



Your Guide to the

Cervical Screening Self-test Study

He Taonga, He Tapu

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Kia ora! Welcome to the Cervical Screening Self-Test Study

In this study, wāhine are offered a new 'self-test' for cervical screening instead of the usual smear test taken by a doctor or nurse. The self-test is a swab that will be tested for Human Papillomavirus (HPV), which can cause changes to cervical cells.

- The new self-test is safe and effective for cervical screening.
- Self-testing will become part of the National Cervical Screening Programme in 2023.
- This study will help guide how women will be offered self-testing in the future.
- If your self-test shows you have HPV, a follow up smear test or a visit with a specialist is recommended.
- All screening tests and any follow-up is free during this study.

What is self-testing for cervical screening?

Self-testing is when women collect their own sample for cervical screening using a swab in their vagina. This can be done in private or with the support of a nurse or doctor – it's your choice.

The sample is then tested for the presence of the human papillomavirus (HPV), which can cause changes to cervical cells.

What is included in the pack?

- A swab in a sealed tube
- A plastic specimen bag for you to put your self-test in
- A pre-printed lab form that has your name and details on it

If you take your test at home, it will also have:

- A lab test form for you to fill in
- A pre-addressed courier bag for you to return your sample

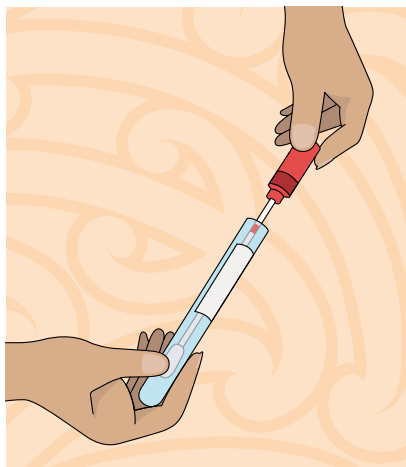
If you have any questions, you can ring our Cervical Screening Self-Test Support Team on 0800 747 354.

How to take your Self-test for Cervical Screening

Taking your self-test is simple; you can do it! Research shows that 99% of people do it correctly. **You don't need to find your cervix to do the test.**

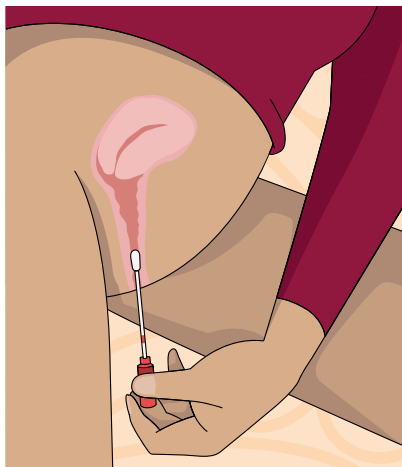
Before you begin, take a moment to relax; you may wish to take a few deep breaths beforehand to relax your body and mind.

1



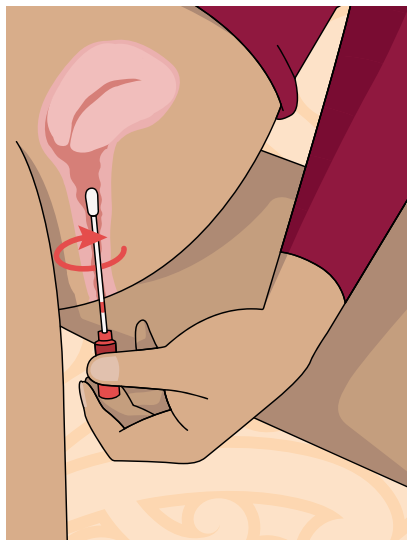
- Open the plastic specimen bag and take out the swab. Be careful not to touch any surfaces with the swab tip.
- The red mark on the stick is to guide you about how far to insert the swab.

2



- Get in a comfortable position. You can stand, sit or lie down.
- Insert the swab into your vagina, about as far as the red mark. You can hold the stick close to the red mark if you like.

3



- Rotate the swab gently for at least 10 seconds.
- Gently remove the swab.
- It should not hurt.

4



- Put the swab in the tube. Push it into the tube until it closes.
- Put the tube back into the plastic specimen bag.

It is okay to continue with the test if you:

- Have touched the swab with your fingers
- Have dropped it onto a dry surface
- Have inserted the swab into your vagina but are unsure if the distance is correct.

If you are worried you have made a mistake, or have any questions, please get in touch with our Cervical Screening Self-Test Support Team on 0800 747 354.

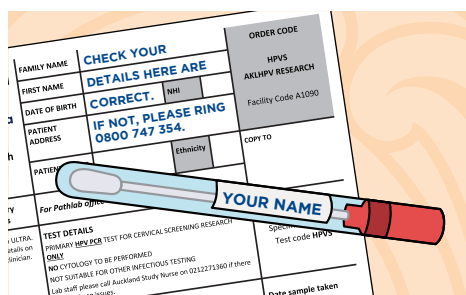
Are there any special handling requirements?

Your self-test can be stored at room temperature. Please arrange for your self-test to be returned as soon as possible.

How to return your Self-Test

Step 1

Check that the lab form and the sample tube are both labelled with your name. If this does not have your details on it, please ring our Cervical Screening Self-Test Support Team on 0800 747 354.



The illustration shows a lab form with the following sections:

- CHECK YOUR DETAILS HERE ARE**
 - FIRST NAME: [blank]
 - DATE OF BIRTH: [blank]
 - PATIENT ADDRESS: [blank]
 - PATIENT: [blank]
 - TEST DETAILS: PRIMARY HPV/PCR TEST FOR CERVICAL SCREENING RESEARCH ONLY. NOT SUITABLE FOR OTHER INFECTIOUS TESTING. Lab staff please call Auckland Study Nurse on 0212271360 if there are any queries.
- HPV'S ARLHPV RESEARCH**
 - Facility Code A1090
 - COPY TO: [blank]
- ORDER CODE**
 - HPV'S ARLHPV RESEARCH
 - Facility Code A1090
 - COPY TO: [blank]
- YOUR NAME** (on the sample tube)

Step 2

Write the date you took the sample on the lab form.

Step 3

Place the lab form inside the plastic specimen bag so that it is with your self-test sample tube. Place the plastic specimen bag into the prepaid and preaddressed courier bag, or if you are in a clinic, give the test to the nurse when you have finished.



Step 4

Return your test as soon as possible.

There are three ways that you can do this, please pick the option that works best for you.

- You can phone our free courier to pick it up **0800 268 743**
- Drop the courier bag into any NZ Post box **or** NZ Post shop
- Drop it in to your nearest Labtest Collection Centre www.labtests.co.nz/collection-centres.



What happens next?

We will contact you via text message with your result 2 to 3 weeks after you return your self-test.

Kōrero mai

Your feedback is really important and will help determine how cervical screening self-testing is offered to women in the future. After we contact you with your result, we will send a link to a survey – we want to hear what you think, so please let us know!

Participant Information Sheet

- You are being offered a new 'self-test' with a cotton swab for cervical screening.
- The swab will be tested for the virus that can cause cervical cancer (HPV).
- The new self-test is safe and effective for cervical screening.
- Self-testing will become part of the National Cervical Screening Programme in 2023.
- This study will help guide how women will be offered self-testing.
- If your self-test shows you have HPV, a follow up smear test or a visit with a specialist is recommended.

What is this study for?

This study is to find out about different ways to offer a self-test for cervical screening to women, so that more women get checked to prevent cervical cancer. In the self-test, women use a swab to sample their vagina to find out if they have the human papillomavirus (HPV). HPV is a virus spread by skin-to-skin contact and some types are linked to cervical cancer. The new self-test is different from, but as good as, the usual smear test which a nurse or doctor does.

What am I being asked to do?

A nurse, doctor or your service provider will talk to you about the self-test and any advantages or disadvantages compared to the usual cervical screening test. Making a

choice about having a cervical screening self-test is your decision. The self-test is being offered as part of a research study so you will need to provide your consent if you choose to do it. You can then use the kit and instruction sheet to do the self-test

Is doing the HPV test myself right for me?

Many people find doing the self-test easier than getting a smear with their nurse or doctor. If you have had a hysterectomy, or previously had an abnormal smear result, ask the study nurse whether the self-test is right for you. If you have had the HPV vaccine, you can still take part in the study. If, at any time, you wish to opt out of self-testing and have a smear test, talk to the study nurse or your own doctor or nurse.

How will I find out the results of my self-test?

A study nurse will contact you with your results two or three weeks after your test. If your test results show you do not have HPV, you don't have to do anything else. Your nurse or doctor will let you know when you are due for your next cervical screening test. You will have the option of answering some short questions about your experience being offered the self-test.

What if my test results show I have HPV?

A test result that shows you have HPV does NOT mean you have cervical cancer. The study nurse will talk more about what the test results mean. Depending on the result, it might mean you need to have a follow up smear, or it might mean a visit to a specialist (a colposcopy at a hospital clinic – which is a simple procedure to look at your cervix). There will be no charge for any follow-up tests. We strongly recommend that you complete the follow-up tests to look for any cell changes that might need treatment. We will talk with you about the follow-up tests and answer all your questions. We can talk with you and your whānau / family if you want us to. The study nurse can also arrange help so you can get to the clinic.

More about the HPV self-test

The new self-test is a very accurate test to check for HPV.

You don't need to know where your cervix is to do the test. Some HPV tests are currently available with a cervical smear taken by a doctor or nurse. The self-test for cervical screening is not yet available to all women, but is being offered as part of some studies. Self-testing will become an option in the National Cervical Screening Programme in 2023. The new self-test does not check for other sexually transmitted infections (STIs) such as chlamydia or HIV.

More about HPV

HPV is very common. Four out of five people will have HPV at some time in their lives. Some types of HPV stay in the body for a long time. For most people, having HPV does not cause any problems. Your body gets rid of the virus by itself. Having HPV doesn't mean that your partner is being unfaithful to you. You could still have HPV even if you are in a long-term relationship with one partner, not currently having sex or have not had sex in a long time. You can find out more about how HPV is linked to cervical cancer here www.hpv.org.nz

How is HPV treated?

There are treatments for cell changes to your cervix caused by HPV. This is why it is important for you to have follow-up tests if your results show you have one of the types of HPV that can cause cervical cancer. Treatment happens at a hospital clinic and is successful at stopping serious cell changes from becoming cervical cancer.

National Cervical Screening Programme

You can find more information about cervical screening and follow up tests online at www.timetoscreen.nz. Everyone who participates in this study will be invited back for another cervical screening test when they are next due. If you have unusual bleeding, pelvic pain, or discharge, please talk with your doctor or nurse – don't wait for your next screening test.

Who is doing the study?

The study is a joint project between Total Healthcare PHO (Tāmaki Health clinics), Te Whatu Ora – Waitematā,

Te Toka Tumai Auckland, and Counties Manukau districts with additional funding from the National Screening Unit to help inform the new National Cervical Screening Programme.

Withdrawing from this study

Being part of this study is your choice. You can choose not to take part, or to withdraw from the study at any time. Your care won't be affected in any way. If you withdraw from this study, we will keep the information we have collected up until the time of your withdrawal. We will not collect any new information after that.

Privacy and Confidentiality

Your test results will be shared with your usual nurse or doctor to make sure you get the correct follow-up. Other people who will have access to information that identifies you (your name, date of birth or address) are study team staff (to track participants and complete study assessments) and laboratory staff (to process and report your screening tests). You have the right to access and correct your information. In the same way as with a smear, your name and test results will also be held on the National Cervical Screening Programme Register and one of the laboratory registers (TestSafe / Éclair). Your self-test or smear sample will be stored by the laboratory for the usual amount of time (for quality

checking). To keep your information confidential during the study, you will be identified by a code so that your name will not be used on the study documents. People and providers working with or for the study sponsor (about 20 people) may have access to coded information for the purposes of this study. Although all efforts will be made to protect your privacy, absolute confidentiality of your information cannot be guaranteed, even with coded information. The risk of people accessing and misusing your information is very small. The results of the study may be published or presented, but not in a form that would reasonably be expected to identify you. De-identified data may be available for use in future related research. Participants will have the option to receive a summary of the overall study results when available.

ACC Statement

It is not likely that you will get injured in this study. If you did, you would be eligible to apply for compensation from ACC just the same as if you were injured in an accident at work or at home. You would have to put in a claim to ACC, which might take some time to be assessed. If your claim was accepted, you will receive funding to help you recover. If you have private health or life insurance, you may wish to check with your insurer that taking part in the study won't affect your cover.

Further Information

Thank you for thinking about being part of the study. If you have any further questions, or complaints about the study, you can contact:

DR KAREN BARTHOLOMEW

Lead Researcher for this study. Phone 09 486 8920 (ext 5434)
Mobile 021 211 5629. Email Karen.
Bartholomew@waitematadhb.govt.nz

Māori Cultural Support Contact

AUCKLAND AND WAITEMATĀ

He Kāmaka Waiora. Phone 09 486 8900 (ext 42324).

COUNTIES MANUKAU

Te Kaahui Ora Māori Health. Email tekaahuiora@middlemore.co.nz

Frequently Asked Questions

Is a cervical screening self-test right for me?

It's your choice. From July 2023 women can choose how they do a cervical screening test as part of the National Cervical Screening Programme (NCSP).

Many wāhine will want to self-test when the option is available. Some may still prefer to have a cervical smear test in the usual way.

For a small number of people, a self-test might not be recommended due to previous cervical screening results.

Are you researching if self-testing is as effective as the regular smear test?

No, this is not the research topic. Self-testing is as accurate as a test taken by a nurse or doctor to check for HPV; and is a more effective test than the current smear test. Self-testing for HPV is part of cervical screening in other countries like Australia, Denmark and the Netherlands and will become part of the National Cervical Screening Programme in 2023. This study is about how best to offer and deliver self-testing to wāhine, whānau and people in Aotearoa.

I have had the HPV vaccine; do I need cervical screening?

Yes, if you have been immunised you still need regular cervical screening tests. While the vaccine protects against the 9 most common types of HPV it doesn't protect against them all, so it's important to have cervical screening even if you have had the HPV vaccine.

I'm not sure if I'm due for screening, how do I find out?

This study is for women due or overdue for their cervical screening. If you're not sure if you are due, you can talk to your nurse or doctor, or you can ring our Cervical Screening Self-Test Support Team on 0800 747 354.

If I'm pregnant, can I still take part in the study?

Yes, the self-test is safe for hapū (pregnant) māmā. There are no safety concerns with people who are pregnant self-testing with a vaginal swab.

I have had a hysterectomy, am I still eligible for the study?

Some people who have had a hysterectomy are still recommended to have regular screening and may be eligible for a self-test. Some will no longer need screening. Talk to your nurse or doctor about if the study is right for you, or you can ring our Cervical

Screening Self-Test Support Team on 0800 747 354.

I've had recent treatment after a cervical smear test

Talk to your nurse or doctor about if the study is right for you, or you can ring our Cervical Screening Self-Test Support Team on 0800 747 354.

I have never had sex, am I eligible for the study?

No, people who have never had sex are not eligible for cervical screening. Talk to your nurse or doctor if you are worried about HPV and are not eligible for cervical screening.

I'm doing the self-test; can my whānau member also take part in the study?

We can check. This study is for people who are eligible and enrolled in participating clinics. You can talk with our Cervical Screening Self-Test Support Team on 0800 747 354.

How do I know if I've done it correctly.

Research shows that 99% of people take a self-test correctly. Along with each testing kit is an easy-to-follow instruction sheet to help you take the sample. You do not need to know where your cervix is to do this test. HPV lives in the genital area instead of just the cervix, so taking your sample from the vagina will pick up whether HPV is present.

Can I take the sample when I have my period?

You can do the self-test when having your period. However, only do this if you are comfortable – otherwise wait until your period has finished.

Can my self-test be checked for STIs?

The self-test does not check for sexually transmitted infections (STIs) such as chlamydia or HIV.

How is my data going to be used in the study?

The cervical screening self-test study will collect anonymous data on all women who are eligible for the study, regardless of whether they return a self-sample. This data will allow us to assess our study endpoints which will tell us about how effective self-testing is and what groups of women self-testing appeals to. The study will only collect information relevant to cervical screening. All information will be kept confidential and securely.

This study has received ethics approval (21/STH/141) and approval from our Te Whatu Ora district Māori Research Review Committee.

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate:

Phone: 0800 555 050
Email: advocacy@advocacy.org.nz
Website: www.advocacy.org.nz