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German IVD Industry's Commercial Progress: A Case Of 'Light And Shade'

Government must be able to move quickly should another wave of coronavirus emerge

by [Ashley Yeo](#)

COVID-19 drove German IVD sales to new heights in 2021. The industry stands ready to react swiftly to further waves, subject to rapid political decision-making. The shortage of expert IVD staff and the IVDR are front-of-mind concerns. The effects on industry of the war in Ukraine are being monitored.

Although impressive, the €6.3bn (\$6.8bn) revenues recorded by Germany's IVD industry in 2021 must be taken with a pinch of salt, given that the record growth has come off the back of COVID-19.

Unveiling the latest annual facts and figures, Ulrich Schmid, chairman of the German in vitro diagnostic industry association (VDGH), said 2021 delivered both light and shade in terms of the industry's financial performance.

While overall industry sales more than doubled compared with 2020, some 65% (\$4.1bn) of the 2021 tally was earned by sales of COVID-19 tests. Revenues from routine diagnostics tests – the industry's core offering—have stalled since the pandemic took hold, said Schmid.

Core diagnostic product sales totaled €2.2bn in 2021, up slightly from the levels reported in 2020 and 2019, when revenues in both years were marginally below €2.2bn.

The German health system spends just 2-3% of its budget on diagnostic testing, said Schmid.

Pandemic Preparedness Still Required

Omicron is having a negative but less intense impact on the German health system compared with precursor COVID-19 variants. While it is more infectious, its effects on individuals' health are generally less dramatic. Germany's intensive care units have not been called into use to the extent they were during the initial spikes.

VDGH chief executive Martin Walger said that the diagnostic test sector in Germany was well prepared and would be able to react quickly in delivering tests should a new wave of coronavirus arise in autumn and winter of 2022. But he called on the government to think ahead and set the right framework, should that situation arise.

Rapid antigen tests drove COVID-19 test sales in 2021, accounting for 90% of test sales in the wake of the government's decision to broaden the availability of self-testing kits and expand the testing of vulnerable groups.

The tests have been financed from government tax reserves rather than by the sickness insurance funds. The coronavirus test order (TestV), covering COVID-19 testing for individuals not under care (those without COVID-specific symptoms) will no longer be in place after 30 June.

Industry stressed that, if a new wave of coronavirus arose in Germany, the government must quickly set up the necessary testing infrastructures. A large proportion of the rapid antigen tests used globally in 2021 were produced in China, and shipping to Germany takes four to eight weeks.

It is also "extremely important" that the industry should be made fully aware of any government plans at an early stage, Walger said. Were a new German COVID-19 order to be issued "overnight," the industry, having already broken its China supply chains, would have difficulty in guaranteeing renewed supplies of tests for timely use by the German public.

Whether to increase local production infrastructures to guarantee such supplies was a major talking point in Europe as the pandemic intensified. But it has become a less prominent theme over time. Walger asserted that the benefits of more local production would be less than anticipated, given the associated lead times and costs of building new plant.

Indeed, the VDGH's survey showed this to be a lower priority than the implementation of efficient digital systems. This was seen by member companies as the best means of making the country "crisis-proof" during a future pandemic.

Including COVID-19 tests, infectious disease diagnostics accounted for 70% of IVD sales in Germany in 2021; in pre-COVID 2019, the proportion of sales was 10.3%, driven by bacterial infection, HPV, HIV and influenza tests.

2022 Prospects

The IVD industry's expectations for business (excluding the life sciences research sector) in 2022 were gauged in a poll of members in the two months to 21 February—i.e. before the Russian invasion of Ukraine, which will have as-yet uncertain impacts on business forecasting across all industries.

The VDGH survey, completed by 47 IVD company members, revealed that:

- The German IVDs industry is confident about its financial footing in 2022: 80% of respondents saw a “good” or “very good” outlook in the coming year. No companies graded their outlook as “bad”;
- 41% (up from 25% in 2020) of companies saw the home market as offering better commercial prospect than foreign markets;
- 67% of companies thought COVID-19 sales would decline in 2022 – 21% said sales levels would stay unchanged;
- 42% of companies planned to increase staffing by at least 2%, and 20% planned to cut staff levels by at least 2%; and
- 89.4% said the issue of finding and keeping skilled staff in positions such as sales, marketing, customer service, quality management and regulatory affairs was a source of problems.

The microchips shortage also impacts the IVDs industry, although it is not a big user of these components in relative terms. 79% of companies surveyed viewed the current shortages as negative for business in areas such as lab automation and instruments.

Among other findings, only 11% of companies in 2022 (2021, 20%) consider that the industry was not understood or appreciated by wider society; and 24% (2020, 6%) saw rising raw materials and energy cost as having negative impacts on their company's commercial development. That, and the rise in logistics and shipping costs, have seen prices for some IVDs in Germany increase by a factor of 10.

Walger told *Medtech Insight* that the VDGH's members thought that the war in Ukraine would not prompt critical bottlenecks in the supply of raw materials or intermediates for IVDs used in Germany.

IVD exports to both Ukraine and Russia will be affected by the war, but association member companies' individual experiences are prone to be very different, so a representative picture

cannot yet be drawn. The VDGH is also participating in the Ukraine humanitarian effort, Walger said.

Looming IVDR – But EU Structures Still Absent

The EU IVD Regulation comes into force on 26 May, and German IVD companies are prepared for it, said Walger, even if the essential structures are still not all in place at EU level.

Walger said the industry fears processing bottlenecks among the notified bodies, given that just six accreditation bodies have been designated under the IVDR. This is equivalent to around 30% of the real need, in view of the fact that 22 notified bodies were accredited under the directive that the regulation will replace in six weeks' time.

Around half of VDGH survey respondents thought that the IVDR would lead to products no longer being available. Niche products for rare diseases where the need is served by only very few suppliers are at threat of disappearing from the market if they are not certified in time under the regulation.

The European Commission has reacted by implementing additional transition periods for certain products, said the VDGH chief executive. "The time-frames remain very tight," he added.