



Molecular Diagnostics for Infectious Disease.

Markets, Strategies and Trends. Volume & Price Forecasts by Pathogen and by Country. With Multiplex and Point of Care Market Analysis, Executive Guides and Customization.

2020 to 2024



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1.1 What is Molecular Diagnostics

Molecular Diagnostics looks at genetic codes and specific proteins,

biomarkers, to develop a diagnosis

The market will double in the next five years

Molecular diagnostics is a technique used to analyse biological markers in the genome and proteome—the individual's genetic code and how their cells express their genes as proteins—by applying molecular biology to medical testing. The technique is used to diagnose and monitor disease, detect risk, and decide which therapies will work best for individual patients. By analysing the specifics of the patient and their disease, molecular diagnostics offers the prospect of personalised medicine.

These tests are useful in a range of medical areas, including infectious disease, oncology, human leukocyte antigen typing (which investigates and predicts immune function), coagulation, and pharmacogenomics—the genetic prediction of which drugs will work best. Molecular diagnostics has become such an important part of clinical *in vitro* diagnostics that many medical laboratories, especially larger ones, have created a new department in their organization, usually termed Molecular Diagnostics or Genetic Testing. In the industry the abbreviation MDx is often used as shorthand for Molecular Diagnostics and is in many company names. This report uses this shorthand occasionally.

This report is concerned with a global view of the global market for Molecular Diagnostic testing services for Infectious Disease. It is intended to provide information on the spending for such services worldwide. By 2023, the market will, conservatively, be over 140 million tests per year.

of real-time measurements, isothermal amplification, the inclusion of internal quality assurance protocols, device miniaturization and the automation of specimen processing. The result has been a significant increase in the availability of results to a high level of accuracy and quality. Molecular assays are currently widely used for diagnostics, antiretroviral monitoring and drug resistance characterization in developed countries. Simple and cost-effective point-of-care versions are also being vigorously developed with the eventual goal of providing timely healthcare services to patients residing in remote areas and those in resource-constrained countries. Point of care molecular diagnostic testing that delivers diagnostic, pharmacogenomic and management capabilities remains a large opportunity especially where cost competitive tests can be developed. Over 90% of the molecular market opportunity by total dollar expenditure is in viral load testing.

TABLE 3 HIV TESTS - CMS CODES & PRICES

HCPCS Code	Test	Limit	Mid Point
87534	Hiv-1 dna dir probe	27.32	36.92
87535	Hiv-1 probe&reverse trnscrpj	47.80	64.60
87536	Hiv-1 quant&revrse trnscrpj (viral load)	115.92	156.65
87537	Hiv-2 dna dir probe	27.32	36.92
87538	Hiv-2 probe&revrse trnscripj	47.80	64.60
87539	Hiv-2 quant&revrse trnscripj (viral load)	58.35	78.85
86689	Htlv/hiv confirmj antibody	26.37	35.63
87906	Genotype dna/rna hiv	175.35	236.96
86701	Hiv-1antibody	12.11	16.36

2.10 Blood Screening

2.10.1 Collection and Testing

The collecting agency usually identifies whether the blood is type A, B, AB, or O and the donor's Rh (D) type and will screen for antibodies to less common antigens. More testing, including a crossmatch, is usually done before a transfusion. Group O is often cited as the "universal donor" but this only refers to red cell transfusions. For plasma transfusions the system is reversed and AB is the universal donor type.

Most blood is tested for diseases, including some STDs. The tests used are high-sensitivity screening tests and no actual diagnosis is made. Some of the test results are later found to be false positives using more specific testing. False negatives are rare, but donors are discouraged from using blood donation for the purpose of anonymous STD screening because a false negative could mean a contaminated unit. The blood is usually discarded if these tests are positive, but there are some exceptions, such as autologous donations. The donor is generally notified of the test result.

Donated blood is tested by many methods, but the core tests recommended by the World Health Organization are these four:

Hepatitis B Surface Antigen

Antibody to Hepatitis C

Antibody to HIV, usually subtypes 1 and 2

Serologic test for Syphilis

Curetis

<http://www.curetis.com>

Max-Eyth-Str. 42

71088 Holzgerlingen

Tel.: +49 (0)7031 / 49195-10

This is a public company. On Euronext at CURE. Market cap: US\$110M

The key product is a benchtop (point of care) diagnostic instrument line Unyvero. The Unyvero platform developed by Curetis is a fast, comprehensive diagnostics system for severe infectious diseases in hospitalized patients. Using a variety of cartridges, diseases such as pneumonia or implant and tissue infections can be easily and rapidly diagnosed within just 4–5 hours, whether this is in the hospital laboratory or directly at the "point of need" in the intensive care unit. The company is focussed on commercialization and extension of this product line planning for USA introduction in 2018.a

The platform is now FDA approved with a unique segmentation of ID panels as follows:

Pneumonia Application

ITI Application – Implant and Tissue Infections

BCU Application – Blood Infection/Sepsis/Bacteraemia

IAI Application – Intra Abdominal Infection

UTI Application – Urinary Tract Infection

Recent Developments – Importance and How to Use This Section

Importance of These Developments

Many users, especially those in the financial community, have noted that this section of the report can be extremely valuable in helping to understand industry current events and the evolution of key market players. These items are not chosen at random. They have been selected by the author(s) as significant and worth reading about, i.e. important. Please keep this in mind in reviewing them.

How to Use This Section

These items are NOT in date order. They are in the order in which they have been added to the report. This report is updated regularly and new items are incorporated and others removed. Generally newer items are in the lower part of this section and have the highest numbers. Please refer to the date of an item to understand its currency. Reading this entire section is recommended for those not familiar with the industry. Many of the trends and issues noted elsewhere are illustrated in these actual events,

Ares Genetics signs R&D agreement with leading global IVD corporation

20 Sep 2019

Ares Genetics GmbH has entered into a multi-phase partnership with an undisclosed leading global in vitro diagnostics corporation to jointly develop diagnostic solutions for infectious disease testing based on next-generation sequencing technology. The companies signed an R&D and option agreement for the first phase of the partnership.

The partnership follows the successful completion of a feasibility study in which Ares Genetics correctly identified 100% of the pathogen species and successfully predicted antibiotic resistance for over 50 drug/pathogen combinations in line with FDA requirements (<1.5% very major error, i.e. misclassification of resistant isolates as susceptible and <3 % major error, i.e. misclassification of susceptible isolates as resistant).

7.1 France

Volumes: millions of tests. Price: 2019 US\$. Revenues: millions US\$.

7.1.1 HIV – Volumes, Prices, Revenues

TABLE 50 HIV INFECTIOUS DISEASE - VOLUME PRICE AND REVENUE FORECAST

	2019	2020	2021	2022	2023	2024	CAGR
Volume	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Price	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Revenue	xxx	xxx	xxx	xxx	xxx	xxx	xxx

7.1.2 HBV – Volumes, Prices, Revenues

TABLE 51 MDx HBV - VOLUME PRICE AND REVENUE FORECAST

	2019	2020	2021	2022	2023	2024	CAGR
Volume	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Price	xxx	xxx	xxx	xxx	xxx	xxx	xxx
Revenue	xxx	xxx	xxx	xxx	xxx	xxx	xxx

7.1.3 HCV – Volumes, Prices, Revenues

TABLE 52 HCV - VOLUME PRICE AND REVENUE FORECAST

	2019	2020	2021	2022	2023	2024	CAGR