - b) Explaining the steps after the test (please see the 'Results' page)
 - c) Explaining the risks and benefits and off-label use (Please see the 'Risks and Benefits' page)
 - d) Offering the opportunity to ask questions.
4. Record the kit offer below and complete the tQUEST form.
5. Complete the sample tube label and stick on the collection tub.
6. Print the tQUEST form.
7. Individual takes their sample at the Practice
8. Insert the tQUEST form in to the collection bag with the sample.
9. Leave samples in the usual CSL Collection bag.

Resources for healthcare professionals and patients can be found in the 'Resources' page

Past HPVSS offers

Any Previous HPVSS?

Last HPVSS offer:	24-Jul-2025	»
Last HPVSS declined:	No previous entry	
Last inadequate HPVSS:	27-May-2025	»
Last HPVSS or HPV Test Result:	No previous entry	

NHS London Opportunistic HPV Self-Sampling: Professional Guidance

Assessment	
☐ Last menstrual period -1st day	28-Jul-2025
Text:	
Text: 3 Qs for Recent Gynae History	
Abnormal Bleeding?	
Symptoms of vaginal discharge	
Text:	
Text Entry: Symptoms of vaginal atrophy or dryness	
Text:	
☐ Has Pain on sexual intercourse?	No previous entry
Text Entry: Vaginal oestrogen use?	
Text:	
Text Entry: Further history/comments (including HRtuse/current contraception)	
☐ Text: Risks & Benefits of 'Off-label' ie 'Dry' use of swab explained:	
If the patient chooses to have a NORMAL sample by a sample-taker please 1) Code the Offer & Decline on this template & save & then 2) PLEASE USE YOUR NORMAL CERVICAL SCREENING TEMPLATE not this one.	

This HPVSS Offer	
Did the woman or person with a cervix accept the kit? Please select the correct option below and complete the free text box: If "Yes" Tick 'Yes' box and Explain use of kit If "No" Tick 'NO' box & ALSO tick the DECLINED Box & Record the reason in the text box.	
☐ Offer of self-sampling kit - Was the Kit Accepted? "YES"	Text: Was the HPVSS Kit Accepted? "YES"
☐ Offer of self sampling kit - Was the kit accepted? "NO"	Text: Was the kit accepted? "NO"
☐ TICK THIS BOX IF HPVSS DECLINED	Text: Reason for declined?
Explain the HPVSS Results Pathway to Patient Explain the HPVSS results pathway to the Patient (see Results Pathway Page)	
☐ Informing patient of test result process	Text: HPV Self-sampling Results pathway explained to patient -
☐ Text: Patient understands they may need to return for sample taker test if result is positive	Text:
Cancel	

4.2 Optional – Health Data Entry Page

HPV Self-Sampling (NHSE London) v1.0

Pages «

- Main Page - Assessment & Offer
- Optional - Health Data Entry**
- Eligibility Criteria - Info
- Risks and Benefits - Info
- Offer and Test - Info
- Results - Pathway & Data entry
- Resources

Safeguarding

☐ Advice given about domestic abuse Text

☐ Had discussion about female genital mutilation Text

Other screening

☐ Text: Patient is Breast Aware Text

Breast Screening

☐ Text: Patient Bowel Cancer Aware Text

Bowel Cancer Screening Information

HPV Vaccination History

HPV vaccination history

☐ Text: Patient states has had HPV vaccination course Text

Common Health Data

O/E - blood pressure reading / Text

Smoking Status

Smoking Cessation advice

Alcohol status

Alcohol Advice

Body weight kg

Standing height cm

Body Mass Index Text

4.3 Eligibility Criteria - info Page

Pages «

- Main Page - Assessment & Offer
- Optional - Health Data Entry
- Eligibility Criteria - Info**
- Risks and Benefits - Info
- Offer and Test - Info
- Results - Pathway & Data entry
- Resources

Eligibility Criteria

NHSE London HPV Self Sampling Pilot Eligibility Criteria

- Registered with a London GP Practice accredited as participating in the HPVSS

AND

- Any woman and person with a cervix who is:
 - a) aged 24.5 years to 64 years AND at least 6m overdue screening.

OR

- b) aged 65+ AND not screened since 60.

OR

- c) has yet to meet the criteria to be ceased from the programme AND at least 6m overdue screening

AND

- To reiterate At least 6m overdue screening

AND

- Has NOT had a cervical screening result in the last 3.5y for 25-49yo or 5.5 years for aged 50-64

AND

- NOT on an early-recall pathway

AND

- NOT on a test-of-cure pathway

AND

- NOT known to be pregnant or less than 3m after given birth

AND

- NOT new to cervical screening in England (to be eligible for this pathway it must be at least 6m since they became eligible for cervical screening in England)

AND

- NOT ceased/suspended

4.4 Risks & Benefits – Info Page

Pages

«

Main Page - Assessment & Offer

Optional - Health Data Entry

Eligibility Criteria - Info

Risks and Benefits - Info

Offer and Test - Info

Results - Pathway & Data entry

Resources

Explain Benefits & Risks

Benefits

- Ensures the individual has screening (self-screening 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 doctor or nurse. Evidence shows no difference in outcomes and 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 you could say...

"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."

4.5 Offer & Test – Info Page

Pages

«

Main Page - Assessment & Offer

Optional - Health Data Entry

Eligibility Criteria - Info

Risks and Benefits - Info

Offer and Test - Info

Results - Pathway & Data entry

Resources

Offer & Test

Explain the offer:

- Explain that the person is overdue their cervical screening
- This practice 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 nurse or doctor.

Explain the test:

- The test is taken themselves in private.
- It should be done here in the clinic/practice
- 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 to the laboratory, they will look for human papillomavirus (HPV) on the sample, which is a known cause 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

If the patient chooses to have a NORMAL sample by a sample taker please

1) Code the Offer & Decline on this template & save

& then

2) PLEASE USE YOUR NORMAL CERVICAL SCREENING TEMPLATE not this one.

4.6 Results – Pathway & Data Entry Page

HPV Self-Sampling (NHSE London) v1.0

Pages < Results

Main Page - Assessment & Offer
Optional - Health Data Entry
Eligibility Criteria - Info
Risks and Benefits - Info
Offer and Test - Info
Results - Pathway & Data entry
Resources

REMEMBER: It is the clinician's responsibility to follow up and act on the results of this self-screening.

Explain the next steps to the patient:

1st HPVSS - Comes back Negative for HPV

- 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. (Please note for 25-50yo new intervals do not apply to self-screening).

1st HPVSS Comes Back Positive for HPV

- If **HPV is found** on the self-collected sample, the individual **will need to have a "usual" screening test undertaken by a sample-taker nurse or doctor.**
- This sample-taker 2nd sample will be tested again for HPV.
- If **no HPV is found** on this 'sample-taker' 2nd sample the individual will **return to routine recall** and be invited again for screening **under the new recall schedule.**
- If **HPV is found** on this 'sample-taker' 2nd sample, the sample will be checked for abnormal cells. If this **test finds cell changes**, the patient will be invited for a **colposcopy.**
- If the test by the nurse or doctor finds **HPV but no cell changes**, the patient will be invited to have **another HPV screening test in one year** to make sure no cell changes have occurred.

1st HPVSS Comes back Inadequate

- If the 1st self-sample comes back as **inadequate** the patient will be offered a 2nd HPV self-sample.
- If this 2nd HPVSS also comes back **inadequate** then the patient should have a sample done by a sample-taker.

Latest HPVSS results

Last HPVSS or HPV Test Result: 25-Jul-2025

HPVSS Result to enter coding: 28-Jul-2025

Text: Comment:

4.7 Resources Page

HPV Self-Sampling (NHSE London) v1.0

Pages < Resources

Main Page - Assessment & Offer
Optional - Health Data Entry
Eligibility Criteria - Info
Risks and Benefits - Info
Offer and Test - Info
Results - Pathway & Data entry
Resources

Links to useful resources:

Information for Healthcare Professionals:

- [London HPV self-screening webpages](#)
- [HPV SelfScreen Professional Guidance](#)
- [HPV SelfScreen training webinar for healthcare professionals](#)

Information for Eligible Patients:

- [Patient instruction leaflet](#)
- [Patient instruction video](#)
- [Patient Information Leaflet](#)

Template version

Template Version HPVSS (NHSE London) v1.0 08-Aug-2025

5. **If you took Part in YouScreen** – you may need to deactivate a YouScreen protocol that launches when the self-sampling 'offered' code is entered.

5.1. **Test this by entering the code 'HPV self-sampling offered'** code into a test/dummy patient.

5.1.1. If a YouScreen Lab consent for automatically launches then you need to deactivate their protocol

5.1.2. If nothing happens then there is no action needed.

5.2. **How to de-couple the 'Offered' code** from the Youscreen Lab consent form in EMIS

5.2.1. Resource publisher

5.2.2. Protocols & templates

5.2.3. Search 'Youscreen'

NHS London Opportunistic HPV Self-Sampling: Professional Guidance

Protocols and templates	Name	Description	Resource Size	Type	Published	Date Modified	Status
- AT Medica DMS-T - Blood Pressure (BP) Data Entry - Breast Screening Template - Central Team ATN - Childhood Immunisation Project F12 - CORD - Corona Virus - COVID PRINCIPLE - COVID-19 - Digital Central Team - Dr IQ - Flu Vaccination - Hanley - ICPF - ISL Templates - Letters - Nurun - Orphaned Migrated Protocols and Templates - HCS Templates - Practice Template - Protocols - PSDs - QIST - Repeat Dispensing RD Protocol F12 Key - Research/Study - Screening - Sensitive Codes - Smear - SWOKED prep - Superadmin - Test - YouScreen - Emis Library - Emis Goldmine	- YouScreen - Print Data Opt-Out Notification Form Protocol_V1 - YouScreen - Print Lab Consent Entry Protocol_V1.0_20NOV20 - YouScreen - Print Lab Consent Form Protocol_Version 1.0_13 - YouScreen - Self-sample results entry protocol_V1.0_30OCT20 - YouScreen - Self-sample results template_V1.0_30OCT20	- Imported item. - Imported item. - Imported item. - Imported item. - Imported item.	4.73KB 1.65KB 5.5KB 10.21KB	- Protocol - Protocol - Protocol - Protocol - Clinical Template	- No - No - No - No - No	11-Nov-2020 11-Nov-2020 11-Nov-2020 11-Nov-2020 11-Nov-2020	- Active - Active - Active - Active - Active

5.2.4. Select 'YouScreen – Print Lab Consent Form Protocol...'

5.2.5. Right click

5.2.6. Select 'Status'

5.2.7. Select 'Deactivate'

5.3. **Refresh Resource publisher and re-enter the 'offered' code** to check it has now deactivated.

Appendix C: 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 participating in the HPVSS,
 - Any woman and person with a cervix aged 24.5 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 practice 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 nurse or doctor.
- Ascertain the following – if any of these are present, then suggest another time to complete the self-sample:
 - Recent gynaecological operation or in the case of unusual bleeding or pelvic pains.
 - In the 3 days prior to self-collection, was there use of vaginal ovules, creams or washes, vaginal contraceptives or condoms.
 - In the 2 days prior to self-collection, was there sexual intercourse or ultrasound scans or gynaecological examinations.
- 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 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 nurse or a doctor. 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 nurse or doctor 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 doctor or nurse. Evidence shows no difference in outcomes and 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 D: SNOMED codes for HPV self-sampling

Scenario	Code Name	Code Number
Individual accepts the HPV self-sampling offer	Human papillomavirus self-sample screening offered	1091941000000105
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 E: tQuest HPV self-sample form

All participating practices should be presented with these options. Please select “Self-sample HPV test.”

EDITEPATIENT, SEVEN (01/01/1945) (NHS#: 999 999 9522)

Patient Request Order

▼ Cervical Screening London

Cervical Screening London

☐ Cervical Screening ☐ Self-sample HPV test

The following screen will appear for completion.

EMIS Health | tQuest - Additional Questions / Information Regarding This Test -- Webpage Dialog

Additional questions / information regarding Self-sample HPV test

1. Last clinician collected sample date *

None

2. Reason for Self Sample Test

☐ At least 6 months overdue routine screening

☐ One previous invalid/inadequate HPVSS result

3. Date of self sample collection *

None

4. Patient acknowledges sample collection instruction? *

☐ Yes ☐ No

5. Correspondence to patient's home address? (Y/N) *

☐ Yes

☐ No

6. Ethnic Origin

☐ White

☐ Asian

☐ Black

☐ Mixed

☐ Other

☐ Unknown

<

>

Cancel

Save

Appendix F: Patient instructions for collecting self-screen sample

Long version provided in Grab Bag



HPV SELF-COLLECTION PACK

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

Important information

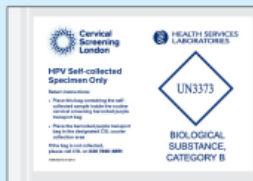
- Please read these instructions carefully and completely before attempting to collect your sample.
- If the instructions are followed you should experience minimal discomfort and no pain.
- Sample collection should not be performed: during menstruation (your period), during pregnancy, in the three months 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



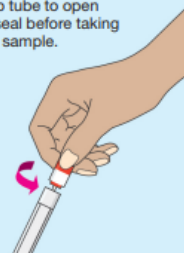
Sample label

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.**
-

- 4** 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.

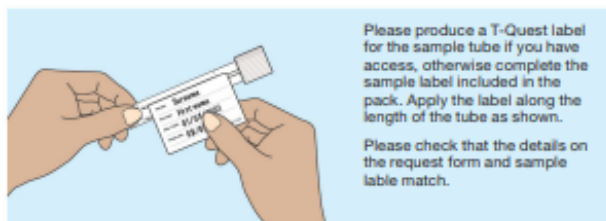
Hand the swab collection tube, clear sample bag, sample label and this instruction sheet to your healthcare professional.



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.



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)

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TAP5696/15-07-25/V6



HPV SELF-COLLECTION PACK

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

Important information

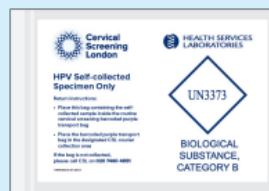
- Please read these instructions carefully and completely before attempting to collect your sample.
- If the instructions are followed you should experience minimal discomfort and no pain.
- Sample collection should not be performed: during menstruation (your period), during pregnancy, in the three months 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



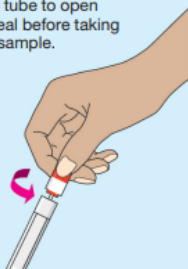
Sample label

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.

- 4 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

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TAP5692/17-07-25/V8

Appendix G: Standard codes for reporting to CSMS

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 H: 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
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