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Newborn Screening Market Size and Forecasts (2020 - 2030), Global and Regional Share, Trends, and Growth Opportunity Analysis Report Coverage: By Product Type (Reagents and Assay Kits, and Instruments), Technology [Tandem Mass Spectrometry (TMS), Molecular Assays, Immunoassays and Enzymatic Assays, Pulse Oximetry Screening Technology, and Others], Test Type [Dry Blood Spot Test, Hearing Screen Test, Critical Congenital Heart Diseases (CCHD) Test, and Others], End User (Hospitals and Clinics, and Diagnostic Laboratories), and Geography (North America, Europe, Asia Pacific, Middle East & Africa, and South & Central America)

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Abstracts

The global newborn screening market is expected to reach US$ 2.484 billion in 2030 from US$ 1.206 billion in 2022. The market is estimated to grow with a CAGR of 9.4% from 2022 to 2030.

The key factors driving the market include rising burden of congenital diseases and increasing prevalence of newborn disorders. However, lack of uniformity of newborn screening policies and procedures across the world and false positive and false negative results hinders the market growth.

Market Opportunities of Newborn Screening Market

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The demand for comprehensive genetic screening of newborns is rising with the deepening knowledge about the genetic causes of medical conditions and advancements in healthcare technologies. As a result, companies in the newborn screening market are developing innovative, cost-effective screening solutions. The US FDA licensed the Kymriah gene therapy in 2017 for use in pediatric patients with a particular kind of acute lymphoblastic leukemia. During this therapy, a new gene that codes for a chimeric antigen receptor is inserted into the patient's T cells, stimulating the altered T cells to go after and destroy the leukemic cells. Yescarta and Zynteglo are two more examples of authorized gene treatments for large B-cell lymphoma and beta-thalassemia. Further, the emergence of technologies conferring an ability to identify genetic predispositions to diseases at birth pave the way for personalized healthcare, aligning with the broader trend of precision medicine.

Screening for genetic diseases during pregnancy also focuses on the early detection of pregnancy-related problems. Next-generation sequencing aids in the prenatal screening of neonates with a sensitivity of above 95% for detecting aneuploidies (such as Down syndrome and Trisomy 21) or partial chromosomal abnormalities (duplications or deletions) in all chromosomes. Fluorescence in-situ hybridization (FISH) is employed to detect monogenic illnesses such as sickle cell anemia; it also aids in an effective preimplantation genetic diagnosis. Noninvasive procedures such as the cell-free fetal DNA approach using maternal plasma are the recent advancements in genetic tests. The embryonic DNA can be distinguished from maternal DNA pieces based on differences in their sizes. Real-time PCR with fluorescent probes, shotgun sequencing (Solexa or Illumina), or huge targeted parallel sequencing can be used to examine DNA associated with fetal medical conditions. This would allow doctors to provide early molecular interventions with certain pharmacological therapies (pharmacogenetics) and to transform cells, tissues, and organs physically and chemically if this type of genetic screening is further researched. Thus, advancements in methods for screening infants for genetic disorders hold immense potential for the overall newborn screening market.

Factors Hampering Newborn Screening Market

Variations regarding the list of conditions screened for in different countries result in non-uniformity in newborn screening policies and practices worldwide. A few nations screen for a comprehensive range of disorders, while others focus on a limited set. This difference creates barriers for companies developing screening tests and technologies, as they need to modify their products to specific markets, limiting economies of scale. Moreover, the lack of standardized protocols can result in inconsistent quality control

and data collection practices. This leads to inaccuracies in screening results and difficulties in comparing data between regions, making it challenging for researchers and healthcare providers to assess the effectiveness of screening programs implemented in localities understudy. Additionally, the absence of universal standards complicates the regulatory landscape for companies operating in the newborn screening market, as they need to focus on complying with a complex web of regulations for seeking approvals in different countries, which can be time-consuming and expensive. The lack of uniformity can also hinder international collaborations and data sharing, limiting the potential of newborn screening research and technology development. Thus, the lack of uniformity in newborn screening policies and procedures limits the progress of the newborn screening market.

Newborn Screening Market: Segmental Overview

The newborn screening market, by product type, is segmented into reagents and assay kits and instruments. In 2022, the reagents and assay kits segment held a larger market share and is expected to grow at the fastest rate in the coming years. Different reagents and assay kits for newborn screening are categorized into DNA-based assays, immunoassays, and enzymatic assays. Various companies in the market have developed a range of reagents and assay kits specifically for neonatal screening. Firstly, Labsystems Diagnostics launched a fluorometric microplate-based assay for detecting phenylketonuria (PKU) in newborns based on phenylalanine content, as increasing the phenylalanine level in the baby can cause intellectual disability. All the reagent kits offered by the Company are manual modular systems or fully automated hands-off systems.

The newborn screening market, by technology, is segmented into tandem mass spectrometry (TMS), molecular assays, immunoassays and enzymatic assays, pulse oximetry screening technology, and other technologies. In 2022, the pulse oximetry screening technology segment held the largest share of the market. Moreover, the immunoassays and enzymatic assays segment is expected to grow fastest during the coming years. Congenital heart disease (CCHD), one of the most common congenital disabilities, is a duct-dependent congenital heart disease. It may be detected during the prenatal and postnatal period, while it can be life-threatening if it goes undiagnosed and untreated in the neonatal period or infancy. Pulse oximetry screening is used to detect critical CCHD in infants. It is a painless, noninvasive, and cost-effective method of screening infants. The pulse oximeter screening determines the percentage of hemoglobin in the blood saturated with oxygen.

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The newborn screening market, by test type, is segmented into dry blood spot tests, hearing screen tests, critical congenital heart disease tests, and other tests. In 2022, the blood spot test segment held the largest share of the market. The newborn screening market for the same segment is estimated to grow at a significant CAGR during 2022 -2030.

The newborn screening market, by end-user, is segmented into hospitals, clinics, and diagnostic laboratories. In 2022, the hospitals and clinics segment held a larger market share. However, the hospitals and clinics segment is estimated to grow at a CAGR during 2022-2030. healthcare provider performs newborn screening tests in a room or a newborn/nursery area at hospitals. The hospitals and clinics segment is projected to hold a larger share of the newborn screening market in the coming years as these facilities receive maximum patient footfall for newborn baby screening. Better facilities, and the availability of different treatment options and good nursing care under one roof attract patients toward these facilities for different diagnostic and therapeutic procedure.

Newborn Screening Market: Geographical Overview

The newborn screening market in North America has experienced significant growth in recent years. The demand for newborn screening services has increased significantly with the surging awareness among parents and healthcare professionals about the importance of early screening for identifying and managing congenital disorders. Additionally, improvements in medical technology have been crucial in enhancing newborn screening capabilities—laboratory automation has boosted screening accuracy, speed, and cost-effectiveness. This has made it possible for medical professionals to give thorough newborn screening panels that cover a larger spectrum of genetic and metabolic disorders. Favorable legislation and regulatory measures also benefit the newborn screening market in North America. Many states and provinces have implemented mandatory newborn screening programs, ensuring all infants are screened shortly after birth. For instance, every state in the US offers newborn screening as a public health program; yearly, ~4 million babies are screened under this program for illnesses that aren't often present at the time of delivery. The Texas Department of Health and Human Services began screening newborns for Spinal Muscular Atrophy (SMA) in June 2021.

A few of the major primary and secondary sources referred to while preparing the report on the newborn screening market are the World Bank Data, National Health Service (NHS), FDA (Food and Drug Administration), EMA (European Medicines Agency), and WHO (World Health Organization).

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