



22 FACTS ABOUT THE IVD MARKET

This White Paper discusses some of the most recent trends in in vitro diagnostics (IVD). The information is from our Worldwide Market for In Vitro Diagnostic Tests report, published every year and now in its 14th edition, and from other reports.

01

The Market in 2021 **Reached \$117 Billion.**

This is per our most recent report, The Worldwide Market for In Vitro Diagnostic Tests.

02

In 2005 it was **Only \$32 Billion.**

That's growth of almost four times in less than 20 years, as better tools to improve healthcare decision making have been developed.

03

The Market is **Projected to Grow to \$129 Billion in 2026.**

That's not as fast as the growth of the last two years (largely fueled by COVID-19 testing) but still a large market and reflects resumption of office visits and preventive care.

Kalorama Information Has two decades covering the IVD market. We size markets, identify competitive positions, make projections and analyze trends.

04

Infectious Disease is **Nearly Half** the Market.

Microbiology tests in all their forms—both specific and general, COVID-19 and tests for other pathogens—were 46% of the market in 2021. This is compared to only 15% in 2005.

05

This is **Due to COVID-19**.

COVID-19 is 26% of revenues between PCR, lab-based antigen, antibody and rapid PCR and antigen tests. Specific breakouts are in The Worldwide Market for In Vitro Diagnostic Tests.

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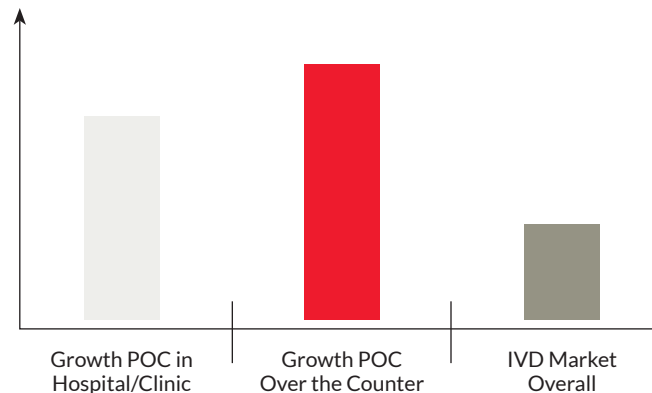
But **Not Only Due to COVID-19**.

Other infectious diseases still make up 20% of the market. Hepatitis and healthcare infections (HAIs) are among the top categories for IVD sales.

07

Besides COVID-19, **Hepatitis** and **Hospital Infections** are **Large Sales Categories**.

Within infectious disease testing markets, these diseases are the largest revenue contributors for infectious diseases. There are scores of other major categories of infectious diseases.



Revenue Growth '20 to '21 POC (red) vs. non-POC (grey)

08

Besides Infectious Diseases, **Diabetes** and **Cancer** are **Top Testing Categories**.

Diabetes is the 2nd largest area of IVD revenues when that is segmented by disease category.

09

Since Jan 2020 stocks of **COVID-19 Test Companies** have shown gains. Wall Street has noticed IVD firms between **Jan 1 - Dec 31 2020**:

Abbott grew from \$89 to \$140, **Quidel** grew from \$78 to \$134, **Thermo Fisher** from \$212 to \$644, & **Hologic** from \$53 to \$73 a share.

There are other examples as well.

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Point of Care Tests Show Faster Revenue Growth.

Tests that are near patient and can affect outcomes positively grew revenues much faster than other tests between 2020 and 2021. Growth rates were 35% for professional point of care and 48% for POC home tests vs. overall IVD market growth of 10%. (Is this due to COVID-19? Yes, but higher growth in POC has been observed for at least a decade).

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Roche and Abbott are the **Largest IVD Companies.**

Roche and Abbott have been 1 and 2 in the market for decades.

In 2020 and 2021 this became more of a tie due to Abbott's point of care COVID-19 sales and home test strength.

12

Market Share has **Tightened.**

Roche's lead over its nearest competitor in IVD was 12% in 2015. The Top Company in the IVD Market was once 12% ahead; now, market leadership is estimated to be tied at the end of year 2021.

More information on the top 19 and second-tier IVD company market share is provided in our report, *The Worldwide Market for In Vitro Diagnostic Tests.*



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19 Companies Control the IVD Market.

The top 19 companies in vitro diagnostics earn **80% of revenues.** Siemens Healthineers, Bio-Rad, Beckman Coulter, Radiometer, DiaSorin and Quidel (*along with soon to be acquired Ortho Clinical*) dominate multiple test areas.

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There is Still **Plenty of Room** for **Small, Mid-Size** and **Startup** IVD Companies.

80% of revenues earned by the top 19 companies leaves \$23 billion dollars, there are hundreds of various sized IVD companies (The Worldwide Market for In Vitro Diagnostic Tests profiles over 200 companies) that may operate in a few test fields or specialize in one.

15

Immunoassays are **One-Fourth** of the Market.

Immunoassays were invented in the 1960s, yet still have a host of applications from COVID-19, to heart disease, to allergies.

16

Cancer is \$5.5 Billion and Growing.

Cancer is the 2nd largest IVD disease category, per our recent report, The World Market for Cancer Diagnostics.

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China's Cancer Test Market is an Opportunity.

China's IVD market has slowed in its rate of increase over the years, but one problem that remains where testing will be needed is cancer. The burdens of several forms of cancer—breast, lung, colorectal stomach, and liver—proportional to population are significantly above global averages. In terms of lung cancer, China alone is home to more than 300 million smokers, driving rates. New cervical cancer cases are estimated at 110,000 with deaths of 59,000 for 2020.

18

Shake Up in Glucose Market Over CGM, as **CGM Will Lead** Glucose in 2022.

Growth of continuous blood glucose monitors (CGM) from Medtronic, Dexcom and other companies has spurred an otherwise maturing industry. Expect CGM to overtake the traditional glucose monitors market this year.

While more patients use traditional monitors, cost differences account for greater revenues from CGM.

19

Venture Capital in IVD **Over \$3 Billion.**

According to BioWorld.com/Clarivate, capital investment in IVD was \$3.4 billion in 2021. Molecular point of care and COVID-19 tests were VC interest areas.

20

Sepsis Remains a **Significant Health Problem** and Test Market Opportunity.

Sepsis accounts for 1 in 3 hospital deaths and has a mortality rate between 10% and 40%. It also generates \$62 billion in care costs every year. Testing to identify crucially ill patients is a small investment considering those staggering costs. One solution? Day Zero Diagnostics won AACC's Disruptive Technology award in 2021 for its test that uses whole-genome sequencing (WGS) to speed up diagnosis from days to hours.

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Fastest Growing Single Country IVD Market Next 5 Years is Chile.

Looking ahead, Korea, Columbia, Singapore, Philippines, and Saudi Arabia will all beat overall world IVD market growth averages.

22

Liquid Biopsy Grew While the World Focused on COVID-19.

Despite the focus on COVID-19, the market exceeded a billion dollars in 2021, and numerous approvals for liquid biopsy products were achieved.

The desire for a non-invasive NGS-based method of assessing cancer has not diminished. The market is up from \$548 million in 2019, per Kalorama Information's The World Market for Liquid Biopsy report released December 2021.

Liquid biopsy is not included in IVD market numbers, but the use of NGS-based biopsies spawns lab developed test supply sales that are counted in our market figures, such as diagnostic purposed sequencing consumables.

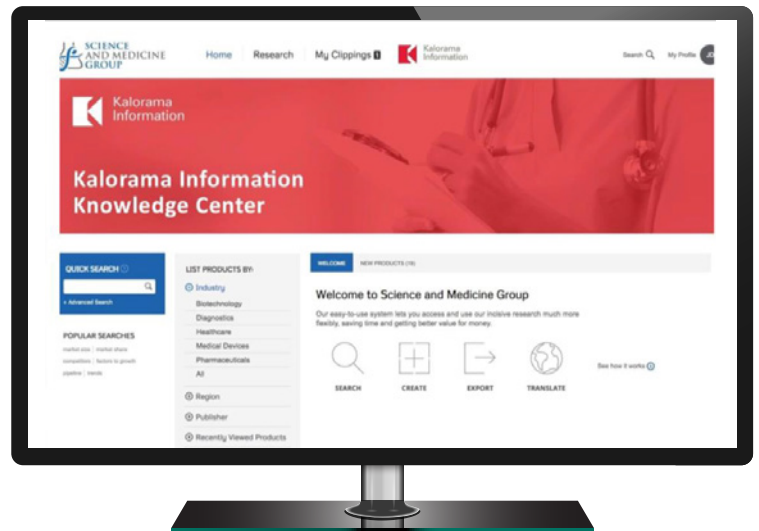


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