

Side-by-side comparison of the IONA[®] test for Non-Invasive Prenatal Testing (NIPT)

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the **IONA**[®] test
non-invasive prenatal screen: safe, fast, accurate

OBJECTIVE

There has been a large increase in tests being offered for NIPT in the recent years. All purveyors of NIPT claim to have similar sensitivity and specificity in performance.^{1,2,3} The purpose of this study was to compare the results of two tests, in a blinded manner, looking at outcomes (where available), to determine functionality and rate of redraws, discordance and no-results obtained.

LEARNING OBJECTIVE

The aim of this study is compare and contrast two available NIPT tests. While sensitivity and specificity in all tests appear to be similar, on further inspection, there may be subtle but tangible differences. It is important these are reported and understood by providers and patients.

METHODS

This study was performed at a private prenatal screening clinic (This Is My, Leeds, UK). All women consented to have two samples of blood taken, one for the NIFTY[™] test and one for the IONA[®] test. The samples were analysed by BGI and Premaitha respectively and This Is My collected and collated the data. If no result was obtained with the NIFTY[™] test, on the first sample, a second sample (redraw) was obtained. The IONA[®] test did not have a second sample taken if the IONA[®] test failed on initial sample. Data was compiled by This Is My with Premaitha blinded to the results until all samples were analysed.

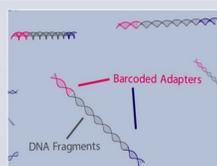
PROCEDURE

Step 1



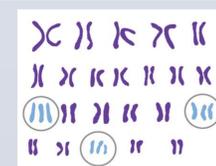
A small blood sample is taken from the mother's arm and sent to a local laboratory for analysis

Step 2



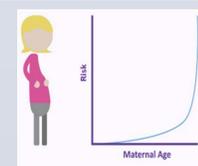
The DNA from the mother's blood is extracted and the test is performed on a small amount of DNA

Step 3



The IONA[®] test directly measures the amount of cell-free DNA and can detect small changes in the DNA ratio between the maternal and cell-free DNA

Step 4



The IONA[®] Software for analysis calculates the relative amount of chromosomes 21, 18 and 13 to calculate a likelihood ratio to predict the presence of a trisomy.

RESULTS

Samples were received from 518 women (504 singleton and 12 twin pregnancies) with paired results generated in 514 cases. The IONA[®] test and NIFTY[™] test each had two no results, resulting in 4 non-paired samples. Ten (10) women required a redraw to obtain a result for NIFTY[™], while no redraws were obtained for the IONA[®] test. The NIFTY test had one false positive, a T18 that IONA[®] correctly identified as low risk, as proven on amniocentesis. Outcomes are currently available in 71 cases.

	The IONA [®] test	NIFTY [™]
Total subjects	518	518
Age of women (Mean/median/range)	36/36 (21-52)	36/36(21-52)
*Paired samples	514	514
Redraw from mother	0	10
Trisomy 21	15	15
#Trisomy 18	3	4*
Trisomy 13	0	0

*Each group had 2 no-results; no overlap, therefore 514 paired-samples
#Discordance between IONA[®] and NIFTY[™], IONA[®] was correct based on amniocentesis

CONCLUSIONS

The one discordance result, with NIFTY[™] giving a false positive, required the woman to undergo an invasive procedure, which was negative. The NIFTY[™] test required 10 redraws, while theoretically the IONA[®] test would have only required 2 redraws. Therefore the IONA[®] test performed better than the NIFTY[™], in respect to redraws, and accuracy, compared to NIFTY[™] in this observational study.

ACKNOWLEDGEMENTS

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FURTHER INFORMATION

For further information on the IONA[®] test please visit www.Premaitha.com or email iona@Premaitha.com