

LifeCodexx receives CE mark for its novel NIPT solution based on methylation-specific quantitative PCR

The proprietary qNIPT technology to become a cost efficient and rapid NIPT

Konstanz, December 7, 2016 – LifeCodexx AG, Europe’s first NIPT provider, announced today CE marking of its PrenaTest® BioIT analysis software based on an innovative methylation-specific qPCR assay for the detection of fetal trisomy 21 (qNIPT). Now the proprietary PrenaTest® software is cleared for the analysis of data from next generation sequencing as well as from qPCR.

The innovative qNIPT was developed and validated with around 2,500 maternal blood samples in total. A recent blinded prospective validation study with close to 1,000 samples demonstrated a 100% test concordance with results obtained from NGS-based PrenaTest®, for which a recent prospective clinical follow-up study with more than 2,200 patients also confirmed 100% test accuracy for fetal trisomy 21. Moreover, the new performance evaluation demonstrated that the new qNIPT provides reliable results from blood samples with a fetal fraction as low as 2.4%. This latest study also confirmed additional advantages such as increased cost-efficiency and rapid turnaround time.

“This is a significant innovative step in the field of non-invasive prenatal testing,” said Wera Hofmann, Chief Scientific Officer of LifeCodexx AG. “Ten years after the first publication about the use of fetal epigenetic markers for the non-invasive prenatal detection of a fetal trisomy, we are proud to bring such an epigenetic and qPCR-based NIPT finally into clinical practice.”

“Our smart qNIPT will allow more pregnant women to opt for NIPT as a reliable and affordable prenatal testing method which provides rapid results under highest quality standards,” said Michael Lutz, Chief Executive Officer of LifeCodexx AG. “As our qNIPT is based on the most widely used platform within the molecular diagnostic space, this technology will offer the advantage of simplified integration into the lab routines of many laboratories around the world.”

The PrenaTest® is currently available in more than 35 countries worldwide and is locally performed at four sites in Germany and Switzerland. It is the only non-invasive prenatal test that has been developed in Germany since 2010 in strict conformity with the highest quality standards as per the European Directive on In-vitro Diagnostic Medical Devices.

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