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Global Prenatal & Maternal Diagnostic Market To 2020

https://marketpublishers.com/r/GC135016CA4EN.html
Date: December 2015
Pages: 359
Price: US$ 3,800.00 (Single User License)
ID: GC135016CA4EN

Abstracts

Prenatal tests (fetus, embryos and newborns) currently on the market analyze chromosomes, DNA, RNA, genes, and/or gene products to determine whether an abnormality is present that is causative of a specific disease. Since 2011, the launch of noninvasive prenatal tests (NIPTs) is revolutionizing the prenatal screening industry providing detection rates of >99% and false positive rates of 0.1%. These screening results are only indicative of the risk and not confirmative. To confirm positive results of NIPT screening tests, prenatal diagnostic tests such as amniocentesis and chorionic villus sampling (CVS) are performed. Prior to NIPTs, ultrasound and maternal serum tests were routinely used to screen fetusus for genetic abnormalities.

Globally, 50 countries have effective newborn genetic test programs, the implementation of which is in various stages. In the U.S., four million newborns are tested annually, with 3,000 found to have metabolic and genetic diseases. The purpose of newborn screening is to identify affected newborns quickly and provide them with treatment to prevent mental retardation, prolonged illness and death. The newborn genetic screening market is crowded with different technologies, the common being tandem mass spectrometry, pulse oximetry, enzyme-based assays, DNA assays and electrophoresis.

Preimplantation genetic screening and preimplantation genetic diagnosis (PGS/PGD) are genetic tests performed in eight-celled embryos before implantation during in vitro fertilization (IVF) for the detection of genetic abnormalities and sex. These tests can detect and diagnose chromosomal rearrangements, X-linked diseases and help in reducing the incidence of spontaneous abortions, increase implantation rates, prevent trisomic offsprings and avoid the risk of transmitting single gene disorders. However, PGS and PGD results are not 100% accurate and after pregnancy, if required the diagnostic tests such as amniocentesis and CVS are to be performed to confirm the positive results of PGS/PGD. In the U.S. alone, more than 63,000 babies were born

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through IVF in 2013 and compared to 2012 data; it was an increase of 2,000 births.

The most important development in the field of prenatal screening, is the introduction of NIPTs using cell-free fetal DNA (cffDNA) in 2011. Obstetricians and patients who are deterred by the 10% to 15% false positive rates of ultrasound screening and 5% false positive rates of maternal serum tests are eagerly embracing NIPTs which claim to have only 0.1% of false positive results.

Within just four years, molecular genetics firms have successfully produced eight different types of kits for the detection of genetic abnormalities in the fetus. These products have been gradually marginalizing the maternal serum tests and in another decade, maternal serum tests are expected to become obsolete. If, companies can develop NIPTs with a 100% accuracy rate, maternal serum tests, amniocentesis and CVS will all be completely overshadowed by NIPTs. Despite the growing popularity of NIPTs, maternal serum tests still continue to have some market due to their low price. While the maternal serum tests are available for just $x to $x, NIPTs are priced between $x and $x. However, Sequenom reportedly sold over x tests in 2013 and so pricing does not seem to be a deterrent factor. The introduction of technologies such as digital PCR and next-generation sequencing (NGS) or massively parallel sequencing (MPS) have also enabled accurate estimation of very small differences in chromosome-specific sequences in maternal blood.

The objective of this report is to provide an overview of the various technologies being employed for detecting genetic diseases in embryos, fetuses and newborns. The various chapters describe common pregnancy disorders, numerical chromosome disorders and structural chromosome disorders, single gene disorders inherited by fetuses, newborns and embryos. The global prenatal and maternal diagnostic test market is assessed with respect to:

Fetal Ultrasound

Prenatal MRI Screening

Maternal Serum Screening Tests

Noninvasive Prenatal Tests (NIPTs) using cffDNA

NIPTs by Product

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Prenatal Diagnostic Invasive Tests

Newborn Screening for Genetic Diseases

Newborn Screening Market by Technology

Preimplantation Screening/Diagnosis (PGS/PGD)

SWOT and merger/acquisition analysis is also performed as is a comprehensive documentation of the legislation pertaining to newborn screening by geography and how clinical programs are implemented in developed and developing markets.

Emerging trends in associated markets are also analysed in order to give the reader a comprehensive overview of how prenatal and maternal diagnostic testing is affected by the following industries:

Molecular Diagnostics Market

Liquid Biopsy Market

Personalized Medicine Diagnostics Market

In vitro Diagnostics (IVD) Market

This is a comprehensive 359 page report strengthened with over 260 figures and tables. Published in January 2016, the GLOBAL PRENATAL & MATERNAL DIAGNOSTIC MARKET TO 2020 report by KellySciPub has a detailed overview of 114 companies in the market with specifics pertaining to financial and business strategy, current products on the market and pipeline products.

Key Questions Answered in this Report

What are the major prenatal pregnancy complications?

What are the major genetic diseases detected in fetuses?

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What are the appropriate technologies for the detection of aneuploidies, microdeletions, duplications, copy number variations and translocations?

How far is genetic counseling important in educating pregnant women and healthcare professionals?

What is the impact of recent advances in clinical genomics on genetic counseling?

What different noninvasive and invasive prenatal screening tests are performed during a pregnancy?

What are the detection rate, true positive rate and true negative rate for NIPTs?

Currently, in which countries are the NIPTs available?

What is the cost of NIPTs region-wise?

What is the uptake of conventional maternal serum tests, NIPTs and invasive diagnostic tests in the U.S.?

What is the average cost of maternal serum screening, NIPTs, fetal ultrasound screening and invasive diagnostic tests in the U.S.?

What are the strategies to be adopted for clinical implementation of NIPTs for all pregnancies?

What is the “patient directed model” for the integration of NIPTs into healthcare systems?

How does the detection rate of NIPTs compare with the rates of conventional maternal serum screening tests?

What are the genetic disorders detectable by different prenatal screening and diagnostic tests?

What is the reliability of amniocentesis and CVS results?

Is the future of invasive diagnostic tests uncertain?

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Do the intact fetal cells in maternal blood have use in noninvasive prenatal diagnosis (NIPD)?

What about the use of trophoblast cells obtained from cervix in NIPD?

How many genetic conditions are detected during newborn genetic screening in the U.S.?

What is the status of newborn genetic screening in developed, developing and other countries?

What are the different preimplantation genetic screening (PGS) and preimplantation genetic diagnosis (PGD)?

What are the currently available PGS/PGD testing products available in the market?

What are the currently used advanced technologies in prenatal, newborn and PGD testing?

What is the global market for fetal ultrasound screening, through 2021?

Who are the market leaders in fetal ultrasound systems?

What is the global and regional market for prenatal screening by fetal MRI, through 2021?

What is the global and regional market for maternal screening tests, through 2021?

What is the global and regional market for NIPTs using cffDNA, through 2021?

What is the global and regional market for invasive prenatal diagnostic tests, through 2021?

What is the global and regional market for newborn screening tests, through 2021?

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What is the global market for newborn screening tests by technology, through 2021?

What is the global and regional market for pre-implantation genetic diagnosis (PGD), through 2021?

What is the global market for molecular diagnostics, through 2021?

What is the global market for liquid biopsy tests, through 2021?

What is the overall global market for personalized medicine diagnostics, through 2021?

What is the overall global market for in vitro diagnostics (IVD), through 2021?

What are the recent acquisition activities in prenatal screening industry?

What are the important factors that drive the growth of prenatal & newborn genetic testing industry?

What are the challenges faced by the prenatal screening industry?

What are the possible future developments in prenatal screening industry?

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Contents

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3. TYPES OF GENETIC DISEASES IN FETUSES: AN OVERVIEW

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8. PREGNANCY, PRENATAL, NEWBORN AND PGD-RELATED TECHNOLOGIES: AN OVERVIEW

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12. COMPANY PROFILES

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APPENDIX

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Index Of Figures

INDEX OF FIGURES

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Index Of Tables

INDEX OF TABLES

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