FAQ for Clinical Laboratories

1. Does the IONA® test require additional validation?

No, all of the validation has been performed as part of the CE marking process. During installation, the IONA® test will be qualified by our Technical Support team who will perform a PQ. This ensures a fast and smooth set up and laboratories can be up running with routine cfDNA screening very quickly.

2. What is included in the IONA® kit?

A complete solution from sample to result that includes: DNA extraction reagents, plastic consumables, sequencing chips and reagents, IONA® Library Preparation Kit, IONA® Software, technical support and the Premaitha Workflow Manager. We also offer the MyNIPT® data exchange portal which gives clinical labs the ability to quickly and securely deliver test result to healthcare practitioners.

3. What does the CE mark mean?

The CE mark ensures that international quality standards are upheld in the design, development and manufacture of the test, to give a robust, reliable and reproducible test of the highest standards. The IONA® test received its CE mark in February 2015. The IONA® test has been externally reviewed by a Notified Body in line with regulatory requirements for the screening of Down's Syndrome. This ensures that labs can run the test without requiring any further validation and can count on our comprehensive technical support and quality assured reagents. Some NIPT providers claim to have a CE mark, but may not comply fully with the regulatory requirements. If meeting regulatory requirements with the highest quality, most reliable NIPT test is important to you then please contact us for more information.

4. Does the IONA® test include fetal sex determination?

The IONA® test offers optional fetal sex determination for parents who wish to know the sex of the fetus. This is only available in regions where fetal sex determination is permitted.

5. How many samples can I run on the IONA® test?

The IONA® test runs on a highly scalable workflow suitable for both low and high throughput laboratories. As little as 8 samples is all it takes to get started. Please contact us for more information.

6. Is the IONA® Software cloud-based?

No, all analysis is done locally on a dedicated server. This ensures the highest level of patient confidentiality and avoids lengthy up and download times to external services.

7. Does the IONA® test report microdeletions?

International professional bodies (FIGO, ESHG, ASHG and RCOG) are currently not recommending routine screening for microdeletions therefore at present, the IONA® test does not report these.

8. Does the IONA® test report fetal fraction on the test results?

Yes, the IONA® test does incorporate fetal fraction into the test and it is reported on the test result page as a percentage. All samples must have at least ≥2% fetal fraction. In addition, all samples at risk of a false negative or false positive result are further evaluated using our proprietary dynamic fetal fraction assessment. This adapts the level of required fetal fraction for the sample to the quality of the sequencing data to ensure a reliable result.

9. Are there any hidden licensing fees?

No, our clinical laboratory customers pay a fixed price per sample which includes the reagents, consumables, software use and technical support. Reporting and software upgrades are offered at no additional cost.

10. What is the difference between a CE-IVD kit and a tech transfer?

When you use a CE-IVD solution for NIPT you will receive a validated and verified product which enables a fast setup without the need to determine difficult cut-offs. All this work has already been done for you. Customers who go through a tech transfer will have to develop their own NIPT method and validate it with clinical samples and set their own analysis cut-off. This process can take several months of time consuming and expensive efforts. Support for the lab developed test is also limited as the reagent manufacturer does not take responsibility for the performance of the test. The IONA® test eliminates this challenge and offers you easy integration, full support and peace of mind.