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Point of Care Testing

Simplifying Market Access for Point of Care Solution Provicers

The POCT landscape

Given increased interest in areas such as anti-microbial resistance (AMR) and viral/bacterial patient stratification, Point of Care Testing (POCT) has recently attracted a lot of attention. With the entry of large diagnostic solution providers in the POCT market, a strong competition on market shares can be observed, therefore time to market and reduction of development risks is mandatory for fast followers.

The Point of Care Testing market is currently highly fragmented. POC tests and devices are utilized in a variety of settings and applications, employing different concepts and technologies.

For each method, the following questions have to be addressed:

- What is the role and benefit of POCT compared to centralized clinical laboratory testing?
- How does POCT improve patient management, patient outcomes or medical effectiveness?

POC solutions include lateral flow (hCG), small, compact instruments (blood gas, urinalysers), and microfluidics (molecular diagnostics).

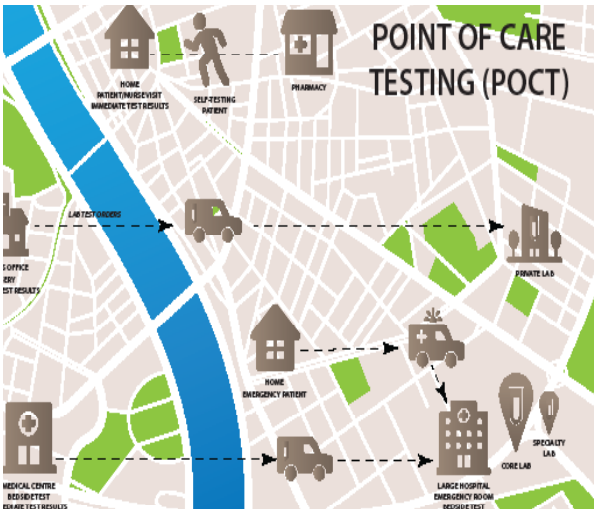
POC tests can be found in the following application fields: molecular diagnostics, microbiology and virology, immunoassay, clinical chemistry, coagulation, blood gas and urinalysis.

POCT market opportunities

Many applications served by POC tests benefit from the massive increase of knowledge about the causes and heterogeneity of diseases and the consequences of these findings in diagnosis and patient treatment. Companion diagnostics then help to identify and monitor those patients who are most likely to benefit from a particular therapy. Nevertheless, the current POCT market faces continued cost pressure and the limitations through reimbursement systems.

POC tests are used in various settings:

- Emergency room (hospital)
- Near-patient testing (hospital)
- Clinical laboratory (hospitals, private labs)
- Doctor’s office
- Patient self-testing



Schematic drawing of POCT locations

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Challenges for POC solution providers

From wearables to doctor's offices, and from bedside testing to centralized clinical laboratories, clinical data - including test results - is generated at different locations. This creates challenges for user qualification and quality control.

Increasing amounts of data have to be consolidated. Data security during transfer and storage is key. All of which presents major challenges for the healthcare ecosystem.

Managing the resulting costs and ensuring effectiveness equals to optimizing the equation of where to provide which type of test infrastructure to which user, while protecting the interests of the care-givers.

Today, many diagnostics tests follow a differential diagnosis approach, meaning that the result of a particular test/parameter may require to perform another test. Depending on the technology and application, tests are run on different platforms.

The type of instrumentation may also look different based on the intended use / user group:

- Test strips for patient self-testing
- Handhelds for bedside testing
- Compact benchtop instruments in the emergency department, doctor's office or clinical laboratory

POC tests are performed in different settings corresponding to different needs:

- Core labs with high throughput and a large but preserved test portfolio
- Specialized labs with a lower test volume but a very diverse test portfolio
- Laboratories in smaller hospitals with low to medium test volume and a reduced test portfolio based on key needs for hospitalized patients
- Special clinical workflow integrations such as a single test with short TAT for triage purposes in an emergency setting
- Decentralized settings with a low amount of essential tests under a low quality control
- regime
- Self-testing by an untrained user in an uncontrolled environment

Besides glucose monitoring, most POC parameters are low volume tests compared to centralized laboratory testing. It is important for POC solution providers to offer multiple parameters that can be run on the same device. Many POC instruments have multiple channel capabilities.

Increased versatility and reduced instrument footprint are important, enabling greater usage across different settings and locations - from ambulance, emergency room and critical care unit to doctor's office and patient self-testing. Combining reader modalities contributes to achieve these goals.

All these requirements add up to an extremely heterogeneous and demanding need-spectrum for POC solution providers.

Opportunities for success

Faced with such a complex environment, POC solutions providers entering this market segment need to set up programs that ensure both a short time to market and a more rigorous risk management in the development of the product / test portfolio they want to offer.

There are a number of ways that project complexity can be reduced:

- Focusing on assay and application-level data processing and running tests on open platform instrumentation or OEM instrumentation developed with an external OCM partner

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- Focusing on assay and application-level data processing and striving for standards that allow the integration of third party modules into compact instrument designs
- Partnering with competent module development partners and driving OEM module system integration

How Volpi can help POC solution providers

By drawing on Volpi's expertise in the design, development, and manufacturing of customized, integrated optical measurement modules for IVD and Life Sciences, POC solution providers can reduce complexity in system development and focus on the development of assays. We understand the clinical requirements for dedicated parameters within each application and technology. In-built design and manufacturing flexibility enables us to accommodate fluctuating requirements, while our smart customization ensures seamless integration with manufacturers systems, processes and approaches.

Our proven expertise covers the complete measurement chain from light emission to pick-up and transformation, transmission, sample interaction, detection, and data pre-processing.

Based both in the US and Europe, our comprehensive design, development and manufacturing services span the entire product lifecycle, guaranteeing the highest quality standards.

Volpi has designed, developed and manufactures numerous optical modules for fluorescence readout modalities, several of which are applied in the context of POC instrumentation.

Partnering with Volpi equips manufacturers with:

- The problem-solving expertise, system engineering and delivery capability that minimizes and manages complexity
- The operational excellence that includes engineering ingenuity and project management across distributed settings
- The collaborative approach that excels in LEAN thinking, risk management from every perspective and six sigma quality criteria throughout the entire production process

Volpi delivers:

- De-novo design of measurement modalities
- Maturing product designs, with fast transfer from feasibility to design freeze
- Mature production processes featuring fast transfer from feasibility to design freeze
- Flexible production processes, with the ability to smoothly scale up and down
- Product Lifecycle Management that safeguards optimum quality standards

Optoelectronic module for a Molecular Diagnostics POCT device

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Example: Molecular Diagnostics POCT device

For the depicted product, Volpi was selected by a top 10 IVD company to support product and production industrialization for high volume manufacturing after their acquisition of an molecular diagnostics start-up company.

During this product transfer project, Volpi:

- Matured the product design with the customer after M&A
- Matured the production processes
- Set up a LEAN production line
- Ensured a specific focus on criticality flow down and implemented LEAN-compatible risk mitigation of part traceability for key components

By ensuring flexibility in output volume with our LEAN production workflow, we enabled our customer to accommodate resource modulation without compromising the production process quality.

We also enabled quick implementation timelines in the adaptation process of four product revisions within the ramp-up period of the product, to a final production capacity of >1,000 modules/month. This was achieved through our robust supplier and inventory management, based on KANBAN principles, combined with our sound, engineering change process implementation.

In addition, we developed a dedicated, fully automated tester to secure stable production output quality over a sustained period.

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Summary

Volpi is a trusted OEM partner for the development and manufacturing of smart optical modules in the IVD market. Our in-depth knowledge of IVD applications and POC devices, combined with optical technologies and workflow integration of optical modules, have been proved to reduce complexity for POC solution providers. By working with Volpi, companies can successfully enter the Point of Care market in their field of expertise, as well as refine their existing POC portfolio to improve test quality and patient outcomes.

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