

update medical systems



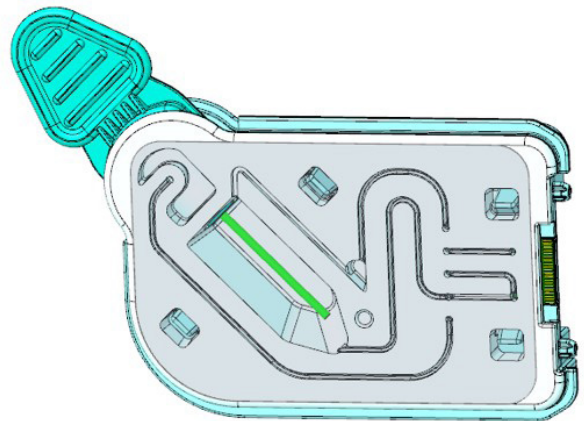
february 2021

Test cartridge and reagent block for innovative blood analyzer

Plastic-suitable design and ergonomic optimization
for biochip reader from *CAMPTON Diagnostics*

On behalf of our customer *CAMPTON Diagnostics*, we have developed a test cartridge and reagent block for a fully automatic blood analyzer which can be used to identify biomarkers for various diseases right at the point of care.

In the process, we optimized the design of the unit test cartridge and the reagent block for series production through injection molding and the easiest possible handling. Initially, we provided the customer with several concepts for both the test cartridge containing the analyzer's innovative biochip and the reagent block, from which up to four test liquids (reagents and sample diluents) are supplied and waste products are purged after testing. We then optimized the developed solutions further.



Design draft test cartridge

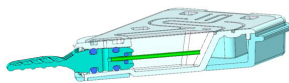


Plastic-suitable optimizations and improved ergonomics

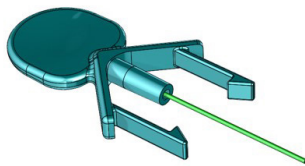
During development, we optimized both components for plastics and ordered cost-effective prototypes in a very short period of time. In addition, we improved the ergonomics of the cartridge to ensure simple, reliable testing at the point of care.

First, we created the requirements documentation for the cartridge and reagent block, describing the requirements the components have to meet, the functions they must have, and how many should be produced.

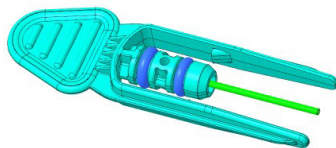
The final design of the cartridge made of three plastic parts and three O-rings was a combination of the features of the various concepts. Three major changes were made to the initial concept:



Inserting the fragile glass capillary tube with the patient's blood sample into the cartridge can be difficult in practice. In our draft, a corrugated finger rest and two extended guide rails simplify this process. Two O-rings also ensure the glass capillary tube is sealed in the cartridge and another O-ring fixes the capillary in place.



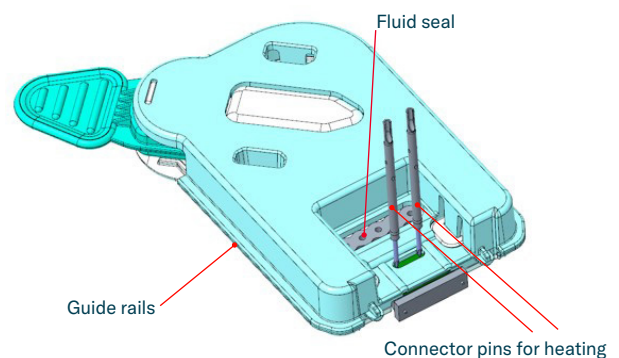
Initial concept



Optimized glass capillary holder design

The cartridge itself was rounded to simplify production using injection molding. Ultra-transparent COP plastic was selected as the material for parts of the cartridge so that the user can check to make sure the capillaries are filled completely before inserting them into the test unit.

Third, we optimized the interface to the reader. Additional guide rails ensure correct alignment of the cartridge in the reader while increasing the cartridge rigidity. Furthermore, the liquid interfaces between the glass capillary and cartridge as well as between the cartridge and reader had to be sealed tight to prevent any test liquid from leaking.



Optimized interface between the cartridge and reader

During design development, we also performed a volume check to ensure that the chamber for mixing the blood sample with the test liquids has the required volume. The electronic contacts for heating the cartridge and reading the test results present another interface to the reader. Here, we had to make sure there was a good electrical connection to the biochip.

Designing the reagent block, we also refined a combination of multiple concepts, optimizing it based on prototypes. For example, we reduced and standardized the thickness of the block walls to achieve the highest possible stability and production speed with the lowest possible material costs. Preferred concepts with an initial risk assessment are now available for the cartridge and reagent block, based on which the next phases of product and process development can begin.



Flexible Gx phase model for customer-specific development processes

CAMPTON Diagnostics selected us as their development partner because we have years of experience with similar test systems and offer a development process tailored to the specific requirements of start-up companies. One especially important factor for the customer was agile project development, which allows for quick responses to change.

In addition, the development partner had to be capable of designing multiple options for the reagent block and disposable cartridge and come up with solutions meeting the technical specifications as well as the demanding time to market schedule.

“We are well positioned to work both with start-ups and large pharmaceutical companies,” explains Manfred Baumann (Global Executive Vice President Sales & Marketing, Administration & TCC). “Thanks to our multi-stage Gx phase model, we can flexibly adapt to the needs of our customers.”

The milestone perspective of the phase model is helpful for start-ups especially, not to mention fast availability of functional prototypes or small series for clinical tests, which are major factors for bringing investors on board.

Product scalability for high-volume production is postponed specifically to later phases for start-ups, reducing costs in initial phases and placing the focus on the functionality of the product. Of course, all regulatory requirements are met for the respective product classification, despite the high rate of development.”



Fully automatic testing via biochips

Headquartered in Itzehoe, CAMPTON Diagnostics GmbH was established in 2016 as a spin-off of the local *Fraunhofer Institute for Silicon Technology (ISIT)*, which it still maintains a technology partnership with to date.

With the company's innovative analyzer, indications of various infections, types of cancer, or autoimmune diseases can be identified right at the point of care, depending on the test cartridge used. For the test, a small amount of capillary blood is taken from the patient, for example from a drop of blood from the finger. The blood is drawn



Structured product development for methodical risk minimization and maximum flexibility. You decide in how many phases we can support you.



The Gx phase model can be flexibly adapted to the different needs of large companies and start-ups.

by a glass capillary, which is inserted into a test cartridge. The cartridge and a reagent block with all the liquids required for the test are then inserted into the unit. This is where the actual test takes place, with the results shown on the unit display. They can also be saved digitally.

The key element to the analyzer is an innovative biochip in the cartridge, where disease-specific biomarkers in the blood react with the corresponding antibodies on the chip.

Unlike with the standard ELISA (enzyme-linked immunosorbent assay) tests, the results are not identified by visual changes in color, but are instead analyzed through electrical signals of the coupling reaction on the chip. This makes the test

especially fast and sensitive, allowing multiple parameters to be determined at once.

Besides applications for immunologic tests, the analyzer can also be used for molecular biological testing. With these tests based on nucleic acid amplification technology, biomarkers can not only be detected in full blood samples, but also in nasopharyngeal samples and saliva in the future.

Until now, samples for both analysis types had to be sent to a lab with the equipment for serologic and molecular biological tests as well as specially trained staff. In some cases, it takes days to get the results. With the analyzer from *CAMPTON Diagnostics*, both tests can be performed within a matter of minutes.



Design and editing

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