



Stockholm³

A NEW BIOMARKER BASED ENHANCED PSA TEST ORDER YOUR TEST THROUGH GFCT

A new advanced prostate cancer test is now available through GFCT. This test, **Stockholm³**, improves the efficiency of existing basic PSA testing and reduces some of the uncertainty that can come from PSA testing.

Whilst the **Stockholm³** test has been extensively clinically validated in studies around the world, and currently is being evaluated in a dedicated NHS study, it is not yet available through the NHS. This means that when ordering this enhanced test, it is essential to ensure that you have a suitable medical professional with whom you can discuss the result - particularly if the result indicates you to have an elevated risk for having aggressive prostate cancer.

About the Stockholm³ Test

It is generally accepted that the two biggest challenges in diagnosing prostate cancer are difficulties detecting aggressive cancers early, combined with risk for over-treatment. **Stockholm³** is a blood test that addresses these challenges by assessing the risk of having aggressive prostate cancer – i.e. cancer that requires treatment - more accurately than current practice with PSA.

This means that **Stockholm³** can help identify aggressive prostate cancer at an early stage – even with low PSA levels – and therefore at a stage when it might still be curable. **Stockholm³** can also help reduce over-diagnosis leading to unnecessary MRIs and biopsies – and unnecessary anxiety for the man and his family.

Stockholm³ BIOMARKERS

One of the problems with using only a single biomarker like PSA is the same result can mean different levels of risk to different men. The age-related cut-offs improve this slightly, but the problem remains if someone for example has genetic risk factors that differ or have a family history of prostate cancer. Using more than one marker to assess risk helps to individualise the risk score.

Stockholm³ also tests for genetic markers called single nucleotide polymorphisms (SNPs). These are small variations in codes for the same gene. The presence of specific genes is not measured.

Stockholm³ combines PSA with three other protein markers, a range of genetic markers and clinical information, to provide a more accurate risk calculation than PSA alone. The results are personalised based on age and family history, enabling an individual risk assessment. This approach ensures that people who are at high risk, but have a low PSA level, can be identified at an early stage through further investigation. This prevents diagnoses from being made too late and expands the range of potential treatments. The test includes a clear recommendation for action, which makes it easier to interpret the results and determine the next diagnostic steps. This means that, in most cases, patients can be treated safely, and in a resource-efficient manner, by their GP, without being referred to a urologist.

Stockholm³ tests for the following 5 protein biomarkers:

1. Total Prostate Specific Antigen (PSA)
2. Free or "unbound" PSA (Free to Total)
3. PSP94 - Prostate Secretory Protein
4. Growth Differentiating Factor 15
5. Kallikrein-related peptidase 2 (KLK2 similar to PSA which is KLK3)

NEW
ADVANCED
PROSTATE
CANCER
TEST

ALGORITHM TO DETECT RISK MORE ACCURATELY

More than 11 years of painstaking research, including testing of more than 90,000 men in clinical validation studies, has determined how the levels of these biomarkers contribute specifically to the risk of having aggressive prostate cancer. The algorithm also adjusts these levels according to clinical information that is obtained when the man takes the test.

Clinical Information Obtained

- Age
- Father, brother or son having incidence of prostate cancer
- Whether a previous negative prostate biopsy has taken place
- Use of a specific medicine, 5-alpha reductase inhibitor

A MORE PRECISE TEST

Stockholm3 has in clinical studies been shown to identify high-risk men with PSA levels as low as 1.5 ng/ml, while also identifying men that have low risk for aggressive prostate cancer, even if their PSA levels as high as 20 ng/ml. In this way, **Stockholm³** improves early detection while also reducing the problem of over treatment.

EVIDENCE

As mentioned, **Stockholm³** has been validated in over 90,000 men and has been used in health systems in Sweden, Norway, Finland, and Switzerland. The test has also recently been introduced in Germany. Results have been published in international peer-reviewed journals, and the National Institute of Clinical Excellence (NICE) have undertaken a thorough innovation medtech review of the product - For further information, please visit: www.nice.org.uk/advice/mib303

NICE have summarised that the evidence is adequate and of good methodological quality. They say that the evidence suggests that **Stockholm³** is more effective at predicting risk than PSA testing alone for men 45-74 with PSA of at least 1.5 ng/ml. This means that it is beneficial to test the PSA level before taking **Stockholm³**, and only testing with **Stockholm³** if the PSA level is >1.5 ng/ml.

TEST RESULT

The result from **Stockholm³** is a risk score that indicates the risk of having aggressive prostate cancer. Stockholm3 provides clear recommendations on how to proceed:

- High risk: referral to a urologist for further investigation with MRI and/or biopsy
- Low or normal risk: repeat the test in two to six years (specific recommendation is included in the report; during this interval, it is not required that additional PSA testing happens.

PROCESS FOR THE RESULTS

You will be advised when your result of the test is with your clinician.

Due to its clinical value, GFCT has decided to offer **Stockholm³** testing.

However, the test order must be arranged in coordination with a clinician or a medical advisor. If you would like to discuss how to order **Stockholm³**, please contact us on **01926 419959**.

Stockholm³ is approved for men aged 45 to 74 years with a PSA of at least 1.5 ng/ml. who have not yet been diagnosed with prostate cancer.

For help or assistance or further details contact us as follows:

Phone **01926 419959**

Email info@psatests.org.uk

For all information on GFCT the PSA testing charity and latest statistics about PSA, please visit www.psatests.org.uk or www.tgfct.org.uk

Thank You for taking the time to read this leaflet.

We hope this is the start of a journey that helps you learn more about this important health issue



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