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Global Breath Molecular Diagnosis Market Growth 2025-2031

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Abstracts

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The global Breath Molecular Diagnosis market size is predicted to grow from US$ 284 million in 2025 to US$ 567 million in 2031; it is expected to grow at a CAGR of 12.2% from 2025 to 2031.

Exhaled breath molecular diagnosis is an emerging in vitro diagnostic (IVD) technology. Generally speaking, in vitro diagnosis requires the use of diagnostic reagents and equipment to analyze samples such as blood or urine. Sampling is done first and then analysis is done. Cells, microorganisms and biochemical molecules can be analyzed. It is mainly used for the diagnosis of blood circulation or systemic diseases. Exhaled breath molecular diagnosis does not require diagnostic reagents, and sampling and analysis can be performed at the same time. The gas molecules produced by cell and microbial metabolism are analyzed, which is particularly suitable for the diagnosis of respiratory and digestive diseases. Exhaled breath molecular diagnosis complements blood tests and imaging diagnosis. Like existing in vitro diagnosis, exhaled breath molecular diagnosis is also divided into two categories: professional laboratories and point-of-care diagnosis (POCT). Professional laboratories use laboratory analysis equipment such as gas chromatography, mass spectrometry and spectroscopy to perform exhaled breath analysis on patients' exhaled gas sampling bags or gas sampling tubes; due to the lack of exhaled breath sensor products, Europe and the United States currently provide analytical services for exhaled metabolomics of H2, CH4 and VOC (volatile organic compounds) through professional laboratories. Point-of-care diagnosis (POCT) uses exhaled breath detection sensors, which integrate sampling and analysis. It only takes a few seconds for patients to sample their exhaled breath, and only tens of seconds for the instrument to analyze the results.

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Exhaled breath molecular diagnostic equipment is classified as a low-risk medical device by European and American drug regulatory authorities. The US FDA believes that breath testing will affect the results of medical diagnosis. As a Class II medical device, it only tests and certifies the performance of breath testing. The EU regulates it as a special Class I medical device similar to a sphygmomanometer. It only needs to be tested by itself or by a third-party laboratory according to the EN standard. Therefore, exhaled breath molecular diagnostic equipment was first listed in Europe, and there are a large number of them now. China currently regulates exhaled breath molecular diagnostic equipment as a Class II medical device, and it takes a long time to register. At present, most medical devices related to exhaled breath molecular diagnostic technology are in the market cultivation or introduction stage, requiring a large number of clinical trials, certification and registration.

POCT based on exhaled breath molecular diagnosis can provide detection items that blood test POCT lacks, such as detection of airway inflammation and gastrointestinal flora metabolic disorders. Moreover, POCT based on exhaled breath molecular diagnosis does not require blood drawing, and has the characteristics of non-invasive, instant, and biopsy. It can be used to make up for the shortcomings of in vitro diagnosis such as blood tests and imaging, avoid the risks of invasive in vivo diagnosis, and is more suitable for the use of common diseases and chronic diseases in hospitals, grassroots physical examinations, and family self-examination. In recent years, exhaled breath molecular diagnosis technology has been increasingly valued by domestic and foreign governments, research and development institutions, and related medical organizations. Various organizations and institutions have formulated relevant policies, development plans, and standard guidelines to jointly promote the rapid development of clinical technology for exhaled breath molecular diagnosis.

Exhaled breath molecular diagnosis or breath testing belongs to the emerging field of POCT technology. At present, the Helicobacter pylori breath test with the largest market size has a market history of less than 25 years, and the development of the inflammatory breath test product with the greatest market potential has only been 10 years, while breath testing technologies such as gastrointestinal flora metabolic disorders are still in the market cultivation stage. In addition, breath detection technologies such as breath NH3, H2S, VOC (volatile organic compounds), breath metabolomics and olfactory artificial intelligence (electronic nose) are still in clinical trials or waiting for drug regulatory certification and approval.

In the past 30 years, with the gradual development of related technologies including

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breath detection abroad, the rapid growth of the domestic economy and the continuous development of the medical and health industry have provided a broad market space for the widespread application of this technology in China. At the same time, the development of domestic breath detection technology is almost synchronized with that of foreign countries, covering almost all areas of foreign breath detection, including the research of breath metabolomics and olfactory artificial intelligence, and many technologies are even ahead of foreign countries. It is one of the few emerging technology fields that may form a global leading breath detection in China.

With the continuous advancement of the construction of the PCCM system, the demand for breath analysis products in secondary and tertiary hospitals will further expand. Portable instrument products, handheld instrument products and other products for primary hospitals and home terminals are constantly being developed, and product application scenarios and usage needs will be further expanded.

With the development of science and technology and artificial intelligence, future breathalyzers will be more intelligent and automated, with functions such as automatic identification, data analysis and report generation, reducing human intervention and improving diagnostic accuracy and efficiency.

LP Information, Inc. (LPI) ' newest research report, the “Breath Molecular Diagnosis Industry Forecast” looks at past sales and reviews total world Breath Molecular Diagnosis sales in 2024, providing a comprehensive analysis by region and market sector of projected Breath Molecular Diagnosis sales for 2025 through 2031. With Breath Molecular Diagnosis sales broken down by region, market sector and sub-sector, this report provides a detailed analysis in US$ millions of the world Breath Molecular Diagnosis industry.

This Insight Report provides a comprehensive analysis of the global Breath Molecular Diagnosis landscape and highlights key trends related to product segmentation, company formation, revenue, and market share, latest development, and M&A activity. This report also analyzes the strategies of leading global companies with a focus on Breath Molecular Diagnosis portfolios and capabilities, market entry strategies, market positions, and geographic footprints, to better understand these firms’ unique position in an accelerating global Breath Molecular Diagnosis market.

This Insight Report evaluates the key market trends, drivers, and affecting factors shaping the global outlook for Breath Molecular Diagnosis and breaks down the forecast by Type, by Application, geography, and market size to highlight emerging pockets of

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opportunity. With a transparent methodology based on hundreds of bottom-up qualitative and quantitative market inputs, this study forecast offers a highly nuanced view of the current state and future trajectory in the global Breath Molecular Diagnosis.

This report presents a comprehensive overview, market shares, and growth opportunities of Breath Molecular Diagnosis market by product type, application, key manufacturers and key regions and countries.

Segmentation by Type:

C13 Type

NO Type

H2/CO Type

VOCs Type

Segmentation by Application:

Hospital

Clinic

Physical Examination Center

Other

This report also splits the market by region:

Americas

United States

Canada

Mexico

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- Brazil

APAC

- China
- Japan
- Korea
- Southeast Asia
- India
- Australia

Europe

- Germany
- France
- UK
- Italy
- Russia

Middle East & Africa

- Egypt
- South Africa
- Israel
- Turkey

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GCC Countries

The below companies that are profiled have been selected based on inputs gathered from primary experts and analysing the company's coverage, product portfolio, its market penetration.

NIOX Group plc

Headway

Sunvou Medical Electronics Co

Richen Holding

Meridian Bioscience

CAPNIA, Inc.

Kibion??

Otsuka Electronics

LEYI BIOLOGY

Eco Physics AG

Shenzhen Breax

QUINTRON

Beijing Wanliandaxinke Instruments Co

SIMES SIKMA

Beijing Safe Heart Technology

e-LinkCare Meditech Co

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ChromX Health

Huiyuen Tech

Key Questions Addressed in this Report

What is the 10-year outlook for the global Breath Molecular Diagnosis market?

What factors are driving Breath Molecular Diagnosis market growth, globally and by region?

Which technologies are poised for the fastest growth by market and region?

How do Breath Molecular Diagnosis market opportunities vary by end market size?

How does Breath Molecular Diagnosis break out by Type, by Application?

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