Orthotype™ Patient Information Sheet

The Orthotype™ test

Orthotype™ is a novel HLA based algorithmic test that identifies which patients may be more or less likely to develop painful, inflammatory responses to cobalt chrome metal alloy, a metal which is commonly used in joint replacements.

When a patient with a joint replacement mobilises, tiny particles are shed from the implant surfaces due to wear. Over time, the body's immune system can become sensitised to these wear particles. The patient can then reject the implanted joint in a process similar to how a transplanted organ (such as a liver transplant) may be rejected over time and become loose. It is this process which is main reason why artificial joints do not last forever. In some patients, the inflammation caused by the immune response may not require repeat surgery, but it may cause pain which interferes with their lives.

Through our research, we know that some individuals have DNA which make them more or less compatible with particular materials used to manufacture joint replacements. Orthotype™ provides doctors with a way of testing patient DNA (genotyping) to identify patients who may be more likely to develop inflammatory responses to cobalt chrome implants used as part of their joint replacement.

Genetic differences and the immune system

While most genetic information (in other words, DNA) is identical between humans, there are differences in small parts of our DNA. Some of these differences are in the genes that control our immune systems. The human leucocyte antigen (HLA) genes are the most varied in humans, and these genes play a vital role in controlling how our immune systems respond to foreign agents such as implanted joints.

HLA genes can show how some individual's immune systems can respond more effectively to these foreign agents, as a direct result of their 'HLA type' (also known as 'tissue type'). Unfortunately, some individual's immune systems may react to non-biological foreign bodies such as hip or knee implants leading to pain and inflammation.

Identifying a patient's HLA type alongside other characteristics plays a useful role in identifying who is at a greater risk of developing an adverse immune response to implants made from specific materials.

Who will have access to my genetic results?

Only ExplantLab and the NHS approved gene testing laboratory will hold your personal data. We will follow guidelines laid out in the national Good Clinical Practice guidelines, as well as the data protection act.

You are free to write to us at any time to instruct us to remove your data.

Ongoing product surveillance

We want to ensure that the Orthotype™ test functions as well as possible. To do this, we would like your permission to gain access to your record held in the National Joint Registry (NJR) database in order to monitor the results of your operation. This will allow us to ensure Orthotype™ performs to our expectations and that we are able to continuously improve it.
If you would like to help us carry out this important work, please tick the appropriate box on the consent form, or write to us at the email address given below.

The consent document can be found here: Consent information

Future research?

We also work with the NHS to carry out Health Research Authority approved research. This research includes looking at genetic links between the success of joint replacement and other factors such as diet. The overall aim of this research is to help all patients enjoy pain free, unrestricted mobility following joint replacement surgery. We want to try to make joint replacements last longer, so that patients avoid having to undergo repeat surgery.
If you are interested in contributing to this research, please tick the appropriate box on the consent form or write to us at the email address given below.

This patient information leaflet does not replace the guidance provided by your treating clinical team. Your treating clinical team should advise you of the options for treatment, advise of any alternative treatment and associated risks. Your treating clinical team should ensure that you are aware of the material risks associated with the treatment advised.
It is the responsibility of the requester submitting your sample, to ensure informed consent has been obtained for all tests, including genetic tests in accordance with current guidance and legislation.
If you are unsure about any aspects of the treatment/care, ask your treating clinical team to explain.

ExplantLab

ExplantLab is an independent medical research company based in Newcastle-upon-Tyne. It is directed by Dr David Langton, a medically qualified doctor, registered with the General Medical Council. For several years, ExplantLab has worked in collaboration with the National Health Service of the United Kingdom and the Food and Drugs Administration (FDA) of the United States to improve the function of joint replacements.

NHS Blood and Transplant

NHS Blood and Transplant (NHSBT) saves and improves lives by providing a safe, reliable and efficient supply of blood and associated services to the NHS in England and North Wales.

All information provided to NHS Blood and Transplant is used in accordance with the General Data Protection Regulation (GDPR) and all other applicable privacy legislation. For more information on how we look after your personal details or to find out more about your privacy rights visit www.nhsbt.nhs.uk/privacy or call 0300 123 23 23.
NHSBT is committed to keeping your data safe and confidential.

Contact information:
Email: orthotype@explantlab.com.
Company website: www.explantlab.com
Address: The Biosphere, Newcastle Helix, Newcastle-upon-Tyne, NE4 5BX
ExplantLab is a trading name of PXD Limited, company number 07483251.