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Newborn Screening Market - Global Industry Size, Share, Trends, Opportunity, and Forecast, 2018-2028 Segmented by Technology (Tandem Mass Spectrometry, Pulse Oximetry, Enzyme Based Assays, DNA Assays, and Other Technologies), By Test Type (Dried Blood Spot, Hearing Screening, Critical Congenital Heart Defect (CCHD), and Other Test Types), By End User (Hospitals, Diagnostic Centers, and Other End Users), and By Region, Competition

https://marketpublishers.com/r/NC767AE9C1A7EN.html
Date: October 2023
Pages: 170
Price: US$ 4,900.00 (Single User License)
ID: NC767AE9C1A7EN

Abstracts

Global Newborn Screening Market has valued at USD 801.07 Million in 2022 and is anticipated to witness an impressive growth in the forecast period with a CAGR of 7.37% through 2028. Newborn screening is a public health program that involves the systematic testing of newborn infants for a range of genetic, metabolic, and congenital disorders shortly after birth. The primary goal of newborn screening is to identify infants at risk of certain serious or life-threatening conditions early in life, often before symptoms appear, so that appropriate medical intervention and treatment can be initiated promptly. Newborn screening is typically part of a public health program administered by government health agencies. It is offered to all newborns as part of routine healthcare shortly after birth. The specific disorders included in newborn screening panels and the timing of screening can vary by region and country. Local healthcare policies and resources influence the scope of newborn screening programs. The increasing prevalence of genetic and metabolic disorders among newborns is a significant driver. Early detection through newborn screening allows for prompt intervention and better management of these conditions.

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Technological advancements, including next-generation sequencing (NGS), mass spectrometry, and improved biochemical assays, have enhanced the accuracy and scope of newborn screening. These innovations attract healthcare providers and laboratories to adopt advanced screening methods. Growing awareness among parents about the availability of comprehensive newborn screening tests has increased consumer demand. Many parents are willing to pay for private screening services that offer more extensive panels. The expansion of newborn screening panels to include a broader range of disorders has increased the market size. This trend is supported by advancements in genetic testing and the inclusion of rare diseases. The emphasis on quality assurance and accreditation for laboratories conducting newborn screening has boosted confidence in the accuracy and reliability of screening results, attracting more healthcare providers and parents.

Key Market Drivers

Advancements in Technology

Next-Generation Sequencing (NGS) has revolutionized newborn screening by enabling the simultaneous analysis of multiple genes associated with various genetic and metabolic disorders. It allows for more comprehensive screening, including the detection of rare and novel genetic mutations that were previously challenging to identify. NGS also enables the diagnosis of conditions with complex genetic underpinnings, such as spinal muscular atrophy (SMA) and some forms of intellectual disability. Tandem Mass Spectrometry (MS/MS) technology has become a standard tool for the analysis of metabolic disorders in newborns. It allows for the simultaneous measurement of multiple metabolites in a single blood sample, making it efficient and cost-effective. MS/MS has expanded the range of disorders that can be screened for, including amino acid disorders and fatty acid oxidation disorders. Multiplex assays enable the simultaneous measurement of multiple biomarkers or analytes within a single sample. These assays are used for the detection of various metabolic and genetic disorders, including lysosomal storage disorders and primary immunodeficiencies. Advances in DBS (Dried Blood Spot (DBS)) technology have improved the stability and sensitivity of blood samples collected on filter paper.

DBS allows for easy collection, transport, and storage of blood samples, making it a practical choice for newborn screening. Bioinformatics tools and software play a crucial role in interpreting the complex data generated by NGS and other advanced screening methods. These tools help identify disease-causing mutations and variations in the newborn's genome. POCT (Point-of-Care Testing) devices have been developed for

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specific newborn screening tests, allowing for rapid results at the bedside. For example, POCT pulse oximetry is used to screen for critical congenital heart defects (CCHD) shortly after birth. Miniaturization and automation of laboratory equipment have improved the efficiency and throughput of screening tests. Automated systems can process a higher volume of samples while maintaining accuracy and reducing human error. Advances in biomarker discovery have led to the identification of novel markers associated with various disorders. These biomarkers are used to develop new screening assays and expand the scope of newborn screening. Telemedicine and digital health platforms enable the efficient sharing of screening results with healthcare providers and specialists. Data integration with electronic health records (EHRs) facilitates the seamless flow of information and follow-up care for affected infants. Quality control measures and standards have improved the reliability of newborn screening tests, ensuring accurate results. This factor will help in the development of Global Newborn Screening Market.

Increasing Consumer Demand for Comprehensive Screening

Expectant parents and families today have access to a wealth of information about healthcare and medical testing. This increased access to information has raised awareness about the benefits of comprehensive newborn screening. Parents often want to ensure the best possible start for their newborns and value the early detection of potential health issues. Comprehensive screening offers a more thorough assessment of a newborn's health, providing greater peace of mind to parents. Many private healthcare providers and diagnostic centers offer comprehensive newborn screening packages. These packages often include a broader range of tests compared to standard public health screening programs. Some parents prefer the convenience of having all necessary screening tests conducted in one place and at one time. Comprehensive screening packages can provide this convenience. Some families may have a history of genetic or metabolic disorders, increasing their interest in comprehensive screening to assess their newborn's risk. Comprehensive screening can provide additional reassurance to parents, knowing that their newborn has been thoroughly assessed for a wide range of conditions.

In an increasingly globalized world, families may come from diverse backgrounds and regions with varying screening protocols. Comprehensive screening can help address potential gaps or differences in screening practices. Social media platforms and online parenting communities play a role in spreading information about newborn screening and influencing parental choices. Positive experiences shared by other parents can encourage comprehensive screening. Advances in technology and medical research

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have made comprehensive newborn screening more feasible and accessible, contributing to consumer demand. Some parents may seek customization of screening panels to align with their specific concerns or genetic history, driving the demand for personalized screening options. This factor will pace up the demand of Global Newborn Screening Market.

Rising Incidence of Genetic and Metabolic Disorders

Newborn screening allows for the early detection of genetic and metabolic disorders, often before symptoms appear. Early intervention and treatment can prevent or mitigate the severity of these conditions, improving the long-term health outcomes for affected infants. Many genetic and metabolic disorders, if left undetected and untreated, can lead to severe health complications, developmental delays, and even death. Newborn screening helps reduce the mortality and morbidity associated with these conditions by enabling early medical management. Timely diagnosis and intervention through newborn screening can significantly improve the quality of life for affected infants and their families. Early treatment can prevent irreversible damage and support better long-term outcomes. Identifying affected infants through newborn screening also has broader public health implications. It helps prevent the transmission of certain genetic disorders within families and populations by facilitating informed family planning decisions.

The incidence of genetic and metabolic disorders varies by population and region, but some conditions have become more prevalent due to factors such as changing demographics, increased consanguinity, and other genetic risk factors. Advances in screening technology have expanded the range of conditions that can be screened for efficiently and accurately. This has made it possible to include more disorders in newborn screening panels. As awareness about the benefits of newborn screening has grown among healthcare professionals and parents, there has been increased demand for these services. Education and outreach efforts have emphasized the importance of early detection. In many countries and regions, newborn screening is mandated by law or is part of standard healthcare practices. These mandates have contributed to increased screening rates and demand. International health organizations and initiatives have promoted the expansion of newborn screening programs, especially in low- and middle-income countries where the burden of genetic and metabolic disorders may be higher. The rise of precision medicine and genomics has underscored the importance of early genetic testing and diagnosis, further emphasizing the demand for newborn screening. This factor will accelerate the demand of Global Newborn Screening Market.

Key Market Challenges

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Education and Awareness

Many parents and caregivers may not be fully aware of the importance of newborn screening or may have misconceptions about the purpose and benefits of screening. Lack of awareness can result in missed opportunities for early detection and intervention. Healthcare professionals, including obstetricians, pediatricians, and midwives, play a crucial role in informing parents about newborn screening. However, not all healthcare providers may have the latest information or prioritize discussing newborn screening during prenatal and postnatal care visits. In multicultural and multilingual societies, language and cultural barriers can hinder effective communication about newborn screening. Ensuring that information is accessible and understandable to diverse populations is a challenge. Different countries and regions have varying healthcare systems, policies, and practices related to newborn screening. This can lead to disparities in awareness and access to screening services. In some low- and middle-income countries, resource constraints may limit the capacity for education and awareness campaigns about newborn screening. This can result in inadequate dissemination of information. Some genetic and metabolic disorders screened for in newborns may be poorly understood or carry stigmas. This can lead to reluctance among parents to participate in screening or follow-up testing.

Rare Diseases and Variability

Rare diseases encompass a wide range of conditions, each with their unique genetic and clinical characteristics. This heterogeneity makes it challenging to develop standardized screening tests that can detect all rare diseases efficiently. For many rare diseases, there is limited epidemiological data and clinical research available. This lack of information can hinder the development of effective screening protocols. Rare diseases, by definition, have low prevalence in the general population. This means that screening programs must test many newborns to identify a small number of affected individuals, which can be resource intensive. Rare diseases often have variable onset and clinical presentation. Some affected infants may not exhibit symptoms until later in life, making early detection through newborn screening more challenging. For some rare diseases, there may be limited or no effective treatments available. Early detection may not always lead to better outcomes if there are no viable treatment options. Genetic mutations responsible for rare diseases can vary widely between individuals. Developing screening tests that can detect all possible genetic variations is a complex task. Balancing sensitivity and specificity in screening tests for rare diseases is difficult. High sensitivity may lead to more false positives, while high specificity may result in

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false negatives.

Key Market Trends

Rise in Private Testing

Some parents are willing to pay for more extensive newborn screening panels that include a broader range of genetic and metabolic disorders than what is typically offered in public health programs. The trend toward personalized medicine has influenced newborn screening. Parents may seek customized screening options based on their family medical history or genetic predispositions. Private healthcare providers and diagnostic centers often invest in the latest screening technologies and methods, which can offer more comprehensive and accurate results. Private testing facilities may provide faster turnaround times for screening results, providing parents with peace of mind, and enabling earlier intervention if needed. Some families value the privacy and confidentiality offered by private testing centers, especially when it comes to genetic information. Private testing allows parents to have more control and autonomy over the screening process, including the choice of tests and the timing of testing. Private testing centers may offer additional services such as genetic counseling, family planning advice, and ongoing support for families with infants identified as having specific conditions. Families who travel or relocate internationally may opt for private testing to ensure continuity of care and consistent screening practices, especially if they come from regions with varying screening protocols.

Segmental Insights

Technology Insights

In 2022, the Global Newborn Screening Market dominated by Pulse Oximetry segment and is predicted to continue expanding over the coming years. Pulse oximetry is a non-invasive and relatively simple test that measures the oxygen saturation levels in a newborn's blood. This screening can help identify newborns with critical congenital heart defects (CCHD) early, allowing for prompt intervention and treatment. Pulse oximetry is a painless and non-invasive procedure that can be performed quickly and easily. It doesn't require drawing blood or other invasive methods, making it well-tolerated by infants and their parents. Many countries and regions have included pulse oximetry screening as part of their newborn screening guidelines, contributing to its widespread use for CCHD detection. Many healthcare organizations and professional societies recommend the use of pulse oximetry in newborn screening protocols, which

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can lead to its widespread adoption.

Test Type Insights

In 2022, the Global Newborn Screening Market dominated by Dried Blood Spot (DBS) segment and is predicted to continue expanding over the coming years. DBS is a non-invasive and convenient method for collecting blood samples from newborns. It involves a simple heel prick to obtain a few drops of blood, which are then absorbed onto filter paper. This minimally invasive approach is well-tolerated by infants and is less traumatic for both the baby and parents compared to traditional venous blood draws. DBS samples are stable and can be stored for an extended period, allowing for the convenient transportation of samples to centralized laboratories for testing. This makes it a practical choice, especially in regions with limited access to advanced healthcare facilities. And they are cost-effective compared to other sample collection methods, such as venous blood draws. The use of filter paper as the collection medium is inexpensive, and the simplicity of sample collection reduces labour and equipment costs.

End User Insights

In 2022, the Global Newborn Screening Market largest share was dominated by Diagnostic Centres segment in the forecast period and is predicted to continue expanding over the coming years. Diagnostic centres often have highly trained and specialized personnel who are well-equipped to perform a wide range of screening tests. They have the expertise required to handle and analyse newborn screening samples accurately. Diagnostic centres typically invest in state-of-the-art equipment and technology for newborn screening. This includes advanced instruments for biochemical, genetic, and metabolic testing, which can improve the accuracy and efficiency of screening. Some diagnostic centres offer both private and public services. This means that while public healthcare systems may refer newborns to these centres, parents who prefer private testing can also avail themselves of these services for a fee.

Regional Insights

The North America region dominates the Global Newborn Screening Market in 2022. Due to government legislation, the availability of a strong healthcare infrastructure, the high prevalence of birth abnormalities in the region, and new technological advancements in newborn screening technologies by the players operating in the region. The United States is predicted to have the greatest market share in the North

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American area. This is due to both the expanding need for sophisticated systems and the rising incidence rates of diseases in neonates. The study of diagnostic markers in blood spots collected on filter paper on an infant's second day of life is how every newborn in the United States is examined post-birth.

Key Market Players

Bio-Rad Laboratories Inc.

GE Healthcare

Masimo Corporation

Medtronic Inc.

Natus Medical Incorporated

PerkinElmer Inc.

Trivitron Healthcare

ZenTech SA

Demant A/S

Thermo Fisher Scientific

Hill-Rom Holdings Inc.

Report Scope:

In this report, the Global Newborn Screening Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

Newborn Screening Market, By Technology:

Tandem Mass Spectrometry

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Pulse Oximetry

Enzyme Based Assays

DNA Assays

Other Technologies

Newborn Screening Market, By Test Type:

Dried Blood Spot

Hearing Screening

Critical Congenital Heart Defect (CCHD)

Other Test Types

Newborn Screening Market, By End User:

Hospitals

Diagnostic Centers

Other End Users

Global Newborn Screening Market, By region:

North America

United States

Canada

Mexico

Asia-Pacific

China

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India

South Korea

Australia

Japan

Europe

Germany

France

United Kingdom

Spain

Italy

South America

Brazil

Argentina

Colombia

Middle East & Africa

South Africa

Saudi Arabia

UAE

Competitive Landscape

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Company Profiles: Detailed analysis of the major companies present in the Global Newborn Screening Market.

Available Customizations:

Global Newborn Screening Market report with the given market data, Tech Sci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

Company Information

Detailed analysis and profiling of additional market players (up to five).

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