



FAQs for Providers.

Self-collection updates to the
National Cervical Screening Program
Clinical Guidelines

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NATIONAL
CERVICAL SCREENING
PROGRAM

A joint Australian, State and Territory Government Program

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FAQs for Providers

Who is eligible for self-collection of a vaginal sample from July 1st 2022?

Self-collection of a vaginal sample is available for anyone who is eligible for National Cervical Screening Program (NCSP) and who only needs an HPV test. In some specific cases, a co-test (both an HPV test and cytology on the same sample) is recommended – for example in those recently treated for a high-grade abnormality, who were exposed to Diethylstilbestrol (DES) in utero, or symptoms suggestive of cervical cancer, after a total hysterectomy with a history of high-grade changes, suggestive of cervical cancer. Self-collection of a vaginal samples is not suitable for those who require a co-test, because cytology cannot be performed on a self-collected vaginal sample. If a co-test is required, a clinician-collected sample is needed.

[Refer to REC 6.1](#)

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Is self-collection sample as accurate as using a clinician-collected sample?

Yes. Earlier evidence suggesting that self-collection of a vaginal sample was not as accurate was based on results using older HPV test technology (signal-based tests). There are now results based on newer PCR-based HPV tests. This evidence[^] shows that when a PCR-based HPV test is used, HPV testing works equally well on clinician-collected cervical and self-collected vaginal samples. In Australia, labs are required to use PCR-based tests on self-collected vaginal samples.

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Why is self-collection of a vaginal sample being offered to everyone from 1st July 2022?

Self-collection of a vaginal sample is safe, effective and acceptable to people eligible for screening, especially those who are under-screened.

Self-collection of a vaginal sample has been available to never- and under-screened people since the National Cervical Screening Program (NCSP) transitioned to HPV screening, for the explicit purpose of increasing participation in screening. In practice, the previous restrictions on eligibility for self-collection of a vaginal sample made it difficult for clinicians to offer self-collection, as there were challenges in identifying whether people met the eligibility criteria. The restrictions also made it hard for self-collection of a vaginal sample to be promoted to under-screened people and awareness that it was an option was limited. This meant that self-collection of a vaginal sample was not reaching its full potential and not having the intended effect of making screening more accessible to those who were under-screened.

Providing a universal option of self-collection of a vaginal sample removes these barriers and means it becomes part of the suite of normal practice. This will make it easier to reach its original target of under-screened people and to prevent many more cervical cancers. As self-collection of a vaginal sample is just as accurate as HPV testing on a clinician-collected cervical sample, there is no reason to not offer everyone the choice of how they want their sample to be collected.

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Are there cases when women should not be offered self-collection of a vaginal sample?

Self-collection of a vaginal sample is not suitable for those who require a co-test. Co-tests are required for test-of-cure after treatment of high-grade or glandular abnormality, investigation of symptoms suggestive of cervical cancer and DES-exposed in utero. Note that self-collection of a vaginal sample is safe in pregnancy.

[^]Arbyn et al, BMJ 2018 <https://www.bmj.com/content/363/bmj.k4823>

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Will there be a change to the pathology MBS items for self-collected vaginal samples?

Yes, as of the 1st of July 2022, Medical Benefits Schedule (MBS) items 73071 (routine screening on a self-collected vaginal sample) and 73073 (follow-up testing for those originally screened on a self-collected vaginal sample) will be amended to remove the restriction that they can only be used for under-screened people.

In addition to these changes, it is expected that amendments to relevant MBS items to support testing on a self-collected vaginal sample at the follow-up test for people whose initial screening test was done on a clinician-collected cervical sample will be effective from 1 November 2022. Follow-up testing can still be done using a self-collected vaginal sample if the original screening sample was also self-collected vaginal sample.

As is the case for screening on clinician-collected cervical samples, Medicare reimbursement for routine screening on self-collected vaginal samples is restricted to those aged at least 24 years and 9 months and only once in a 57-month period (4 years and 9 months). This reflects the recommended start age and frequency of routine cervical screening. The [NCSP Clinical Guidelines](#) allow for a single HPV test between 20 and 24 years of age for those who experienced their first sexual activity at a young age (<14 years) if they had also not received the HPV vaccine before first sexual activity, although this HPV test is not actively recommended due to a lack of evidence for its value. Medicare reimbursement for this single test between the age of 20 and 24 in a very specific group of people is expected to be effective from 1 November 2022.

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Can self-collection of a vaginal sample only be offered in a clinic?

No. Patients attending an in-person consultation should be encouraged to collect a sample while they are still at the clinic, because this is expected to increase the likelihood that the sample will be collected and returned. However, with the aim of maximising participation in cervical screening, collection of the sample can occur in any setting that the healthcare professional ordering the test believes is appropriate. This includes settings outside a clinic or in the context of a telehealth consultation. The Guidelines allow for flexibility around where the sample can be collected, to enable providers to develop models that will best meet the needs of their communities.

The healthcare professional who requests the test is responsible for facilitating patient access to, and return of, self-collection swabs, requesting tests from laboratories and communicating results and any follow-up requirements to patients.

The pathology laboratory that processes the sample is responsible for delivering the results to the healthcare professional who requested the test, and the healthcare professional who requested the test is responsible for informing the patient of their results and any required follow-up.

[Refer to REC 6.17](#)

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Which settings can a self-collection of a vaginal sample be offered in?

The setting where the sample is collected must be one that the healthcare professional ordering the test considers appropriate. This could include, for example, at home or in a community setting. The Guidelines deliberately provide flexibility in relation to setting to enable providers to develop models of care that will best meet the needs of their community.

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Do I need to supervise the patient collect their sample?

No, this is not necessary, unless it is the patient's preference or request. The patient should be provided with information on how to collect the sample, but there is no requirement to observe the patient collecting their sample (unless that is what the patient prefers).

[Refer to REC 6.17](#)

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Can the patient take the self-collection swab home? What happens if they don't return it?

Patients attending an in-person consultation should be encouraged to collect a sample while they are still at the clinic, as sample collection is considered more likely in this context. However, collection of the sample can occur in any setting that the healthcare professional ordering the test believes is appropriate, including the patient's home. Use of electronic medical record reminder and recall systems would be useful in this context to ensure the swab is returned to the clinic or the laboratory.

The healthcare professional who requests the test is responsible for providing patient access to self-collection of vaginal swabs, and facilitating access to return self-collected vaginal samples.

The NCSR will continue to send the usual reminders to people who are overdue for screening, if no sample is received, and providers have access to their patients' screening histories via the [NCSR Provider Portal](#).

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Will self-collection kits be mailed out to everyone?

The NCSP is not delivering a home mail-out program to everyone. The connection between a primary care provider and a patient is considered essential to providing appropriate care and follow-up for screening participants. The NCSP Clinical Guidelines allow for flexibility in where the sample can be collected, and this can be done anywhere that the healthcare professional ordering the test believes is appropriate. This could include sending the swab to patients, for example in conjunction with a telehealth consultation, if providers consider that this will best meet the needs of their communities.

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As a health professional, am I expected to offer self-collection to everyone, and in different settings?

NCSP Clinical Guidelines recommend that anyone who is eligible for cervical screening should be offered the choice of HPV testing on a self-collected vaginal sample or on a clinician-collected cervical sample. Offering people the choice of either self-collection or clinician-collection is an important opportunity to increase participation in the NCSP and make screening more accessible to those who have previously been reluctant to screen.

The NCSP Clinical Guidelines around the settings where self-collection of a vaginal sample can be offered are intended to provide flexibility for health care professionals and services to develop models of care that will best suit their communities, to maximise participation in screening. The setting where the sample is collected must be one that the healthcare professional ordering the test considers appropriate.

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Can a healthcare provider assist someone to take a swab, for example, people with a disability or who are uncomfortable doing it themselves?

Yes. People who have difficulty collecting a vaginal sample by themselves could be assisted to do so by the provider. The provider could also collect the sample using a self-collection swab but without using a speculum if people have difficulty collecting the sample or if they would prefer a non-speculum sample collected by a clinician. This approach might be especially helpful for those who experience discomfort when a speculum is used.

A vaginal sample collected in this way is still classified as self-collection on the pathology request form.

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Does this change mean everyone has to use self-collection of a vaginal sample? What if my patients prefer to have a clinician-collected cervical sample?

Patients who prefer to have a clinician-collected cervical sample can continue to do so. The change simply means that people should be offered the choice of testing on either a clinician-collected cervical or a self-collected vaginal sample. There are some advantages of testing on a clinician-collected cervical sample, in particular that if HPV (not 16/18) is detected, LBC can usually be done directly on the same sample, reducing the number of clinic visits.

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What occurs if the self-collected sample comes back positive for HPV?

If HPV 16 or 18 are detected – direct referral for colposcopy is recommended. LBC is not required before colposcopy and a sample for LBC will be collected at colposcopy.

If HPV (not 16/18) is detected – in most cases, a clinician-collected cervical sample is required for LBC to assist in further management, with a recommendation for the patient to return to the clinic as soon as practical.

In some cases, colposcopy referral is recommended for all patients with any HPV detected, regardless of the type. This includes, for example, if any HPV is detected in those aged 70-74 who are attending for an exit test, in those living with HIV or who are immune-deficient, or in some people attending for a follow-up test after a previous positive HPV test. In these cases, a clinician-collected sample for LBC is not required before colposcopy.

[Refer to Flowchart 6.1](#)

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How will my patient and I know if they have collected the vaginal sample correctly?

Cervical cells are not required for an HPV test. Most people who have used self-collection report that they found it easy to do, and unsatisfactory HPV tests are very rare. HPV tests used in the NCSP have a cellularity control and a control for inhibition/assay failure, and so can detect if the test is not satisfactory. The cellularity control can detect if the sample has insufficient or no cells for analysis, so an empty sample will not result in an incorrect result and recommendation to rescreen in 5 years. The control for inhibition/assay failure is able to detect if contaminants, such as blood, have affected the test's ability to detect HPV.

If the test result is unsatisfactory, the process is the same as for a clinician-collected cervical sample: the patient should be advised of the result and the potential reasons why this might have occurred, and recommend that another sample is collected as soon as is practical. Unlike cervical samples, it is not necessary to wait 6-12 weeks after a vaginal sample before repeating the test. If the reason for the unsatisfactory sample has been identified, then this problem should be corrected if possible before the repeat sample is collected.

[Refer to REC 4.3](#)

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Can a self-collected vaginal swab be collected if the patient is menstruating?

While the presence of blood may rarely result in inhibition of a sample and patients can be advised to present at time when they are not menstruating, a self-collected CST should not be deferred if it is unlikely the patient will return at a later date. HPV tests used in the NCSP have a control for inhibition/assay failure, and so can detect if blood has affected the test.

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Will I need to send self-collected vaginal samples to a different pathology laboratory for processing?

It depends which self-collection swab your laboratory supports and can process themselves, if any. There is a range of collection devices available for use under the NCSP for self-collected vaginal samples. These, and the processing and handling requirements, will vary across laboratories.

Talk to your usual pathology provider in the first instance to:

- confirm that they can process self-collected vaginal samples, or
- confirm that they have an arrangement in place to send on self-collected vaginal samples to a laboratory that is accredited to process self-collected vaginal samples, and
- order the correct swabs and other consumables for offering self-collection.

If your local pathology provider is unable to process self-collected vaginal samples and does not have an arrangement in place to send samples to an accredited laboratory for processing, healthcare professionals can contact an accredited pathology laboratory directly to arrange for processing of the sample.

From 1st July 2022, the Australian Government Department of Health website provides a list of accredited pathology laboratories who can process self-collected vaginal samples and where samples can be sent. The list will continue to be updated over time as additional laboratories can provide this service. The pathology laboratory can advise on the time allowed between the sample being collected and received at the laboratory.

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How do I get a self-collection kit?

Talk to your laboratory for advice on the type of self-collection swab it supports or can process and to get advice on how to order the swabs.

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What do patients need to know when I offer them self-collection of a vaginal sample?

Some key information for your patients includes the following:

- The test is just as accurate, regardless of whether they choose self-collection with the swab or clinician-collection with a speculum.
- They have the choice between self-collected vaginal samples and clinician-collected cervical samples.
- What will happen if HPV is detected, and how this differs for self-collected vaginal and clinician-collected cervical samples. For example:
 - If HPV16/18 is detected, colposcopy will be recommended (regardless of whether they choose self-collection or clinician-collection).
 - If HPV (not 16/18) is detected on a vaginal sample, they will generally need to return for a clinician-collected sample using a speculum, so that LBC can be done to guide further management, which could include colposcopy, or a repeat HPV test.
 - If HPV (not 16/18) is detected on a sample collected by a clinician using a speculum, LBC will automatically be done on the same sample, so in most cases, they won't need to return to have a separate sample taken (this might rarely happen if LBC is unsatisfactory)
 - In some cases, colposcopy referral is recommended for all patients with any HPV detected, regardless of the HPV type (and regardless of the type of sample). For example, if any HPV is detected in patients aged 70-74 who are attending for an exit test, in people living with HIV or who are immune-deficient, or in some patients attending for a follow-up test after a [previous positive HPV test](#). In those cases, LBC is not required before colposcopy, even if their test was performed on a self-collected vaginal sample (a sample for LBC is collected at colposcopy).
- How likely it is HPV will be detected
 - Among those attending for a routine screening test, approximately 2% have HPV16/18 detected and approximately 6% have HPV (not 16/18) detected, although the latter varies by age. HPV is more commonly detected in those who are overdue and in younger people.
- What self-collection involves - how to collect the sample and return it
- Most people find it easy to collect the sample, but if they prefer, they can be assisted in using the swab or a provider can use the swab to collect the vaginal sample without a speculum.

Resources for patients are also available on the [NCSP website](#)

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How can I learn more or access supporting materials to guide conversations with patients?

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What about lost opportunity to inspect the cervix and visually examine the vagina and external genitalia?

Routine inspection of the cervix, vagina and external genitalia is not necessary or indicated for asymptomatic people attending for screening. In cases where there is a clinical indication such as a vaginal discharge, or in populations where there is a high risk for vulvar disease, examination could still be offered.

Refer to [REC 6.20](#)

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Can Aboriginal Health Workers offer self-collection of a vaginal sample? What about other healthcare providers?

Self-collection of a vaginal sample needs to be ordered and overseen by a healthcare professional who can also ensure timely clinician-collected testing if required as part of follow-up assessment, and for Medicare reimbursement. However, within that framework, healthcare professionals have flexibility to develop models of screening in collaboration with other healthcare workers, in order to best meet the needs of their patients and communities.

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Will we be able to offer opportunistic screening for gonorrhoea and chlamydia on HPV self-collection sample for 29-year-olds and under?

Ask your laboratory whether a separate swab is needed when also testing for chlamydia and gonorrhoea.

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