

FAQs – expired samples

Q What is cervical screening?

A cervical screening test checks the health of your cervix. The cervix is the opening to your womb from your vagina. Screening first looks to see if you have any of the high-risk types of human papillomavirus (HPV) that cause cervical cancer. It's not a test for cancer; it's a test to help prevent cancer from developing. If HPV is found, your same test sample will be checked to see if you have any abnormal (pre-cancerous) cells in your cervix. CervicalCheck offers free cervical screening to almost 1.3 million eligible women living in Ireland aged 25 to 65.

People aged 25 to 29 are screened more often because they are more likely to have HPV at that age. If you are aged 25 to 29 you will usually have a cervical screening test every 3 years. If you are aged 30 to 65 you will usually have a cervical screening test every 5 years. It is safe to wait for 5 years between tests if you do not have a HPV infection. This is because the risk of developing cell changes is very low and a test showing that you do not have HPV is more reliable than a test finding normal cells. In most cases, it takes 10 to 15 years for a HPV infection to develop into cervical cancer. Cervical cancer is a rare outcome of a HPV infection.

Cervical screening is one of the best ways to protect yourself from cervical cancer. Regular cervical screening saves lives as it can find HPV before it causes abnormal cells in the cervix. Screening can also find abnormal cell changes before symptoms develop and when they are easier to treat. Finding HPV and abnormal cells early is the best way to prevent cervical cancer developing. This is why having regular screening tests is important.

The main limitation of cervical screening is that it will not prevent all cases of cervical cancer. Some people will still develop cervical cancer despite regular screening because some abnormal cell changes may be missed. Screening will not find every abnormal cell change.

If cervical cancer is found early, it is easier to treat and people have a high chance of a good recovery. Regrettably, not all cancers are detected by cervical screening but the introduction of screening has nonetheless contributed to the reduction of deaths from cervical cancer in countries where such programs operate, including Ireland.

CervicalCheck has provided almost 3.2 million cervical screening tests and detected abnormalities for over 115,000 women, many of which could have developed into cervical cancer if not detected through screening.

If 1,000 people are screened, about 20 people will have abnormal (pre-cancerous) cervical cells: With cytology (the old smear test) 15 of these 20 people will have these cells found through screening, 5 people will not and may develop cervical cancer. With our new test, HPV cervical screening 18 of these 20 people will have these cells found – and 2 people will not and may develop cervical cancer

Population-based cervical screening is most effective among people with a cervix aged 25 - 65 years. Since CervicalCheck started in 2008, the number of women who developed cervical cancer has fallen by 7% year-on-year between 2010-2015 (National Cancer Registry of Ireland latest figures). In the absence of screening, cervical cancer may not have been detected in these people until they developed physical signs or symptoms of more advanced disease.

Q Can a screening programme provide people with complete protection from a disease?

No screening programme in the world can ever provide 100% protection.

A cervical screening test is not a test for cancer. It's a test to help prevent cancer from developing. A screening test looks to see if you might be at risk of developing cancer in the future. This is why it can be effective in reducing the risk of cancer. Like all screening tests, it's carried out on people who are presumed healthy. They do not have any symptoms. But cervical screening, like all screening tests worldwide, is not perfect. Some people will still develop cervical cancer despite regular screening. While the risk of cervical cancer can be reduced, it cannot be eliminated by screening. Regular cervical screening is still one of the best ways to prevent cervical cancer from developing. This is why it is important to attend for a screening test when it is due.

Q Why carry out screening?

Screening is a population health measure for people who are presumed healthy and do not have symptoms. The aim of a population screening programme is to reduce the incidence of disease in a population. Screening is not a diagnostic tool and no screening test is completely accurate.

All screening programmes are limited by the sensitivity of the test which is the ability to detect those with the disease in a population (true positives). Screening programmes are

likewise limited by the specificity of the test which is the ability to detect those who are free of the disease (true negatives). Therefore, a negative test result is not a guarantee that a person is clear of the condition, or that they won't develop the condition between screening appointments. This is why screening programmes call people at regular intervals, as screening is most effective when done regularly.

Despite its limitations, screening is one of the best ways to detect disease in people without symptoms. While cervical screening programmes will not detect all cancers, international evidence continues to support HPV screening tests for population based cervical screening programmes. HPV cervical screening is one of the best ways to protect yourself from cervical cancer.

Australia and Rwanda are set to become some of the first countries in the world to eradicate cervical cancer. This combination of cervical screening and uptake of the HPV vaccine is a proven approach of decreasing cervical cancer.

The HPV vaccine now protects against the types of HPV that cause 90% of cervical cancers. Boys and girls in their first year of secondary school are offered the HPV vaccine as part of the school vaccination programme. The HPV vaccine provides direct protection against HPV-related disease to girls and boys who are vaccinated, and indirect protection to those who have not been vaccinated. The HPV vaccine has greatly reduced cases of pre-cancers of the cervix in young women in many countries including Australia, Sweden, the US and the UK.

However, even if someone has had the vaccine, they will still need to have regular HPV cervical screening. This is because the vaccine does not protect against all types of HPV.

It is important to remember that screening is neither 100% sensitive nor 100% specific – it does not definitively diagnose whether you have, or do not have, abnormal cells/cancer.

HPV cervical screening will result in more people receiving false positive results (transient HPV positivity i.e. the body will clear itself of the virus) compared to primary cytology screening. However the add-on cytology triage test will distinguish between people at sufficient risk to require colposcopy assessment (i.e. people where HPV is detected and there are cytological abnormalities) and those at a lower risk (HPV detected but no cytological changes) that may yet clear the HPV and can be managed by more frequent screening.

Q Where is the screening sample tested? / Can I trust the labs?

Your sample goes to a quality-assured lab provider. It is tested to see if you have a HPV infection. If HPV is found, two experts will examine your sample for abnormal cell changes.

This will help to decide what type of follow-up care you may need. One of our lab providers is Quest Diagnostics Inc, which is headquartered in Teterboro, New Jersey, USA. We use a lab provider in the US because there are not enough quality-assured labs available in Ireland to meet our needs.

To process our samples our lab providers must be certified by the relevant national authorities, meet our quality assurance standards and be subject to regular inspection and assessment.

Our other lab provider is in Dublin. This is the Coombe Women and Infant's University Hospital.

Q Why did my test/ sample expire?

In HPV cervical screening, all screening samples are tested for the presence of human papillomavirus (HPV) first.

If HPV is found, we need to check for changes to the cells in your cervix (neck of the womb). To do this we usually test your sample again (cytology test) for abnormal cells.

We can test for the human papillomavirus (HPV) up to six months after your sample is taken.

However the follow-up test to check for abnormal cells (cytology test) must be done within 6 weeks of the sample being taken.

An expired sample is one that we do not have time to do a follow-up test, if required.

Many women who were unable to attend cervical screening in 2020 had their cervical screening test earlier this year. This led to a larger than expected number of samples taken.

Because of social distancing and COVID-19 infection control measures in our sample collection hub, we could not increase our staff numbers to match this unprecedented demand for screening.

We tested your sample for HPV and HPV was found, but because of the delay we were unable to process your sample in time to offer you the follow-up test to see if abnormal cells are present.

To enable you to have the follow-up test we are asking you to book a second test 3 months after your last test.

Remember, having HPV does not mean you have cervical cancer. Cervical cancer is a rare outcome of a HPV infection. If cervical cancer does develop, in most cases it takes 10 to 15 years to develop.

It is reassuring to know that the majority of people (6 in 10) who have HPV found in their sample do not have abnormal cells. But if you do (4 in 10 people), we will advise on follow-up treatment.

Q What do I do next?

If HPV is found, we need to check for changes to the cells in your cervix (neck of the womb). To do this we usually test your sample again (cytology test) for abnormal cells.

But because your sample was an expired sample, we have not been able to test it for abnormal cells.

You will need to have another cervical screening test 3 months after the date of your first test. We are writing to you and your sampletaker **before the end of July to let you know.**

Your repeat cervical screening test should be at least 3 months after the date of your last test.

You need to wait 3 months so that the cells in your cervix have time to grow back and we can get the best samples.

Your repeat cervical screening test will be free of charge with any GP or sample taker registered with CervicalCheck.

You will need to:

- make an appointment with a GP or sample taker
- bring all the information we have sent you about this issue

Q Will my second sample be prioritised? How do I know my second sample won't expire too?

Your GP is given a label marked URGENT to put on your sample box after they take it. This is to let the lab know that your cervical screening test sample needs to be done as a priority. We will prioritise your sample when we received it.

Q When will I receive my results?

You will receive your results 4 to 6 weeks after your sample is taken. We will send you a letter when your results are ready. Your GP will also get a copy of your results.

Q How do I know if my sample has expired? If I am affected?

This issue does not affect all women who have cervical screening tests.

It only affects women who we have contacted. This is about 200 in 194,000 women screened in the first half of 2021.

Q What do my results mean?

If your retest result is “HPV not found”

Your previous test found HPV. But if your retest result is 'HPV not found', this means your body has cleared the virus. You are safe to return to screening every 3 or 5 years, depending on your age.

For most people, HPV goes away on its own and does not cause any harm. Your body's immune system clears it.

[Read more about a 'HPV not found' result](#)

If your retest and result is HPV found

This means that you still have HPV. We will check your sample for abnormal cervical cells.

If there are no abnormal cervical cells, you should have a repeat test in 12 months. This is to check if your body has cleared the HPV infection.

If you have abnormal cell changes, you will need to have a follow-up test called a colposcopy.

[Read more about cervical screening test results](#)

Your results letter will explain what was tested for and what your results mean.

But screening is not perfect. It has limitations. You still need to attend your next screening test when it's due. You could still get a HPV infection in the future even if you do not change your partner. You may still be at risk of developing cervical cancer in the future.

HPV and abnormal cell changes found

Your results show you have a HPV infection and abnormal cells in your cervix.

You need a follow-up test called a colposcopy.

Your GP or nurse will have more detail about your result. It's very important you follow their advice.

This result means you need further testing.

It is unlikely you have cervical cancer. Cervical cancer is a rare outcome of a HPV infection. In most case, it takes about 10 to 15 years for cervical cancer to develop.

Abnormal cells

Abnormal cells are not cancer. But they can lead to cancer.

There are 2 different types of abnormal changes to cells in the cervix:

- Low-grade - this means mild cell changes.
- High-grade - this means moderate to severe cell changes.

In most cases, people will be told that the cells of their cervix are healthy. They do not have abnormal cells.

Low-grade changes

Low-grade changes mean that the test has found some minor abnormal changes in the cells of the cervix.

Low-grade changes are common and most clear up on their own.

Having low-grade changes does not mean that you have cancer.

You will need to have an examination called a colposcopy.

High-grade changes

High-grade changes mean that the test has found moderate to severe abnormal changes in the cells of the cervix. These changes are less likely to clear up on their own.

This does not mean you have cancer.

You will need to have an examination called a colposcopy.

If you need a colposcopy

A colposcopy is a more detailed look at your cervix. It is similar to having cervical screening. But it is carried out in an out-patient department in a hospital.

A colposcopy usually takes 15 to 20 minutes. If you are referred through CervicalCheck, it is free. Your GP or nurse will arrange the colposcopy for you.

Inadequate or unsatisfactory sample

This means that the lab could not process your screening test sample.

This may be because:

- the sample was not suitable for HPV testing
- not enough cells were collected
- the cells could not be seen clearly enough
- inflammation was present
- the sample has expired
- the sample may have been mislabelled
- the vial (tube the sample is put in) has expired
- the vial has been damaged

You'll need to have a repeat test in around 3 months. You need to wait 3 months so that the cells in your cervix have time to grow back and we can get the best samples.

An inadequate result does not mean there is something wrong. Talk to your GP or nurse if you have any questions.

There is further information on the CervicalCheck website, www.hse.ie/cervicalcheck or contact CervicalCheck's Freephone line on **1800 45 45 55** or contact info@cervicalcheck.ie

If you receive 3 inadequate results in a row you will be referred for a colposcopy.

Q How do I know that the service is safe? / What quality standards are in place?

CervicalCheck plays an important role in preventing cervical cancer and has provided almost 3.2 million cervical screening tests and detected abnormalities for over 115,000 women, many of which could have developed into cervical cancer if not detected through screening.

The quality assurance requirements and standards for the cervical screening programme are based on European guidance, as set out in the European guidelines for quality assurance in cervical cancer screening: Second Edition and the Standards for Quality Assurance in Cervical Screening. Key performance indicator (KPI) data are reviewed in several levels of detail at a number of forums and published annually. They are grouped under the principal components of the cervical screening pathway: programme operation, primary care/ sample taking, human papillomavirus (HPV) testing, cytopathology, colposcopy and histopathology. The process is governed via the National Screening Service Quality Assurance Committee for Cervical Screening, which reports to the CervicalCheck Senior Management Team.

Governance structures for Quality Assurance, including oversight of key performance indicators and audits, are well established within the screening programme. All screening programmes report to the Chief Executive Officer of the National Screening Services who is accountable to the Chief Clinical Officer of the HSE.

Q What if I am worried about symptoms of cervical cancer?

Talk to your GP straight away if you're worried about symptoms of cervical cancer. Do not wait for your next cervical screening appointment. Even if you have had a recent normal screening result, you should never ignore symptoms. The most common symptom of cervical cancer is abnormal bleeding. Abnormal bleeding can include irregular vaginal bleeding, bleeding between periods, vaginal spotting or discharge, post-menopausal bleeding and/or bleeding after sex.

Q Will there be a charge for the second test?

This repeat test is free.

Q What happens if HPV is not found / I am negative / that I am clear of HPV in my repeat test?

If HPV is not found this means your body has cleared the virus and we will let you know when your next test is due. For most people this is either 3 or 5 years, depending on your age. It is highly unlikely that abnormal cells will develop or remain without the presence of the HPV virus.

Q Is my GP aware of this?

We have written separately to your GP about this matter. If you have further questions or concerns about it, and in particular if you have worries about symptoms of cervical cancer, talk to your GP or nurse without delay.

There is further information on the CervicalCheck website, www.hse.ie/cervicalcheck or contact CervicalCheck's Freephone line on **1800 45 45 55** or contact info@cervicalcheck.ie

Q What is a colposcopy?

A colposcopy is a simple procedure used to look at the cervix, the opening to your womb from your vagina. It may be done if a cervical screening test (smear test) finds that you have abnormal cells in your cervix.

These cell changes often go away on their own. But sometimes there's a risk they could turn into cervical cancer if you do not have treatment. A colposcopy helps your doctor or nurse to confirm if cells in your cervix are abnormal. It also helps them decide if you need treatment to remove the cells.

If it's obvious that you have abnormal cells, you may have treatment to remove the cells at the same time as your examination. If it's not clear and if you have abnormal cells, a biopsy sample may be taken and sent to a lab. You'll need to wait until you get your biopsy results to have treatment.

A colposcopy is free if you are referred through the CervicalCheck screening programme.

Q How do I make a colposcopy appointment?

Your GP or nurse will contact a colposcopy clinic and ask them to make an appointment for you. The colposcopy clinic will send you a letter with your appointment details.

There are 15 colposcopy clinics in Ireland that CervicalCheck use. All are located in hospital out-patient departments.

Q Between this and the delays caused by COVID-19 and the HSE cyber-attack, it is a long time since I was due my test. Should I be worried?

Although cancers can behave differently in different people, for most people with abnormal cell changes or even an early cancer, a delay of a number of months will not adversely affect their outcomes.

In cervical screening, women are called at different intervals depending on their age and level of risk. The natural history of cervical cancer would indicate that disease would normally develop over a period of 10-15 years and repeated screening offers an opportunity for picking up disease over time.

Q Can I have a private screen now instead?

Whether your test is private or part of the CervicalCheck population screening programme, your repeat cervical screening test should be at least 3 months after the date of your last test. You need to wait 3 months so that the cells in your cervix have time to grow back and we can get the best samples.

A private test is your choice, but you will have to pay for it. This is an out-of-programme (private) screening test. People who have out-of-programme cervical screening tests can opt to access public or private colposcopy services.

If you have an out-of-programme (private) screening test, CervicalCheck will not have access to your screening test result or your private screening history. It will not be part of the information we have about your screening history. The lab testing your private test sample will also not have access to your screening history. Having an accurate record of your screening history helps CervicalCheck make sure you get the best treatment or clinical advice.

We apologise for the inconvenience and any concern this may cause.

Ends