

Non-Invasive Prenatal Testing (NIPT) (also known as cfDNA screening)

Please note: The information provided in this section has been sourced from the ARC website and was not created by Ellie's Gift. ARC has been instrumental in supporting the development of Ellie's Gift and their contribution has been significant to the content within our specific TFMR area. ARC were also involved in the focus groups that helped inform and shape the content that has been developed to support families experiencing TFMR.

Non-Invasive Prenatal Testing (NIPT) (also known as cfDNA screening)

Non-invasive prenatal testing (NIPT), which is also known as cell-free DNA screening has been available (mainly in the private sector) in the UK since 2012. It involves a maternal blood test. The blood sample is sent to a laboratory and cell-free DNA material is extracted and analysed. Most of the DNA comes from the mother but a small amount comes from the baby's placenta.

It is important to know that NIPT does not give a yes/no answer about chromosomal conditions. However, large scale studies show that the test has a high detection rate for Down's syndrome. So it is currently a very sensitive screening test for Down's syndrome, and it can also look for Edwards' and Patau's syndrome, though it is not as reliable for these two conditions.

In 2016, after a detailed review of the international evidence and a public consultation, the UKNSC recommended that NIPT should be carefully implemented into the NHS as part of the current Fetal Anomaly Screening Programme, (to be offered only to those women who have a screening result between 1 in 2 to 1 in 150). The Government accepted this advice.

NIPT was implemented in Wales in April 2018, in Scotland in September 2020 and in England in July 2021.

Individual clinicians and private clinics are offering NIPT provided by a number of different laboratories, based here and overseas. There is no 'direct to consumer' testing available; it must be done via a health care professional. You can find out more about the labs doing the analysis below. They all claim high detection rates but some differ in the way they analyse the cfDNA. One way to check their claims is to look at the published data* they have on their test performance. You should be able to find this on their websites.

- [VeriSeq](https://www.illumina.com) (illumina.com)
- [The IONA Test](https://www.yourgenehealth.co.uk) (Yourgene Health)
- [The Maternit21 Plus Prenatal Test](https://www.labscorp.co.uk) (Labscorp)
- [Panorama Prenatal Screen](https://www.natera.com) (Natera)
- [Lucina NIPT](https://www.nhs.uk) (NHS West Midlands Regional Genetics Laboratory, Birmingham)
- [PrenatalSAFE](https://www.eurofins.com) (Eurofins Biomnis)
- [Vanadis](https://www.revvity.com) (Revvity)
- [Future Health NIPT](https://www.futurehealthbiobank.com) (Future Health Biobank)

NIPT can be performed from 10 weeks of pregnancy. Before this it is difficult to collect enough cell-free DNA (cfDNA) from the blood sample. Even after 10 weeks there is a chance that they will not be able to collect enough cfDNA to provide a result. This can happen in about 3% of cases. Women who are significantly overweight have been found to be at higher risk of being in this 3%. Most providers will do a second test for free if this happens.

Results usually take a week to 10 days to come back from the laboratory. Remember NIPT does not give a yes/no answer; it gives a probability. If the result is reported as 'low chance' or 'very unlikely to be affected', it is extremely unlikely that the baby has the condition. If the test result given is 'high chance' or 'likely to be affected' you will be offered a CVS or amniocentesis to give a definite diagnosis. It is important to realise that in this case the CVS or amniocentesis will most often confirm that the baby has Down's syndrome.

Our research suggests that costs for NIPT range from £350 to £550. If a provider is charging significantly more than £500, ask what the fee includes. Most clinics will include an ultrasound scan in the cost. If you are interested in having the test at a private clinic, make sure you check that they have a clear link with an NHS unit, so that there is a co-ordinated care pathway in place if you were to have a worrying test result.

Questions to ask when you are having NIPT in the private sector

Things to think about when considering whether to have NIPT/cfDNA prenatal screening in the private sector.

Which conditions do I want NIPT for?

There are many biotech laboratories offering NIPT in the UK (see above) through clinics and independent providers. While all will include a screening result for Downs syndrome, Edwards' syndrome and Patau's syndrome (also known as trisomies), many will also screen for sex chromosome anomalies (e.g. Turner's syndrome, Triple X etc.). Some tests include results for other genetic conditions that are the result of a deletion or duplication of genetic material on a chromosome.

There is now enough good evidence to make us confident that NIPT is the most accurate screening test we have for Downs syndrome, Edwards' syndrome and Patau's syndrome. However, there is less in the literature about other conditions. So we suggest restricting use of NIPT to the main trisomies, unless advised otherwise by your genetics specialist.

While most parents will be reassured by their NIPT result, a small number will be told that it is likely that their baby has one of the conditions. Before

you have any testing, you might want to think about what you know about the conditions and how you might feel about getting news that your baby is likely to have one of them.

How much will it cost?

At the time of writing this, costs for NIPT for the trisomies seem to range from around £350 to £550. The cost should include a scan along with the blood test as it is important you have a scan before NIPT.

What should I ask the NIPT provider?

NIPT is offered in many different settings and they can vary in the quality of service they provide. To check a clinic or provider in England , you could look them up on the [Care Quality Commission website](#). It can be tempting to go for the cheapest NIPT option, but you need to check that a cheaper price doesn't mean that the laboratory performing the NIPT is of poor quality. Laboratories in the UK should be accredited by [UKAS](#).

Private sector NIPT providers may have information on their website about which of the tests they offer so it can be helpful to read that as it may help you decide on the questions you want to ask.

Your questions might include:

How long will I wait for a result?

The 'turnaround time' for your NIPT result will depend partly on which laboratory your blood sample is sent to. Most testing now is done in UK-based labs, but one or two companies send the sample to laboratories abroad. So the wait can range from 7 to 14 days. Double-check whether the time they quote is in 'working' or 'calendar' days as some laboratories are open at weekends.

How will I be given my result?

You may want to decide how you want to receive your result. Do you want to call the clinic, or should they call you? Would you prefer to go in and get your result in person? Do you want them to email or text you? Will there be someone expert to speak to if it is an unexpected result?

What will the result say?

Different test providers have slightly different ways of reporting the results. Ask exactly what you will be told. The result should always make it clear that no NIPT result means it is certain that your baby has or doesn't have a condition. You should be given a copy of the laboratory report and someone should be able to talk you through the report and answer any questions you have. In a small number of cases they will not be able to get a result. You might want to check what percentage of women who have the NIPT test you are considering fall into this category. Also make sure that they will give you a second test or 'redraw' if they cannot get a result first time. If this second test comes back with an inconclusive result, it is important to seek expert advice, so check with the clinic how this will be arranged.

What happens if I get a 'positive' result?

If your NIPT says that there is a high chance your baby has a condition, check that the clinic you are considering has a pathway in place if this happens. Some clinics may offer invasive diagnostic testing, but most will have to signpost you back to the NHS for this. Ask what links they have with NHS hospitals and how they can help you access NHS services. It is important that they have established these contacts and don't just insist their responsibility ends once they have given you your NIPT result.

NIPT for other conditions

Some private clinics are offering NIPT for sex chromosome and other conditions and even 'micro deletions' (when small pieces of genetic information are missing). We would advise you to think very carefully before agreeing to be tested for other conditions. The evidence is not so clear on how good NIPT is for these and sometimes you might be given information that leads to great uncertainty. Please feel able to call us on the helpline to talk this through or get expert advice from a clinical geneticist or genetic counsellor. To be of the highest quality, test performance data should be published in a peer reviewed scientific journal and should report pregnancy outcomes from studies involving 1000s of women.

ARC - Call our helpline

Want to talk? We're here as often as you need us. Our helpline is answered by trained staff.

020 7713 7486

Monday to Friday: 10.00am – 5.30pm

Or text: **07908 683004**

Tuesday and Thursday: 8 – 10pm – email
info@arc-uk.org to arrange an evening call.

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