Application Note

Point of Care Instrument Development

What to Look for in a Partner



Introduction

Point of Care testing (POCT) and Molecular Diagnostics (MDx), which often takes the form of a point of care instrument, are the fastest growing segments in the clinical diagnostics market today (Evans, 2018). As the name implies, these compact instruments can be placed at or near the point of patient care, offering significant advantages over traditional central lab in vitro diagnostics (IVD) systems.



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Benefits of POCT Testing

Results from POCT testing are available to caregivers much more rapidly, frequently within an hour instead of days, allowing faster care decisions that shorten patient turnaround time. A recent study showed that use of a POCT system significantly decreased the duration of antibiotic use, the length of inpatient stay, and the time spent in isolation (Rogers, 2015). This benefits both the patient and the healthcare system, providing patients more rapid treatment allowing them to go home earlier, reduce the cost of care, while making room for other patients thereby increasing the capacity of hospitals and clinics.

Healthcare Trends

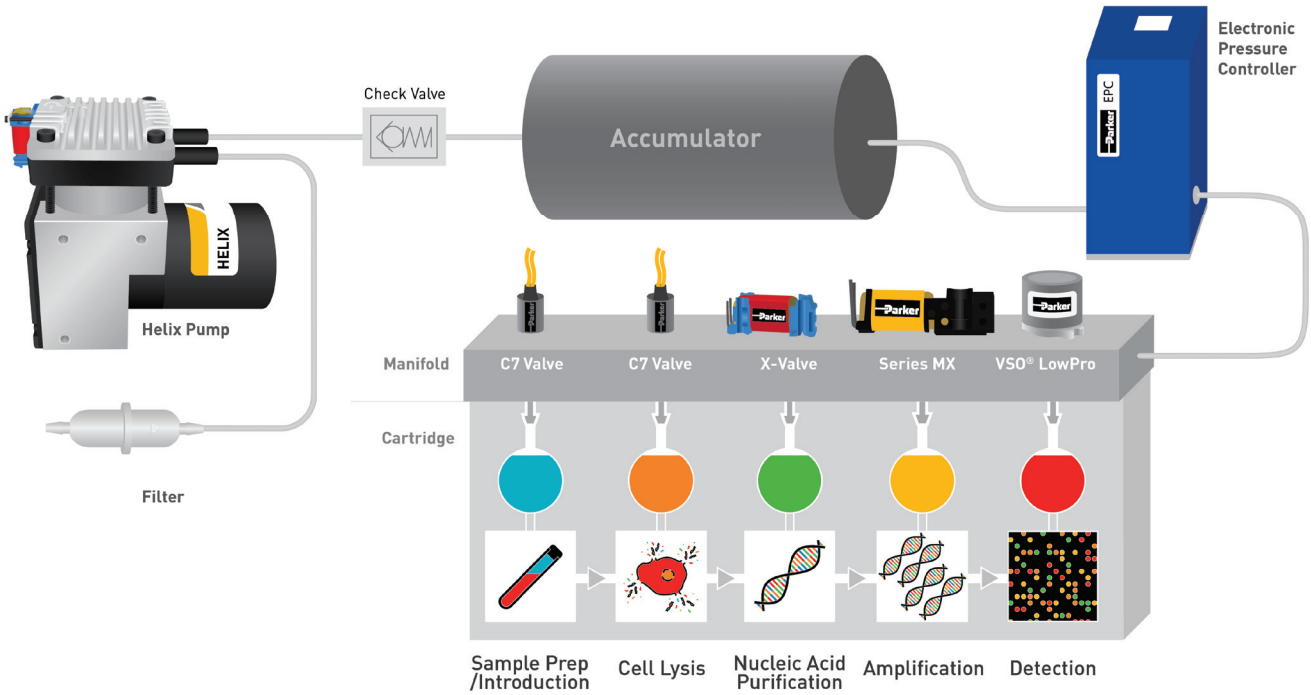
There is a clear trend towards multiplexed systems that can test for multiple disease agents at the same time. For example, a respiratory panel of tests that identifies which of many different bacteria or viruses may have infected the patient. Rather than running multiple single tests in series or parallel a recent study has shown that clinicians prefer to order a comprehensive syndromic panel even when the cost is higher (O'Reilly, 2016). Further studies show that the trend in the POCT market is to consolidate multiple tests into a single instrument rather than spread them over multiple systems.

Fluid Control

POCT instruments are typically designed to accept a disposable cartridge which includes all the reagents needed to complete the assay. The specimen sample and reagent liquids in the cartridge can be moved in a variety of ways, but the most common method of moving liquids in a multiplexed instrument is by using pneumatic pumps and valves to provide the needed pressure or vacuum to precisely move the liquids within the cartridge. Pneumatic fluid control is used because make and break fluid connections are needed when using a disposable cartridge. Liquid controls create challenges with priming the cartridge and concerns about air bubbles impacting the results.

Below is an example of the fluidic circuits in a Point of Care Molecular Diagnostics instrument. Pressure is being provided by a diaphragm pump with pressure regulation via an electronic pressure controller and an accumulator. Sample and reagent flows are controlled using a variety of pneumatic on-off and proportional valves.

POCT Flow Diagram



What to Look for in a POCT Partner

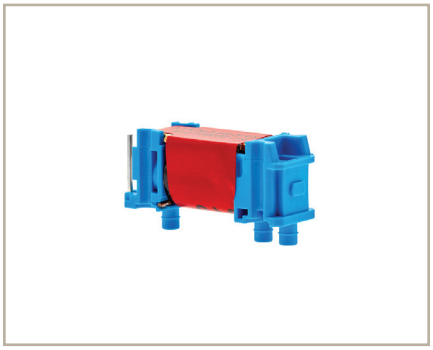
POCT instrument developers often prefer to focus their resources on improving their chemistries and cartridge design. A partner with experience in integrating, pumps, valves, and sensors onto manifolds that interface with the cartridge can accelerate development and allow the OEM to shorten their time to market.

Manufacturing of the instrument can also be accelerated by having a partner that can provide certified pre tested modules with the pumps, valves and other components installed on the manifold. In short, finding the right partner to develop the fluidics for a POCT system can free the OEM to differentiate their product through innovative cartridge designs and chemistries and speed the product to market.

Parker Precision Fluidics is in the unique position of manufacturing both pneumatic pumps and valves. With experience in Point of Care Testing Devices and Molecular Diagnostics, Parker engineers are ready to work with you in developing your instrument.

Parker offers a variety of **miniature solenoid valves** to control delivery of reagents using either on-off, diverter, or proportional control of flow with capability from vacuum to 150 psi (10 bar). Our **pneumatic pumps and valves** can be used to pressurize (or provide vacuum) cartridges up to 100 psi (7 bar) to move liquids using air or our liquid pumps and valves can move liquids directly. **Electronic pressure controllers** are also available to provide precision control of pressure. Because we manufacture both pumps and valves you can rely on our expertise to provide a reliable and cost effective solution. This expertise helps solve your fluidic needs by providing products or integrating them onto manifolds. If you are looking for a pre-tested solution, the entire subsystem can be delivered as a module.

For additional information on how Precision Fluidics can develop the fluidics for your POCT system, please email us at ppfinfo@parker.com or call 603.595.1500.







Top: Miniature Solenoid Valve
Middle: Miniature High Pressure Pump
Bottom: Miniature Pressure Controller

References
Evans, J. (2018). In Vitro Diagnostics: Technologies and Global Markets. Wellesley, MA : BCC Research.
O'Reilly, K. (2016, January). When to fire up large multiplex PCR? CAP Today.
Rogers, e. a. (2015). Impact of a Rapid Respiratory Panel on Patient Outcomes. Archives of Pathology & Laboratory Medicine, 636-641.

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