

Patient Information Sheet

Giving a blood sample for a Marsden360 ctDNA genomic test.

Your doctor has suggested you have a blood sample analysed for circulating tumour (ct) DNA as it is either known or suspected that you have a diagnosis of cancer. This may give extra information as to where the cancer has arisen and highlight possible treatment options either now or in the future.

Cancer and Genomic Variations

Genomics is the study of variations in the DNA of genes that can drive how a cancer behaves, from how fast it grows, to whether it spreads to other parts of the body and also whether it is likely to respond to certain treatments.

Advanced genomic testing is designed to broadly scan for DNA variation changes that may be driving the growth of a person's cancer. Information about genomic variations that are unique to an individual person's cancer may help doctors identify treatments which have been proven to work in cancers with those specific mutations.

Advanced genomic testing and treatment with associated targeted therapies is an evolving area of medicine, so even when the test is performed, it may not produce results that lead directly to a treatment plan. The analyses may help doctors consider more precise therapies in some cases, but not all variations can be matched with known treatment options.

What is the Marsden360 test?

A new approach has been developed to identify genomic variations from a simple blood sample, this is called "liquid biopsy". From a small sample of blood, it is now possible to detect genomic variations by capturing DNA that is shed from a tumour. This means that doctors can gain a full overview of the variations of your cancer from the primary tumour site and any areas that it has spread to.

In partnership with a company called Guardant Health, The Royal Marsden is providing the **Marsden360** liquid biopsy test which provides comprehensive solid tumour profiling in advanced cancers, allowing clinicians to personalise treatments more accurately. The Marsden360 is a 74 gene panel used to identify gene alterations, with reports being tailor made for local treatment and clinical trial options.

What are the next steps?

If you and your doctor decide that you are a candidate for liquid biopsy genomic testing, here's how the process will work:

- A blood sample will be taken and sent to the Royal Marsden's testing laboratory

- Any abnormalities in the DNA found will be analysed to determine whether they match known variations for cancer and those that may respond to specific therapies
- If there's a match, your oncologist may be able to use the results to suggest treatments that are more likely to work
- Your oncologist will explain the results to you and together you will formulate a treatment plan targeted to your individual situation.
- Please note, not all tests work. This can be because the test fails technically (this occurs relatively rarely) or because there are low levels of tumour DNA in the blood stream. This can be related to the type of cancer and where (if anywhere) in the body it has spread to.

What will happen if I say yes?

The first thing you will need to do is give your verbal permission to having your blood taken. You will then be asked to give a blood sample. Once the results are received, your doctor or a member of your clinical care team will contact you regarding the results of the Marsden360 test.

Can I say no?

You are free to say no. You do not have to say yes to giving your blood sample for the Marsden360 blood test. Your routine clinical care will not be affected if you choose not to have the test.

What are the benefits to me?

The hope of using circulating tumour DNA is that it may give you and the doctor quicker and up to date results of the cancer's molecular profile. Most changes in the DNA of the cancer **do not lead to extra treatments**. Your doctor will talk through your report with you and suggest treatment options either through the NHS or within clinical trials if appropriate. **It can still take time** to get a result, this may be approximately 2 weeks; your medical team will tell you of likely time-scales.

What are the risks to me?

There are no more risks of giving blood for the Marsden360 test than for any routine blood sample, which may result in some light bruising and/or pain at the withdrawal site. As your blood contains your normal DNA as well as potentially DNA from the cancer, this will be analysed as part of the test. This can be helpful in determining differences between the cancer and the rest of your body. However there is a small chance that we might detect something in your genetic make-up that may have increased your chance of getting cancer. We will inform you if we find anything of this type, and discuss any further action that may be required to confirm the test, and whether other family members need testing.

What will happen to my blood sample?

Your blood sample (2 blood tubes) will be sent securely via Royal Mail to the Royal Marsden where the test will be performed. The laboratory will extract the DNA from the plasma in the blood sample and analyse the DNA using its own technology.

After the Marsden360 test has been performed, the testing laboratory will safely discard your blood sample. Any remaining plasma and circulating tumour DNA after testing is complete will be retained, as per standard UK laboratory guidelines, should further testing be requested by your oncologist.

Will my information be kept confidential?

When ordering a Marsden360 test, your name, date of birth, hospital number and NHS number, are provided and kept securely within the NHS to ensure the report is matched back to the correct person. Any data used for the purpose of the testing and subsequent analysis to produce your result will be retained within the UK. In the unlikely event that there is a laboratory service issue at the Royal Marsden, your sample will be sent to the Royal Marsden's partner laboratory; Guardant Health in the United States, a certified CLIA (Clinical Laboratory Improvement Amendments) laboratory for processing clinical samples. Your sample and data will be protected by equivalent safeguards as if samples were processed by The Royal Marsden laboratory. Any data used for the purpose of the testing and subsequent analysis will be retained by Guardant Health in case your oncologist requests further analysis. Your data will not be retained by Guardant Health for commercial or research purposes.

Your doctor or a member of your routine clinical care team will be notified by The Royal Marsden testing laboratory when your results are available. The Trust under which your care is being managed will keep all identifiable information about you and the genetic variations of your tumour as part of your medical records, in line with local policies and legal requirements.