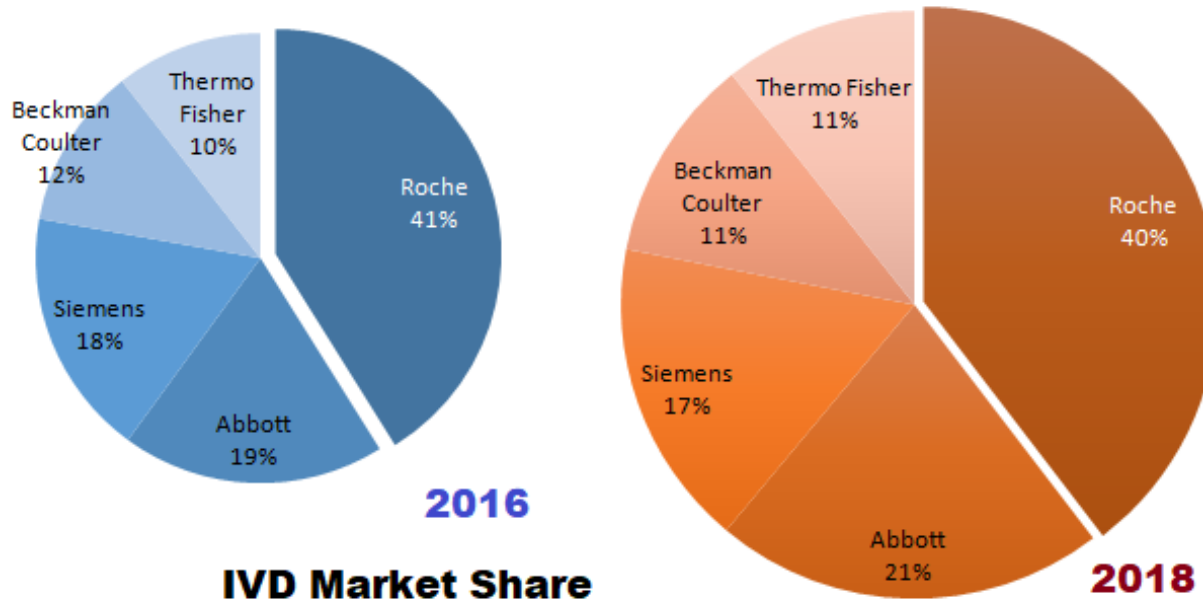
Kalorama Information

Five **Surprising Facts** about the IVD Market

The world market for diagnostics is estimated at $65 billion in 2018 and is expected to grow 4% annually to $77.8 billion by 2023. In this White Paper, Kalorama shares just five of the many trends covered in our Worldwide Market for In Vitro Diagnostic Tests, 11th Edition, market study.

1 Roche Leads, But Top Tier More Competitive Than Ever

As has been the case for the last ten editions of Kalorama's IVD report over two decades, Roche Diagnostics (2017 revenue of $12.9 billion) is the number one IVD company. Top 5 share cooled slightly, and the top tier is a little more competitive. There is a clear No. 2 in the market, where previous editions found the 2,3, and 4 spots in the IVD market to be a bit of a free-for-all. Abbott Diagnostics' acquisition of Alere added some $2 billion to the company's revenue base and opened new vistas in point-of-care testing. The chart above shows **Top 5 Company Market Share in the IVD market**, 2016 and 2018 compared.



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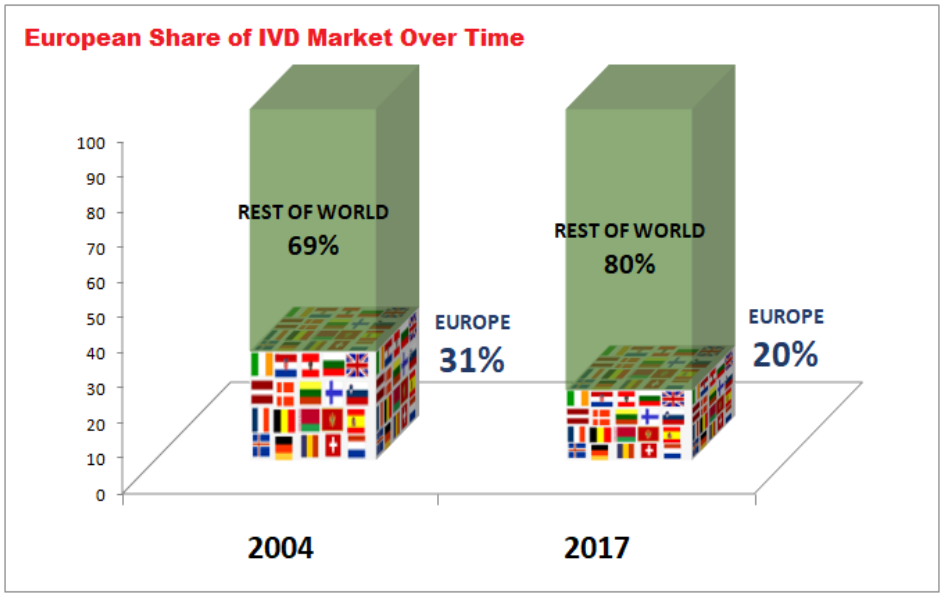
The significant gains made by companies that market infectious disease immunoassays, cardiac markers, histology and molecular diagnostics illustrate several important market phenomena. One is that these areas have been the growth engines for the past 2 to 3 years and will continue to be so for the near future. Companies including bioMérieux, Danaher, Diasorin and Sysmex have capitalized on their investment in emerging markets, in molecular tests and tests for infectious diseases. This has provided them with a five-year growth stream that beats that of the IVD market as a whole.

2 European Cuts, Consolidation Drive Vendors to Eastern Europe

Europe is improved slightly from our last report in 2016, on the strength of German, Swiss and Netherlands laboratory spending. Yet the news could be cold comfort. This was once a region that in 2004 contributed 31% of the market; and now Kalorama estimates Europe is 20%. Not surprisingly, many companies are seeking out **Eastern Europe** as a place to make larger gains. Their healthcare systems with some exceptions are improving. European diagnostics association EDMA reports that new members, (generally Eastern European nations) spend more *three times percentage of their healthcare spend on IVD* than do their older members, generally the Western European nations that are seeing testing as a place to trim. There are several promising markets in Eastern Europe. Czech Republic and Poland represent large markets; Bulgaria and Romania are building test infrastructure and growing faster than Eastern Europe average. Kalorama focuses on Romania and Poland in Chapter 3 of our worldwide market study.



3 Promising Cancer Testing Market in Emerging Countries

Previous assumptions of IVD strategic marketers were that advanced products such as cancer tests were sold in the U.S., Europe and Japan and emerging markets. Emerging countries were the place to target infectious disease test customers and hematology or immunoassay analyzers. As the economy improves in developing nations, concerns adjust to other diseases. Though Brazil struggles with HIV and dengue, cancer is now the second leading cause of death in Brazil. Among urban Chinese, cancer is the leading killer with lung cancer the most dominant contributor. In Eastern Europe the histology/cytology segment is one of the smallest but also the fastest growing. While advanced cancer testing is still a developed world phenomenon, vendors of advanced testing will benefit from the position of these tests in private healthcare spending versus the clinical chemistry and immunoassays funded largely by the public sectors in these nations.

"Among urban Chinese, cancer is the leading killer with lung cancer the most dominant contributor."

4 Glucose Testing Declines and CGM Comes to the Rescue

For the past two editions of Kalorama Information's report, there has not been much good to say about glucose testing markets. As a sizeable piece of the overall worldwide market, the ups and downs of this sector have a noticeable effect. Cases of diabetes are on the increase, and use of systems is up in emerging markets. The challenge is pricing. Glucose testing has suffered as a category due to pricing strategies that continue to discount the cost of meters and strips. Vendors reported losses in glucose segments. European payors continue to restrict support for glucose testing for non-insulin dependent diabetics. This has affected the whole IVD market, particularly the European market. However, continuous blood glucose monitoring is coming to the rescue – adding double-digit growth to an important component of the glucose testing market and fueling this market in developed nations and expansion of the market is driven by government sponsored programs that negotiate the lowest price possible. Kalorama details the exact ratio of continuous glucose and standard glucose meters and associated equipment in Chapter 5 of our worldwide market report.

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5 Tick-Borne Tests: High Demand Area for Testing

Tick-borne testing is an area where providers, payors and even consumers are unsatisfied and looking for new innovations. Diagnosing tick-borne diseases can be tricky. Lyme disease, the most prevalent of the tick-borne tests, can be treated more effectively when diagnosis comes early. Yet, many patients do not notice the initial tick bite and early symptoms of Lyme disease may be vague. Only 70 to 80 percent of infected individuals develop a telltale erythema migrans rash. By some estimates, traditional serology-based test methods identify fewer than 40% of patients with early disease as it takes time for antibody production to rise to detectable levels.

For Lyme disease, the most common tick-borne disease in the United States, the CDC has recommended the same testing process since 1995: a serology-based two-tiered algorithm. The first tier is an immunoassay; then if the immunoassay results are positive or equivocal, it is followed by the second tier, a Western blot. To address the issue of false negatives for early-stage infections, the CDC suggests a provider consider treatment based on clinical presentation alone if the patient has had symptoms for less than 30 days, and offer a repeat immunoassay a few weeks later to confirm the diagnosis.

Some researchers are now advocating for new testing algorithms, in particular a two-ELISA algorithm, where an initial positive or equivocal ELISA result is followed by a second ELISA assay that has slightly different targets. They find this method effective and also 27.1% to 44.0% cheaper than the two-tier algorithm with Western blot. A 2018 study comparing three variations of immunoassay-only algorithms found them all accurate, and in some cases even better than the traditional two-tier algorithm. However, the CDC still recommends the traditional two-tier algorithm.

For the other tick-borne diseases, the diagnostic options are limited. Immunofluorescent assays are available for Babesia, Anaplasma, Ehrlichia and Rickettsia, although accuracy varies by laboratory. Some tick-borne viruses can be detected by specialty labs. For other tick-borne diseases, such as Southern tick-associated rash illness (STARI), there are no immunoassays available. There are no commercially available tests that simultaneously detect multiple tick-borne disease agents.

That explains why the TBD Serochip has gotten so much attention this year and piqued the interest of the

public. U.S. National Institutes of Health director Francis Collins even highlighted the February TBD Serochip study in a blog post in June, noting that it was developed by NIH-funded researchers. The TBD Serochip is a serological test, like the commercially available tests today. However, it detects multiple targets based on a variety of newly identified antigenic proteins, so it has the potential to be more specific to Borrelia than other than previous tests. Also, it can detect antibodies to multiple tick-borne pathogens simultaneously. The lead author of the TBD Serochip journal article, Rafal Tokarz, PhD, told *Infectious Disease Advisor i*n March 2018 that the challenge now is to improve the test and make a simpler version that can be used by clinical laboratories.

Some reference laboratories already offer polymerase chain reaction (PCR) blood tests for Lyme disease, but with the caveat that they may be used as an aid to diagnosis but are not diagnostic alone. In general, direct detection of the spirochete bacteria that cause Lyme disease bacteria has not worked clinically because there are so few bacterial cells in the body. As a result, the sensitivity of PCR to B. burgdorferi DNA in blood, plasma, or serum samples from patients with Lyme disease is low.

While academic researchers pursue these new directions, in vitro diagnostics developers appear to be focusing on improving on serology-based tests that are already available, making them faster and easier to use.

For example, Quidel announced in August 2018 that its Sofia 2 Lyme fluorescent immunoassay received FDA 510(k) clearance and a CLIA waiver. The assay, which runs on the 2-pound benchtop Sofia 2 Fluorescent Immunoassay Analyzer, requires only a fingerstick whole blood sample. It detects IgM and IgG antibodies to Borrelia burgdorferi, returning a result in 3 to 15 minutes. With its new CLIA waiver, the assay can now be used in physician offices or clinics.

Kalorama Information

Now in 11 Editions!

The Worldwide Market for In Vitro Diagnostic Tests

"The Bible of the In Vitro Diagnostics Industry"

Now in its 11th edition, this Kalorama Information report, **The Worldwide Market for In Vitro Diagnostic (IVD) Tests**, is the most essential report on the IVD industry. The 1,600-page report provides in vitro diagnostics market size estimates and projections for the entirety of the in vitro diagnostics testing market.

Current 2018 IVD Market Estimates for Essential Segments

The Worldwide Market for In Vitro Diagnostic (IVD) Tests estimates the current in vitro diagnostics market size and forecasted market size to 2023 for defined segments of the IVD market and various sub-segments, including:

- **Molecular Assays (Infectious Disease, Blood Screening, Inherited Diseases, Oncology, Pharmacodiagnostics, Tissue Typing, Prenatal)**
- **Clinical Chemistry and "Core Lab" Markets (including sub segment revenues for General Chemistries, Workstations, Analyzers, Blood Gases, Urinalysis, Critical Care)**
- **Point-of-Care Testing (POC), (Professional and Self-Testing, Glucose Testing, Pregnancy Tests, drugs of abuse, HIV, H. pylori, Other, OTC/Self Total, Professional POC, Cardiac Markers, Drugs of Abuse, HbA1c, Pregnancy, Other)**
- **Substance Abuse Testing**
- **Microbiology and Virology by Test Type (Immunoassays, ID/AST, Infectious Diseases - DNA; ID/AST: Panels and Reagents, automated; Panels and Reagents, manual; Blood Culture; Chromogenic Media; Rapid Micro; Supplies)**
- **Blood Banking (Grouping, Immunoassay Screens, NAT Screens)**
- **Tissue-Based Testing - Histology and Cytology (Pap, ISH, IHC, HPV)**
- **Infectious Disease Immunoassay Testing Hematology**
- **Flow Cytometry**
- **Molecular Tests in Infectious Diseases**
- **Non-Infectious Disease Immunoassay Sales by Analyte Type (Cardiac markers, Tumor markers, Diabetes/HbA1c, Autoimmune, Allergy, Thyroid, Proteins, Anemia, Fertility, Therapeutic drugs)**
- **Coagulation Tests (Lab-Based, POC, Genetic Markers)**
- **Mass Spectrometry**
- **Next Generation Sequencing**
- **Direct-to-Consumer Testing**

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