Fairfax Cryobank
The Trusted Choice for Donor Sperm

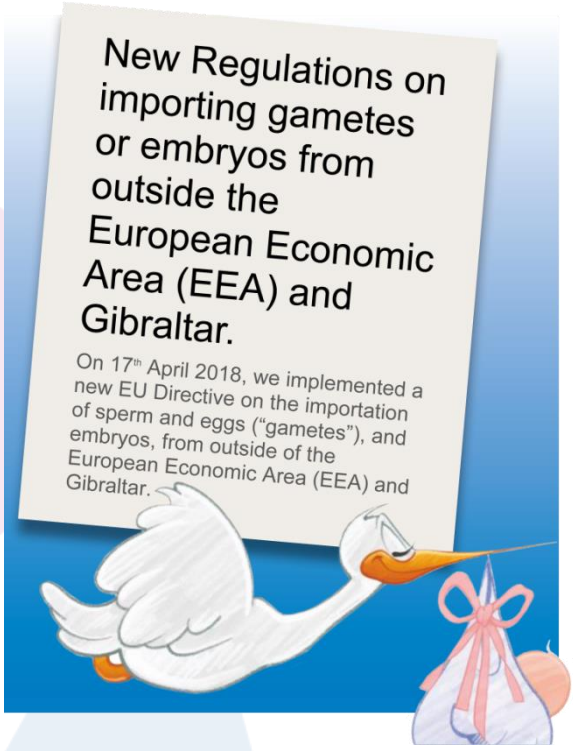
NHS
Manchester University
NHS Foundation Trust

Saint Mary's Hospital
Department of Reproductive Medicine

Information for Patients

Fairfax and Saint Mary's Hospital – your trusted source for compliant donor sperm

Now offering enhanced HPV screening



This EU Directive, which does not apply to imports from other EEA countries, was developed to ensure the quality and safety of tissues and cells being imported into the UK from a "third country supplier" – defined as any country that is outside of the EU, EEA and Gibraltar.

In relation to IVF, this means that imported gametes or embryos for a patient's treatment must meet UK safety and quality standards around the testing, transportation and procurement of gametes.

In practice, this means that a clinic wishing to import from a third country supplier will need to apply to the human fertilization and Embryology Authority (HFEA) for an Importing Tissue Establishment (ITE) certificate.

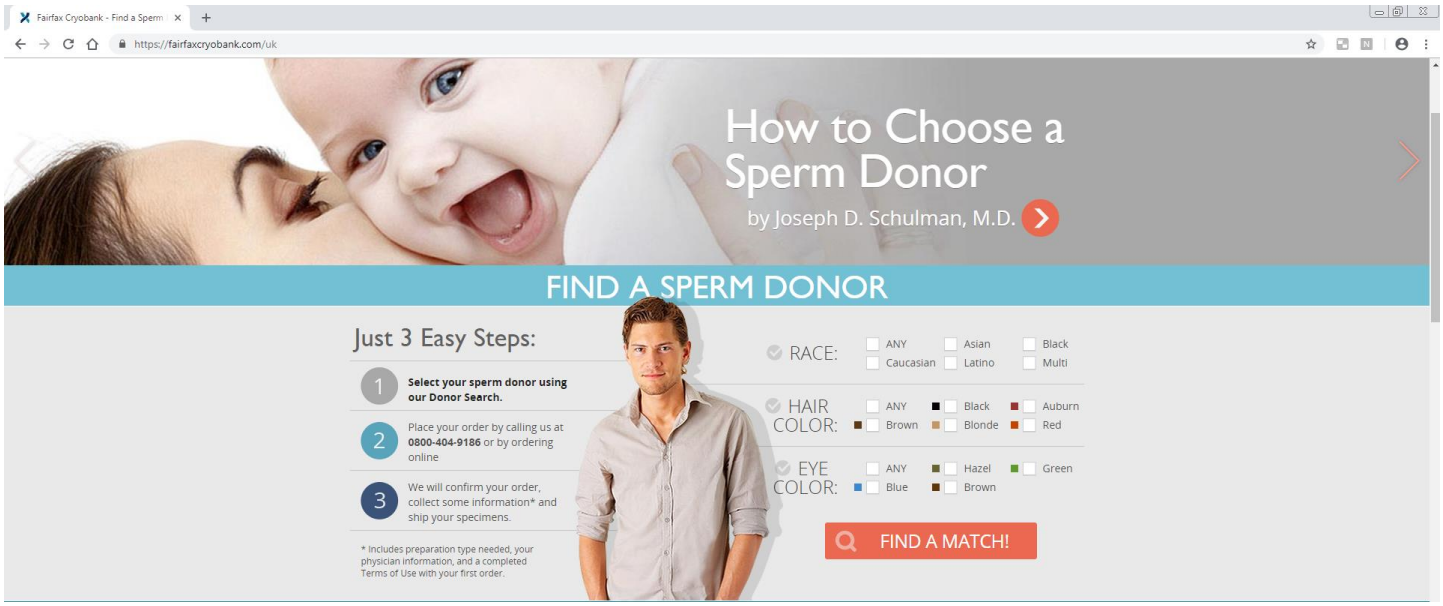
As part of this process, the UK clinic will need to provide documents that guarantee the third country supplier meets UK quality and safety standards. If a clinic imports gametes or embryos without this certificate they will be non-compliant.

However, as Saint Mary's Hospital now has an ITE certificate, they can import donor sperm from Fairfax on your behalf without the requirement of you applying for the ITE certificate yourself.

Link - https://fairfaxcryobank.com/uk

Live birth outcome

Following the announcement in January 2018 of the Fairfax Cryobank Partnership with the Department of Reproductive Medicine Saint Mary's Hospital Manchester, the first live births from IUI and IVF have been recorded in the UK.



What is HPV?

The human papillomavirus, or HPV, is a type of virus that infects the skin and the cells lining body cavities. For most people, the infection will get better on its own and they will never know they had it. There are hundreds of different types of HPV:

- Some infect the skin, usually on the fingers and hands. These can cause minor problems, such as common skin warts and verrucas.
- Others infect the genitals, mouth and throat. These can cause genital warts, or more rarely, cancer.

From this point forward, we'll only be talking about genital and oral HPV, as these types are the ones which can cause cancer.

HPV is a very common infection. Around 8 out of 10 people will be infected with the virus at some point in their lives. It usually doesn't cause any symptoms and most people will never know they had it. HPV spreads through close skin-to-skin contact, usually during sexual activity including oral sex. Having a high number of sexual partners does increase your chances of infection. But it is important to remember that you can still pick up an infection at any time.

HPV infection usually causes no problems at all. But in some people the infection will stay around for a long time and become persistent. Around 13 types of HPV can cause cancer. These are called 'high-risk' types. People with persistent infections with 'high-risk' HPV types are those who are most likely to go on to develop cancer.

https://www.cancerresearchuk.org/about-cancer/causes-of-cancer/infections-eg-hpv-and-cancer/hpv-and-cancer

What does the Food and Drug Administration (FDA) require for HPV detection?

The FDA requires screening donors for HPV by carrying out a physical examination and reviewing a patient's medical history but does not require HPV DNA based testing of sperm donors.

What is Fairfax Cryobank doing for HPV detection?

Fairfax Cryobank screens donors for HPV by reviewing a patient's medical history and carrying out a physical examination, meeting the FDA standard. In addition, Fairfax exceed the standard, having added DNA based testing of donor sperm in 2001. We are looking for the two strains of HPV that are most frequently associated with cervical cancer.

What is the medical evidence that supports this additional testing?

We cite a study (Human Papillomavirus DNA Detection in Sperm Using Polymerase Chain Reaction, Obstet Gynecol 2001;97:357-60) that concludes: "HPV is present in sperm cells from infected and apparently healthy subjects, and sperm washing does not eliminate the risk of HPV transmission to recipients. We suggest that HPV DNA testing should be done on the semen of prospective donors, and those with positive tests should be excluded from donation."

Why is Fairfax doing more than is required by the FDA?

Our view is that self-reported medical histories and physical examinations are insufficient to screen for HPV and that a DNA based test provides an additional level of safety to our donor sperm. At Fairfax Cryobank we believe that all donor sperm should be both screened for HPV and tested for the most prevalent strains of HPV that cause cervical cancer. The medical literature supports our position.

How is the testing for HPV performed on the donors?

We test the semen of our donors for HPV at the time they are being screened for initial donor eligibility, and thereafter every six months while they are donating. By testing semen samples at 6 month intervals, and thereafter while donors donate, we increase the chances of detecting the presence of HPV earlier than via the visual detection methods typically performed during a routine physical examination.

Is the lab doing the HPV DNA test experienced with this kind of testing?

The protocol and validation of our HPV testing was developed at the Molecular Infectious Disease Laboratory (MIDL) of the Genetics & IVF Institute, Fairfax, VA. MIDL was established in 1998 and is a cutting edge CLIA certified facility dedicated to infectious disease diagnostics using exclusively high sensitivity PCR (DNA) amplification methods. All in-house protocols presently in use must

pass a multi-part validation process. Prior to offering the HPV test in 2001 approximately 10,000 assays were performed.

In addition to supporting the activities of various GIVF divisions, of which Fairfax Cryobank is one, MIDL provides high priority testing for prenatal and neonatal units for hospitals in the Washington, D.C. metro. MIDL is directed by Brian D. Mariani, Ph.D., who has 25 years' experience in molecular genetics, microbiology and biotechnology. Trained at Stanford and Harvard universities, Dr. Mariani has applied his expertise at MIDL to the design of molecular genetic-based detection assays for a variety of infectious microorganisms from diverse clinical specimen types.

Has the testing accuracy been validated by outside agencies?

The Molecular Infectious Disease Lab (MIDL) of Genetics & IVF Institute performs in-house validated assays under CLIA certification (#49D0952503) according to all established guidelines. The lab director is qualified for Molecular Virology under N.Y. State Dept of Health guidelines. The lab participates in the College of American Pathology nucleic-acid amplification survey program (including HPV detection) and maintains a 100% accuracy score.

Why are all sperm banks not offering this testing?

It is expensive and requires a relationship with a sophisticated infectious disease laboratory that has experience with semen testing. Fairfax Cryobank has benefited tremendously from our relationship with Genetics & IVF Institute, our parent company. Since our inception as a sperm bank, we have always been at the forefront of genetic screening of our donors.

Link - https://fairfaxcryobank.co.uk
http://manchesterivf.co.uk/