Light. Insight. *Life*.

10 Inevitable Drivers of Multiplexed Molecular Diagnostics

Why multi-assay approaches will soon dominate POC, central lab, and at-home testing for the foreseeable future.

Including:

- Economic Drivers
- Competitive Realities
- Efficiency Demands
- Consumer-driven Changes
- Evolving Approaches to Epidemiology

Tracking a Rapidly Evolving Landscape in Molecular Diagnostics...

Over the last few years, seismic changes—driven (or accelerated) by the global COVID pandemic—have dramatically altered the way we approach molecular diagnostics—as test and device designers, as clinicians and lab managers, and even as public health stewards. Increasingly, the realities of multiplexed molecular diagnostics are generating great momentum, with the promise of cost and labor efficiencies and consumer-level ease-of-use. Making sure multiplexing is top-of-mind as a strategy for meeting your next challenge make good sense as a way to address these critical drivers...

ECONOMIC DRIVERS

1. Your MDx devices need to help conserve human labor

Staffing shortages will continue to be a challenge throughout healthcare, even as testing volumes and throughput grow exponentially. For MDx developers, that means finding new efficiencies at every turn. For example, multiplexing has already been a fast path to category leadership with innovators in respiratory diagnostics packing analysis of a dozen pathogens from a single sample.[1] Wherever commonly ordered diagnostics can be processed simultaneously within an existing protocol, the economic benefits will be compelling—to stressed central labs, in-house labs, and payers alike.

2. You need to design and manufacture MDx devices for cost and reliability

Multiplexing, by its very nature, helps amortize many of the fixed costs in manufacturing, processing, and logistics over a wider number of (billable) diagnostics. Efforts to lower sample costs and reagent volumes are also bolstered when multiple assays are being combined on a single device. Further, for non-commercial environments like nursing homes, schools, and cruise ships—achieving an effective price point is a critical factor. When accounting for manufacturability and reliability, multiplexing offers a compelling strategy, delivering more data within the same (proven) diagnostic infrastructure.

COMPETITIVE PRESSURES

3. You need to watch competitive technologies/designs

Many top producers and emerging companies are already marketing multiplex tests that diagnose multiple respiratory diseases simultaneously (see sidebar.) Market demand is strong for these approaches, as demonstrated by newer research-driven producers who are unseating established category leaders through multiplexed innovation in tech-driven lab platforms.[2] The COVID pandemic saw increased interest in Asian suppliers of multiplexed MDx products by North American and European customers who were forced to look outside of traditional suppliers during peak demand. For many, this meant an expanded set of viable competitors with significant cost and technical differentiators.

4. You need to align your solutions with industry standards/best practices

The MDx space has seen a recent flurry of M&A activity over the past few years—transactions that hold some important lessons for the industry.[4] Building-in compatibility considerations to your IVDs can help improve your appeal to partnerships with established reading, processing, and communications platforms. This is another area where a multiplexed design provides ready "real estate" for additional capabilities and flexibility.

EFFICIENCY DEMANDS

5. Help central labs accommodate volume and turnaround pressures

Commercial laboratories have never been under greater pressure and new solutions that can demonstrate real

RECENT MULTIPLEX POC LAUNCHES FROM SOME MAJOR PRODUCERS:[3]

- Abbott launched a multiplex molecular test on its Ali nity m system to detect COVID-19, flu A, flu B, and respiratory syncytial virus (RSV).
- Cepheid (Danaher) launched Xpert Xpress SARS-CoV-2/Flu/RSV four-in-one test for the qualitative detection of SARS-CoV-2, Flu A, Flu B, and RSV from a single patient sample.
- Abbott launched a molecular test using polymerase chain reaction (PCR) methods on the m2000 RealTime lab-based platform to detect COVID-19.
- Cepheid (Danaher) received Emergency Use Authorization (EUA) from USFDA for XpertXpress SARS-CoV-2, a rapid molecular diagnostic test for the qualitative detection of SARS-CoV-2.
- Abbott launched a molecular test for detection COVID-19 on its ID NOWrapid point-of-care platform in the U.S.

impacts in efficiency and throughput will gain attention in this market. Maximum reliability is the key to success here and devices that contribute to further automation, accommodate large sample volumes, and speed results delivery can be gamechangers. For instrument makers, robust and flexible platforms (e.g. "molecular work areas") with shared reagents and a diverse menu of assays underline many labs' desire to streamline suppliers and vendors. Today, many molecular laboratories are following the lead of clinical chemistry labs by prioritizing the transition towards total laboratory automation (TLA) allowing patient samples to be moved seamlessly from intake all the way through to releasing results to clinicians.[5]

6. Help simplify operations for smaller labs

For smaller labs, such as those being launched or expanded within schools, nursing homes, and large employers, the challenges aren't always volume and throughput concerns (although they sometimes are.) Instead, these labs are trying to "do more with less." That means simplification of processes and speeding of results, while accommodating smaller samples. This represents an excellent area for competitive advantage for easy to apply multiplexed strategies.

CONSUMER-DRIVEN CHANGES

7. Continually push miniaturization limits

To really look forward in MDx's future, a focus on miniaturization, along with multiplexing, is a strong bet. As consumers embrace more wearable and implanted devices for health, wellness, drug-delivery and diagnostics/monitoring, a biochip or system's ability to fit within existing formats (e.g. Fitbit, Apple Watch, etc.) presents a strong competitive advantage. Devices that combine high sensitivity and fast readout with a small physical envelope size (at favorable economics too) are emerging. Many of these use qPCR or isothermal amplification-based testing to achieve their limited footprint goals.[6]

8. Improve the flexibility of your platform or device

Multiplexing beyond a limited disease area (e.g. respiratory) represents another avenue that forward-thinking MDx developers are speeding down. Syndromic testing applications are already being discussed that address a wide spectrum of panels across respiratory, GI, STDs, and women's health markers. To cover broad disease panels, many IVD companies strive for higher degrees of multiplexing to enhance versatility and market adoption of their platforms.

This can be achieved through tailored multi-channel LED light engines (typically 4-6 channels) with solution-specific LED and filter selections, combined with optics for illumination and detection, and detectors.[7]

PUBLIC HEALTH/EPIDEMIOLOGY EVOLUTION

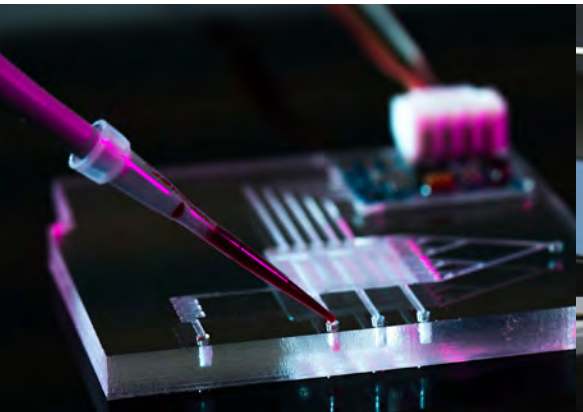
9. Be prepared to incorporate new/adjacent assays

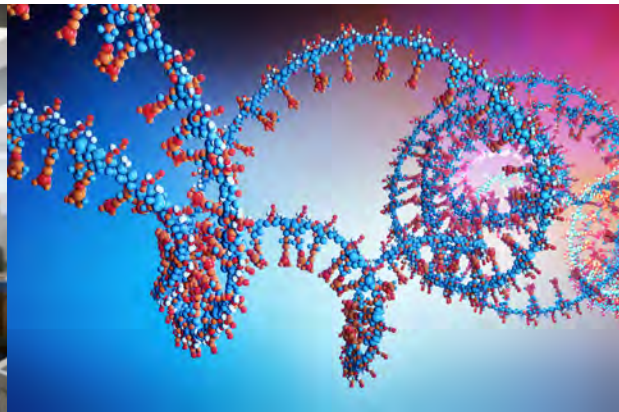
As more healthcare, school, and larger "closed" environments look to drive down their exposure and risks of infection, integrating additional assays aimed at detection and prevention are being incorporated into other protocols. For example, antibiotic resistant gene detection may be used to improve an organization's antibiotic "stewardship," or to advance sepsis-prevention goals. As amply demonstrated with COVID-19, being able to detect virus variants is an essential capability that solutions like dPCR can help address. Requirements here include unprecedented sensitivity and absolute quantification so that researchers can help find "the needle in the haystack" in their genomic research.

10. Be ready for emerging public-health demands—at-scale

Amplification-based assays are gaining importance as tools for microbiologists to track and differentiate a variety of public health concerns. For anti-microbial resistance (AMR) testing, several phenotypic tests involving cell growth imaging in the presence of antibiotics on a cellular level are entering the POC market to assist public health officials (and others) in better detecting and controlling the spread of infection. Additionally, as governments around the world take a more active role in distributing POC and at-home testing, MDx producers will be looking at a new set of requirements and demands for simplicity, reliability, flexibility—and value.

1 Quidel Corporation: "Quidel receives CE mark for Savanna® Multiplex Molecular Analyzer and Respiratory Viral Panel." Published 07/12/2021 Source: ir.quidel.com/news
2 Cambridge team develop test that can diagnose COVID-19 in less than 90 minutes // itv.com/news/anglia/2020-04-02
3 Meticulous Research, Inc. "Point-of-Care Molecular Diagnostics Market to be Worth $2.32 billion by 2027" https://www.globenewswire.com Trends Analysis Report with COVID-19 impact
4 Hologic's acquisition of Mobidiag, Qiagen's acquisition of NeuModDx, DiaSorin's acquisition of Luminex, etc.
5 Cobb, B., Simon, C.O., Stramer, S.L., Body, B., et al. (2017) A new era of automation in molecular diagnostics', Expert Review of Molecular Diagnostics, 17(2), pp. 167–180.
6 https://volpi-group.com/applications/point-of-care-ivd-applications/
7 https://volpi-group.com/applications/point-of-care-ivd-applications/





Light. Insight. *Life*.

About Volpi

At Volpi, we are experts in the emission, transmission and detection of light to create insights.

With the ultimate goal of improving patients' lives, we deliver innovative solutions that enhance the performance of diagnostic instruments, so healthcare professionals can better research and diagnose diseases and make more informed treatment decisions.

If you would like to learn how Volpi is thinking about and working on all of these industry issues, and how we help improve patient lives by optimizing the performance of the instruments used to diagnose and treat them, email us at info@volpi-group.com

United States

5 Commerce Way
Auburn, NY 13021
+1 315 255-1737
+1 315 255-1202

Switzerland

Lagerstrasse 10
CH-8953 Dietikon
+41 44 732 43 43
+41 44 732 43 44