

Patient Consent

Cell-free culture media collection and storage



Name (Patient):
Date of birth: ____/____/____
Address:
IVF Number

Partner's name:
Date of birth: ____/____/____
Address:

I/we have consented to genetic testing, PGT-A, with embryo biopsy. I/we understand that not all embryos will be suitable for biopsy. I/we further understand that an additional PGT-A test, cell-free PGT-A, has previously been offered by Monash IVF and is currently suspended. Like PGT-A with biopsy, cell-free PGT-A is designed to assist in selecting the embryos most likely to achieve a healthy live birth by analysing the genetic complement of the embryo.

Cell-free PGT-A is a relatively new type of Preimplantation Genetic Testing where scientists take a sample of the leftover nutrient solution (culture media) that the embryo has been growing in while in the laboratory. This solution contains DNA produced by the embryo which can be used for genetic testing. Cell-free PGT-A is therefore useful for testing embryos that are not able to be biopsied by day 6. The test is currently suspended due to some new findings about cell-free PGT-A that are inconsistent with the original clinical trial results that need to be further understood.

It is not unusual for the results of new medical procedures to differ from the results of the clinical trial, however we feel it is important to investigate this difference. As transparency and reliability are of utmost importance to Monash IVF, we believe it is in the best interests of patients to suspend the test while a review is being performed.

We understand that the suspension of the cell-free PGT-A test may be disappointing and that should Monash IVF re-commence offering the test, you may feel that you would have liked the opportunity for your embryos that were not suitable for testing with biopsy, to have been tested using the cell-free PGT-A method.

While the testing cannot be offered at this time, we can, if you would like us to, take a sample of culture media for those embryos that are not suitable for biopsy. This sample would be amplified (to make multiple copies of the DNA for later testing), with the resulting DNA sample frozen pending the potential re-introduction of the test. While we are hopeful that we will be able to understand the current observations we are seeing with cell-free PGT-A test, it is important to note that there is no guarantee that Monash IVF will re-commence offering the cell-free PGT-A testing.

Whether you decide to request that we collect the culture media or not, your frozen embryos will be available for you to use at any time until such time as they are tested. The risks associated with any of these untested embryos is the same as that of an embryo that has never undergone genetic testing.

If we do reintroduce cell-free PGT-A testing and your embryo is classified as aneuploid, you will not be able to use it and it will be discarded.

I/we instruct Monash IVF to take samples from the culture media for any embryos unsuitable for biopsy. I/we understand that the DNA from these samples will be amplified and frozen at no cost to me/us, pending the outcome of Monash IVF's investigations into cell-free PGT-A testing. I/we understand that Monash IVF will contact me to discuss the outcomes of the investigation into cell-free PGT-A, to let me/us decide if I/we wish to proceed with cell-free PGT-A testing of the samples at that time. Further consents will be required.

OR

I/we do not wish for Monash IVF to take samples from the culture media for any of my/our embryo/s (or I/we request that Monash IVF discard any currently stored culture media samples). I/we understand that this means that my/our embryos will not be able to be tested using cell-free PGT-A if/when this testing is re-commenced.

Signature (Patient):
Date: ____/____/____

Signature (Partner):
Date: ____/____/____