

Severe Combined Immunodeficiency (SCID) Diagnosis Market – Global Industry Size, Share, Trends, Opportunity, and Forecast, 2018-2028 Segmented by Disease Type (X-linked SCID, ADA-SCID, others), By Test Type (TREC, Complete blood count (CBC), Genetic Test, Biochemical Test, others), By End User (Hospitals, Diagnostic and Research Laboratories, Others), by region, and Competition

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Abstracts

Global Severe Combined Immunodeficiency (SCID) Diagnosis Market is anticipated to witness an impressive growth in the forecast period. Severe Combined Immunodeficiency (SCID) is a rare and severe genetic disorder that affects the immune system, leaving individuals highly susceptible to infections. SCID is often referred to as the bubble boy disease, as individuals with this condition used to live in sterile environments to avoid exposure to pathogens. SCID results in a profound deficiency in both cellular and humoral immunity. This means that affected individuals have severely impaired T cell function (cellular immunity) and often lack functional B cells, which are responsible for producing antibodies (humoral immunity). Due to the absence or dysfunction of critical immune cells, individuals with SCID are extremely vulnerable to a wide range of infections, including bacterial, viral, fungal, and parasitic infections. These infections can be recurrent, severe, and life-threatening. Symptoms of SCID often appear in the first few months of life, as maternal antibodies wane. Infants with SCID may experience persistent, severe infections that do not respond well to treatment.

The growing incidence of SCID, both in developed and developing countries, is a significant driver. Advances in healthcare have led to more cases being diagnosed,

increasing the demand for diagnostic tests. The inclusion of SCID in newborn screening programs in several countries has been a crucial driver. Early diagnosis through newborn screening allows for prompt intervention and better patient outcomes. Ongoing advancements in diagnostic technologies, such as next-generation sequencing (NGS), flow cytometry, and molecular testing, have improved the accuracy and efficiency of SCID diagnosis. The development of targeted therapies, such as gene therapy and enzyme replacement therapy, has created a greater need for precise diagnosis to identify eligible patients for these treatments. The availability of support services and counseling for affected individuals and their families has encouraged early testing and diagnosis.

Key Market Drivers

Rising Incidence of SCID

Efforts to increase awareness and education among healthcare professionals and the public have led to more cases of SCID being identified and diagnosed. As healthcare providers become more familiar with the condition, they are better equipped to recognize potential symptoms and refer infants for testing. The inclusion of SCID in newborn screening programs in many countries has played a crucial role in identifying affected infants early in life. Newborn screening allows for the detection of SCID before symptoms appear, enabling timely intervention and treatment. Advances in diagnostic technologies, such as genetic testing and flow cytometry, have made it easier to diagnose SCID accurately. These tools enable healthcare providers to confirm SCID cases more definitively. Growing knowledge of the genetic mutations responsible for various forms of SCID has improved diagnostic capabilities. Genetic testing can pinpoint the exact genetic defect, aiding in subtype classification and personalized treatment planning. Improvements in healthcare access and infrastructure in various regions have made diagnostic services more widely available. This has contributed to the identification of more SCID cases.

Patient advocacy groups and organizations dedicated to SCID raise awareness and provide resources for affected families. They encourage early testing and diagnosis, leading to increased demand for diagnostic services. Ongoing research into the genetic and molecular basis of SCID has led to the development of new diagnostic tools and biomarkers. Clinical trials for SCID treatments also require accurate diagnosis, boosting the demand for diagnostic testing. In some regions, improved insurance coverage and reimbursement for diagnostic tests have made these tests more accessible to patients and healthcare providers. This can lead to increased testing rates. Collaboration among

healthcare professionals, researchers, and organizations on a global scale has accelerated progress in SCID diagnosis. Sharing knowledge and best practices contributes to improved diagnostic capabilities. This factor will help in the development of the Global Severe Combined Immunodeficiency (SCID) Diagnosis Market.

Advancements in Diagnostic Technologies

NGS (Next-Generation Sequencing) technologies have revolutionized genetic testing for SCID. WES (Whole Exome Sequencing) and WGS (Whole Genome Sequencing) allow for the comprehensive analysis of an individual's entire exome or genome, enabling the identification of genetic mutations responsible for SCID. These methods are particularly useful for diagnosing cases with novel or rare. High-parameter flow cytometry allows for the simultaneous analysis of multiple cell surface markers and intracellular proteins on immune cells. This advanced flow cytometry technique provides detailed information about lymphocyte subsets, aiding in the diagnosis and classification of SCID subtypes. qPCR (Quantitative Polymerase Chain Reaction) is used to measure the levels of T cell receptor excision circles (TRECs) and kappa-deleting recombination excision circles (KRECs) in newborn screening samples. Low levels of TRECs and KRECs are indicative of SCID and other severe immune disorders. Tandem mass spectrometry can be used for newborn screening to detect abnormal levels of metabolites associated with certain forms of SCID, such as adenosine deaminase deficiency (ADA-SCID). Microarray-based comparative genomic hybridization (aCGH) and single nucleotide polymorphism (SNP) arrays can help detect chromosomal abnormalities associated with some forms of SCID.

dPCR is a highly sensitive technique for quantifying DNA mutations associated with SCID. It can provide accurate and precise measurements of specific genetic mutations. Targeted sequencing panels focus on genes associated with SCID. These panels are designed to efficiently analyze a specific set of genes, making them cost-effective and suitable for confirming known mutations or identifying common SCID-related gene variants. Machine learning algorithms and AI are being applied to SCID diagnosis to assist in data analysis, pattern recognition, and interpretation of complex genetic data. These technologies can enhance the efficiency and accuracy of diagnosis. Telemedicine and telepathology enable remote consultation and sharing of diagnostic data, allowing experts to provide guidance and interpretation of diagnostic tests in real-time, even in remote or underserved areas. This factor will pace up the demand of the Global Severe Combined Immunodeficiency (SCID) Diagnosis Market.

Increasing Availability of Targeted Therapies

Targeted therapies, such as gene therapy and enzyme replacement therapy, have been developed for specific subtypes of SCID, such as ADA-SCID and X-linked SCID. To determine eligibility for these therapies, individuals need to be accurately diagnosed and classified into the appropriate subtype using genetic testing and other diagnostic methods. Targeted therapies are often highly personalized, with treatment plans tailored to the specific genetic mutations causing SCID in an individual. Precise diagnosis is crucial for designing effective treatment strategies that address the underlying genetic defects. The availability of targeted therapies has emphasized the importance of early intervention. Early diagnosis of SCID through newborn screening or diagnostic testing allows for prompt initiation of treatment, which can improve outcomes and prevent severe infections. Targeted therapies have transformed the prognosis of SCID, offering the potential for a better quality of life and reduced morbidity and mortality.

Accurate diagnosis is a prerequisite for accessing these life-changing therapies. Once a diagnosis is confirmed, patients and their families can make informed decisions about treatment options. This process often involves genetic counseling and discussions about the benefits and risks of available therapies. Some individuals with SCID may choose to participate in clinical trials for novel targeted therapies. Accurate diagnosis is essential for enrolling in these trials and assessing treatment outcomes. After initiating targeted therapy, ongoing monitoring of the patient's condition is necessary. Diagnostic tests may be used to assess the effectiveness of treatment and make necessary adjustments. The success of targeted therapies has spurred further research and development efforts in the field of SCID diagnosis and treatment. Innovations in diagnostics, such as the development of new genetic tests and biomarkers, continue to advance alongside therapy development. Patient advocacy groups and organizations dedicated to SCID often collaborate with healthcare providers to raise awareness and promote early diagnosis. They play a role in advocating for the availability and accessibility of both diagnostic testing and targeted therapies. This factor will accelerate the demand of the Global Severe Combined Immunodeficiency (SCID) Diagnosis Market.

Key Market Challenges

Genetic Heterogeneity

SCID is not a single disorder but a group of rare genetic conditions, each caused by specific mutations in different genes. These mutations can affect various aspects of immune system development and function. As a result, there is a wide range of genetic

mutations associated with SCID. Due to genetic heterogeneity, SCID is classified into multiple subtypes, each with distinct genetic causes. Common SCID subtypes include X-linked SCID, ADA-SCID, IL7R-SCID, and more. Accurate diagnosis requires identifying the specific genetic mutation responsible for the individual's condition. Diagnosing SCID involves a complex diagnostic process that includes clinical evaluation, immunological assays, and genetic testing. Genetic testing is often required to confirm the diagnosis and subtype, but selecting the appropriate genetic tests can be challenging due to the diversity of SCID-related genes. New, previously unidentified genetic mutations associated with SCID continue to be discovered through research. Identifying novel mutations adds complexity to diagnostic testing, as genetic tests must be updated to include these new variants. Some genetic tests for SCID may not cover the full spectrum of known SCID-related genes or mutations. This can result in a diagnostic gap, as certain mutations may be missed in standard testing panels. Genetic heterogeneity can lead to variability in the clinical presentation and severity of SCID. Two individuals with the same genetic subtype of SCID may exhibit different symptoms and clinical courses. This variability can complicate diagnosis and treatment planning. Genetic counseling is essential for families affected by SCID. The presence of various genetic mutations and subtypes can make genetic counseling complex, requiring a comprehensive understanding of the genetic basis of the condition.

False Positives and False Negatives

False-positive results can lead to significant anxiety and stress for patients and their families. They may undergo unnecessary medical interventions, such as bone marrow biopsies or invasive procedures, to confirm a diagnosis that ultimately turns out to be incorrect. False positives can result in financial burdens for both patients and healthcare systems. Repeated diagnostic tests and unnecessary treatments can be costly. False positives can divert healthcare resources away from individuals who truly have SCID, potentially delaying their diagnosis and treatment. False-positive results can have a lasting psychological impact on families who may live with the fear and uncertainty of SCID, even after the diagnosis is ruled out. False negatives can be even more concerning, as they result in missed diagnoses of SCID. Delayed or missed diagnoses can lead to severe infections, complications, and potentially life-threatening conditions for affected individuals. False negatives can prevent individuals from receiving timely interventions and targeted therapies that could significantly improve their quality of life and prognosis. False negatives may not receive the necessary precautions and isolation measures, putting them at risk of transmitting infections to vulnerable individuals, including infants who are too young to be vaccinated. False negatives can create diagnostic uncertainty, making it challenging for healthcare providers to

determine the cause of recurrent infections and immune system dysfunction in affected individuals.

Key Market Trends

Patient Advocacy and Awareness

Patient advocacy groups and organizations dedicated to SCID, such as the Immune Deficiency Foundation (IDF) and the SCID Angels for Life Foundation, play a crucial role in advocating for individuals and families affected by SCID. They provide support, resources, and a platform for raising awareness. Patient advocacy groups often work with policymakers to advocate for improved access to diagnostic testing, treatment, and research funding for SCID. They play a role in shaping healthcare policies related to rare diseases like SCID. Patient advocacy efforts can lead to increased research funding for SCID, driving advancements in diagnostic methods, treatments, and the understanding of the condition. Advocacy efforts have contributed to the inclusion of SCID in newborn screening programs in several regions. This has dramatically increased awareness about the importance of early diagnosis. Awareness campaigns target healthcare providers, including pediatricians and neonatologists, to ensure they recognize the signs and symptoms of SCID and refer infants for diagnostic testing. Public awareness campaigns, often initiated by patient advocacy groups, aim to educate the general population about SCID. These campaigns may include social media outreach, educational materials, and community events. Events like the International SCID Awareness Day, held on October 15th each year, help raise global awareness about the condition. It is an opportunity for patients, families, healthcare providers, and advocates to come together to educate the public. SCID cases that receive media coverage, such as documentaries or news stories, can significantly increase awareness and prompt individuals to seek diagnostic testing if they suspect SCID in their families.

Segmental Insights

Disease Type Insights

In 2022, the Global Severe Combined Immunodeficiency (SCID) Diagnosis Market largest share was held by X-linked SCID segment and is predicted to continue expanding over the coming years. X-SCID is one of the most common forms of SCID, and it is often the first type of SCID to be identified in affected individuals. This form of SCID is caused by mutations in the IL2RG gene located on the X chromosome. Its

prevalence, compared to other less common forms of SCID, can make it a prominent segment in the SCID diagnosis market. X-SCID is often diagnosed in infancy due to its severe clinical presentation, which includes recurrent infections and failure to thrive. Early diagnosis is crucial for timely intervention and treatment. Some regions have included X-SCID in their newborn screening programs, which has led to early identification of affected infants, further emphasizing the need for accurate diagnostic testing. X-SCID has been the focus of significant research and therapeutic development. Gene therapy approaches, such as the use of autologous hematopoietic stem cell transplantation (HSCT) with gene-corrected cells, have shown promise in treating X-SCID. This has led to increased diagnostic efforts to identify suitable candidates for gene therapy. Ongoing clinical trials for X-SCID and related treatments can lead to increased diagnostic efforts to identify eligible participants, further fuelling the diagnostic market.

Test Type Insights

In 2022, the Global Severe Combined Immunodeficiency (SCID) Diagnosis Market largest share was held by genetic Test segment and is predicted to continue expanding over the coming years. Genetic tests are highly precise and accurate in identifying the specific genetic mutations responsible for SCID. This precision is essential for confirming a diagnosis and determining the exact subtype of SCID, which can guide treatment decisions. SCID is not a single disorder but a group of genetic conditions with varying genetic causes. Genetic tests can differentiate between different SCID subtypes, such as X-linked SCID, ADA-SCID, or IL7R-SCID. This information is critical for treatment planning and genetic counselling. Genetic testing can be performed shortly after birth, allowing for early diagnosis of SCID. Early identification is crucial for initiating timely treatment, which can improve outcomes for affected infants. Some forms of SCID have targeted therapies available, such as gene therapy or enzyme replacement therapy. Genetic testing helps identify patients who may benefit from these specific treatments. Genetic testing provides valuable information to families affected by SCID. Genetic counsellors can help families understand the inheritance pattern, recurrence risk, and options for family planning.

End-User Insights

In 2022, the Global Severe Combined Immunodeficiency (SCID) Diagnosis Market largest share was held by Hospital segment in the forecast period and is predicted to continue expanding over the coming years. Hospitals typically have a team of specialized medical professionals, including immunologists, geneticists, and

paediatricians, who are well-equipped to diagnose and manage rare conditions like SCID. This expertise is essential for accurate and timely diagnosis. Hospitals often have state-of-the-art diagnostic laboratories and equipment that can conduct a wide range of tests, including genetic sequencing and immunological assays, which are essential for SCID diagnosis. Many hospitals, particularly those with maternity and neonatal units, are actively involved in newborn screening programs. SCID is often included in these programs, enabling early detection and intervention. Some hospitals serve as regional or national referral centres for rare diseases like SCID. Patients with suspected or confirmed SCID are often referred to these specialized hospitals for diagnosis and treatment. Hospitals may collaborate with research institutions and universities to stay at the forefront of diagnostic developments and research on SCID. This collaborative effort can enhance diagnostic capabilities.

Regional Insights

The North America region dominates the Global Severe Combined Immunodeficiency (SCID) Diagnosis Market in 2022. North America boasts a well-developed and advanced healthcare infrastructure. It has a large network of hospitals, clinics, and diagnostic laboratories equipped with the latest technology and expertise, facilitating the diagnosis of rare conditions like SCID. North America has been an early adopter of cutting-edge diagnostic technologies, such as next-generation sequencing (NGS) and advanced immunological assays. This allows for more accurate and timelier SCID diagnosis. Many pharmaceutical and biotechnology companies, as well as research institutions, are based in North America. This concentration of research and development efforts contributes to advancements in diagnostics and therapeutics for SCID. Several states in the U.S. have established comprehensive newborn screening programs that include SCID testing. Early diagnosis through newborn screening has become more widespread in North America, leading to better patient outcomes.

Key Market Players

ARCHIMED SAS

PerkinElmer LAS Inc

Health Research, Inc

Winfertility Inc.

Portea Medical

LaCAR MDX Technologies

Labsystems Diagnostics Oy

Devyser Diagnostics

Revcovi

Leadiant Biosciences Inc.

Report Scope:

In this report, the Global Severe Combined Immunodeficiency (SCID) Diagnosis Market has been segmented into the following categories, in addition to the industry trends which have also been detailed below:

Severe Combined Immunodeficiency (SCID) Diagnosis Market, By Disease Type:

X-linked SCID

ADA-SCID

others

Severe Combined Immunodeficiency (SCID) Diagnosis Market, By Test Type:

TREC

Complete blood count (CBC)

Genetic Test

Biochemical Test

Others

Severe Combined Immunodeficiency (SCID) Diagnosis Market, By End-User:

Hospitals

Diagnostic and Research Laboratories

Others

Global Severe Combined Immunodeficiency (SCID) Diagnosis Market, By region:

North America

United States

Canada

Mexico

Asia-Pacific

China

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

Company Profiles: Detailed analysis of the major companies present in the Global Severe Combined Immunodeficiency (SCID) Diagnosis Market.

Available Customizations:

Global Severe Combined Immunodeficiency (SCID) Diagnosis 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).

Contents

1. PRODUCT OVERVIEW

- 1.1. Market Definition
- 1.2. Scope of the Market
 - 1.2.1. Markets Covered
 - 1.2.2. Years Considered for Study
 - 1.2.3. Key Market Segmentations

2. RESEARCH METHODOLOGY

- 2.1. Objective of the Study
- 2.2. Baseline Methodology
- 2.3. Key Industry Partners
- 2.4. Major Association and Secondary Sources
- 2.5. Forecasting Methodology
- 2.6. Data Triangulation & Validation
- 2.7. Assumptions and Limitations

3. EXECUTIVE SUMMARY

- 3.1. Overview of the Market
- 3.2. Overview of Key Market Segmentations
- 3.3. Overview of Key Market Players
- 3.4. Overview of Key Regions/Countries
- 3.5. Overview of Market Drivers, Challenges, Trends

4. VOICE OF CUSTOMER

5. GLOBAL SEVERE COMBINED IMMUNODEFICIENCY (SCID) DIAGNOSIS MARKET OUTLOOK

- 5.1. Market Size & Forecast
 - 5.1.1. By Value
- 5.2. Market Share & Forecast
 - 5.2.1. By Disease Type (X-linked SCID, ADA-SCID, others)
 - 5.2.2. By Test Type (TREC, Complete blood count (CBC), Genetic Test, Biochemical

Test, others)

5.2.3. By End User (Hospitals, Diagnostic and Research Laboratories, Others)

5.2.4. By Region

5.2.5. By Company (2022)

5.3. Market Map

6. ASIA PACIFIC SEVERE COMBINED IMMUNODEFICIENCY (SCID) DIAGNOSIS MARKET OUTLOOK

6.1. Market Size & Forecast

6.1.1. By Value

6.2. Market Share & Forecast

6.2.1. By Disease Type

6.2.2. By Test Type

6.2.3. By End User

6.2.4. By Country

6.3. Asia Pacific: Country Analysis

6.3.1. China Severe Combined Immunodeficiency (SCID) Diagnosis Market Outlook

6.3.1.1. Market Size & Forecast

6.3.1.1.1. By Value

6.3.1.2. Market Share & Forecast

6.3.1.2.1. By Disease Type

6.3.1.2.2. By Test Type

6.3.1.2.3. By End User

6.3.2. India Severe Combined Immunodeficiency (SCID) Diagnosis Market Outlook

6.3.2.1. Market Size & Forecast

6.3.2.1.1. By Value

6.3.2.2. Market Share & Forecast

6.3.2.2.1. By Disease Type

6.3.2.2.2. By Test Type

6.3.2.2.3. By End User

6.3.3. Australia Severe Combined Immunodeficiency (SCID) Diagnosis Market Outlook

6.3.3.1. Market Size & Forecast

6.3.3.1.1. By Value

6.3.3.2. Market Share & Forecast

6.3.3.2.1. By Disease Type

6.3.3.2.2. By Test Type

6.3.3.2.3. By End User

6.3.4. Japan Severe Combined Immunodeficiency (SCID) Diagnosis Market Outlook

6.3.4.1. Market Size & Forecast

6.3.4.1.1. By Value

6.3.4.2. Market Share & Forecast

6.3.4.2.1. By Disease Type

6.3.4.2.2. By Test Type

6.3.4.2.3. By End User

6.3.5. South Korea Severe Combined Immunodeficiency (SCID) Diagnosis Market Outlook

6.3.5.1. Market Size & Forecast

6.3.5.1.1. By Value

6.3.5.2. Market Share & Forecast

6.3.5.2.1. By Disease Type

6.3.5.2.2. By Test Type

6.3.5.2.3. By End User

7. EUROPE SEVERE COMBINED IMMUNODEFICIENCY (SCID) DIAGNOSIS MARKET OUTLOOK

7.1. Market Size & Forecast

7.1.1. By Value

7.2. Market Share & Forecast

7.2.1. By Disease Type

7.2.2. By Test Type

7.2.3. By End User

7.2.4. By Country

7.3. Europe: Country Analysis

7.3.1. France Severe Combined Immunodeficiency (SCID) Diagnosis Market Outlook

7.3.1.1. Market Size & Forecast

7.3.1.1.1. By Value

7.3.1.2. Market Share & Forecast

7.3.1.2.1. By Disease Type

7.3.1.2.2. By Test Type

7.3.1.2.3. By End User

7.3.2. Germany Severe Combined Immunodeficiency (SCID) Diagnosis Market Outlook

7.3.2.1. Market Size & Forecast

7.3.2.1.1. By Value

7.3.2.2. Market Share & Forecast

7.3.2.2.1. By Disease Type

7.3.2.2.2. By Test Type

7.3.2.2.3. By End User

7.3.3. Spain Severe Combined Immunodeficiency (SCID) Diagnosis Market Outlook

7.3.3.1. Market Size & Forecast

7.3.3.1.1. By Value

7.3.3.2. Market Share & Forecast

7.3.3.2.1. By Disease Type

7.3.3.2.2. By Test Type

7.3.3.2.3. By End User

7.3.4. Italy Severe Combined Immunodeficiency (SCID) Diagnosis Market Outlook

7.3.4.1. Market Size & Forecast

7.3.4.1.1. By Value

7.3.4.2. Market Share & Forecast

7.3.4.2.1. By Disease Type

7.3.4.2.2. By Test Type

7.3.4.2.3. By End User

7.3.5. United Kingdom Severe Combined Immunodeficiency (SCID) Diagnosis Market Outlook

7.3.5.1. Market Size & Forecast

7.3.5.1.1. By Value

7.3.5.2. Market Share & Forecast

7.3.5.2.1. By Disease Type

7.3.5.2.2. By Test Type

7.3.5.2.3. By End User

8. NORTH AMERICA SEVERE COMBINED IMMUNODEFICIENCY (SCID) DIAGNOSIS MARKET OUTLOOK

8.1. Market Size & Forecast

8.1.1. By Value

8.2. Market Share & Forecast

8.2.1. By Disease Type

8.2.2. By Test Type

8.2.3. By End User

8.2.4. By Country

8.3. North America: Country Analysis

8.3.1. United States Severe Combined Immunodeficiency (SCID) Diagnosis Market Outlook

8.3.1.1. Market Size & Forecast

- 8.3.1.1.1. By Value
- 8.3.1.2. Market Share & Forecast
 - 8.3.1.2.1. By Disease Type
 - 8.3.1.2.2. By Test Type
 - 8.3.1.2.3. By End User
- 8.3.2. Mexico Severe Combined Immunodeficiency (SCID) Diagnosis Market Outlook
 - 8.3.2.1. Market Size & Forecast
 - 8.3.2.1.1. By Value
 - 8.3.2.2. Market Share & Forecast
 - 8.3.2.2.1. By Disease Type
 - 8.3.2.2.2. By Test Type
 - 8.3.2.2.3. By End User
- 8.3.3. Canada Severe Combined Immunodeficiency (SCID) Diagnosis Market Outlook
 - 8.3.3.1. Market Size & Forecast
 - 8.3.3.1.1. By Value
 - 8.3.3.2. Market Share & Forecast
 - 8.3.3.2.1. By Disease Type
 - 8.3.3.2.2. By Test Type
 - 8.3.3.2.3. By End User

9. SOUTH AMERICA SEVERE COMBINED IMMUNODEFICIENCY (SCID) DIAGNOSIS MARKET OUTLOOK

- 9.1. Market Size & Forecast
 - 9.1.1. By Value
- 9.2. Market Share & Forecast
 - 9.2.1. By Disease Type
 - 9.2.2. By Test Type
 - 9.2.3. By End User
 - 9.2.4. By Country
- 9.3. South America: Country Analysis
 - 9.3.1. Brazil Severe Combined Immunodeficiency (SCID) Diagnosis Market Outlook
 - 9.3.1.1. Market Size & Forecast
 - 9.3.1.1.1. By Value
 - 9.3.1.2. Market Share & Forecast
 - 9.3.1.2.1. By Disease Type
 - 9.3.1.2.2. By Test Type
 - 9.3.1.2.3. By End User
 - 9.3.2. Argentina Severe Combined Immunodeficiency (SCID) Diagnosis Market

Outlook

9.3.2.1. Market Size & Forecast

9.3.2.1.1. By Value

9.3.2.2. Market Share & Forecast

9.3.2.2.1. By Disease Type

9.3.2.2.2. By Test Type

9.3.2.2.3. By End User

9.3.3. Colombia Severe Combined Immunodeficiency (SCID) Diagnosis Market

Outlook

9.3.3.1. Market Size & Forecast

9.3.3.1.1. By Value

9.3.3.2. Market Share & Forecast

9.3.3.2.1. By Disease Type

9.3.3.2.2. By Test Type

9.3.3.2.3. By End User

10. MIDDLE EAST AND AFRICA SEVERE COMBINED IMMUNODEFICIENCY (SCID) DIAGNOSIS MARKET OUTLOOK

10.1. Market Size & Forecast

10.1.1. By Value

10.2. Market Share & Forecast

10.2.1. By Disease Type

10.2.2. By Test Type

10.2.3. By End User

10.2.4. By Country

10.3. MEA: Country Analysis

10.3.1. South Africa Severe Combined Immunodeficiency (SCID) Diagnosis Market

Outlook

10.3.1.1. Market Size & Forecast

10.3.1.1.1. By Value

10.3.1.2. Market Share & Forecast

10.3.1.2.1. By Disease Type

10.3.1.2.2. By Test Type

10.3.1.2.3. By End User

10.3.2. Saudi Arabia Severe Combined Immunodeficiency (SCID) Diagnosis Market

Outlook

10.3.2.1. Market Size & Forecast

10.3.2.1.1. By Value

10.3.2.2. Market Share & Forecast

10.3.2.2.1. By Disease Type

10.3.2.2.2. By Test Type

10.3.2.2.3. By End User

10.3.3. UAE Severe Combined Immunodeficiency (SCID) Diagnosis Market Outlook

10.3.3.1. Market Size & Forecast

10.3.3.1.1. By Value

10.3.3.2. Market Share & Forecast

10.3.3.2.1. By Disease Type

10.3.3.2.2. By Test Type

10.3.3.2.3. By End User

11. MARKET DYNAMICS

11.1. Drivers

11.2. Challenges

12. MARKET TRENDS & DEVELOPMENTS

12.1. Recent Developments

12.2. Product Launches

12.3. Mergers & Acquisitions

13. GLOBAL SEVERE COMBINED IMMUNODEFICIENCY (SCID) DIAGNOSIS MARKET: SWOT ANALYSIS

14. PORTER'S FIVE FORCES ANALYSIS

14.1. Competition in the Industry

14.2. Potential of New Entrants

14.3. Power of Suppliers

14.4. Power of Customers

14.5. Threat of Substitute Product

15. PESTLE ANALYSIS

16. COMPETITIVE LANDSCAPE

- 16.1. ARCHIMED SAS
 - 16.1.1. Business Overview
 - 16.1.2. Company Snapshot
 - 16.1.3. Products & Services
 - 16.1.4. Financials (In case of listed companies)
 - 16.1.5. Recent Developments
 - 16.1.6. SWOT Analysis
- 16.2. PerkinElmer LAS Inc.
 - 16.2.1. Business Overview
 - 16.2.2. Company Snapshot
 - 16.2.3. Products & Services
 - 16.2.4. Financials (In case of listed companies)
 - 16.2.5. Recent Developments
 - 16.2.6. SWOT Analysis
- 16.3. Health Research, Inc
 - 16.3.1. Business Overview
 - 16.3.2. Company Snapshot
 - 16.3.3. Products & Services
 - 16.3.4. Financials (In case of listed companies)
 - 16.3.5. Recent Developments
 - 16.3.6. SWOT Analysis
- 16.4. Winfertility, Inc.
 - 16.4.1. Business Overview
 - 16.4.2. Company Snapshot
 - 16.4.3. Products & Services
 - 16.4.4. Financials (In case of listed companies)
 - 16.4.5. Recent Developments
 - 16.4.6. SWOT Analysis
- 16.5. Portea Medical
 - 16.5.1. Business Overview
 - 16.5.2. Company Snapshot
 - 16.5.3. Products & Services
 - 16.5.4. Financials (In case of listed companies)
 - 16.5.5. Recent Developments
 - 16.5.6. SWOT Analysis
- 16.6. LaCAR MDX Technologies
 - 16.6.1. Business Overview
 - 16.6.2. Company Snapshot

- 16.6.3. Products & Services
- 16.6.4. Financials (In case of listed companies)
- 16.6.5. Recent Developments
- 16.6.6. SWOT Analysis
- 16.7. Labsystems Diagnostics Oy
 - 16.7.1. Business Overview
 - 16.7.2. Company Snapshot
 - 16.7.3. Products & Services
 - 16.7.4. Financials (In case of listed companies)
 - 16.7.5. Recent Developments
 - 16.7.6. SWOT Analysis
- 16.8. Devyser Diagnostics AB
 - 16.8.1. Business Overview
 - 16.8.2. Company Snapshot
 - 16.8.3. Products & Services
 - 16.8.4. Financials (In case of listed companies)
 - 16.8.5. Recent Developments
 - 16.8.6. SWOT Analysis
- 16.9. Leadiant Biosciences Inc.
 - 16.9.1. Business Overview
 - 16.9.2. Company Snapshot
 - 16.9.3. Products & Services
 - 16.9.4. Financials (In case of listed companies)
 - 16.9.5. Recent Developments
 - 16.9.6. SWOT Analysis

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