

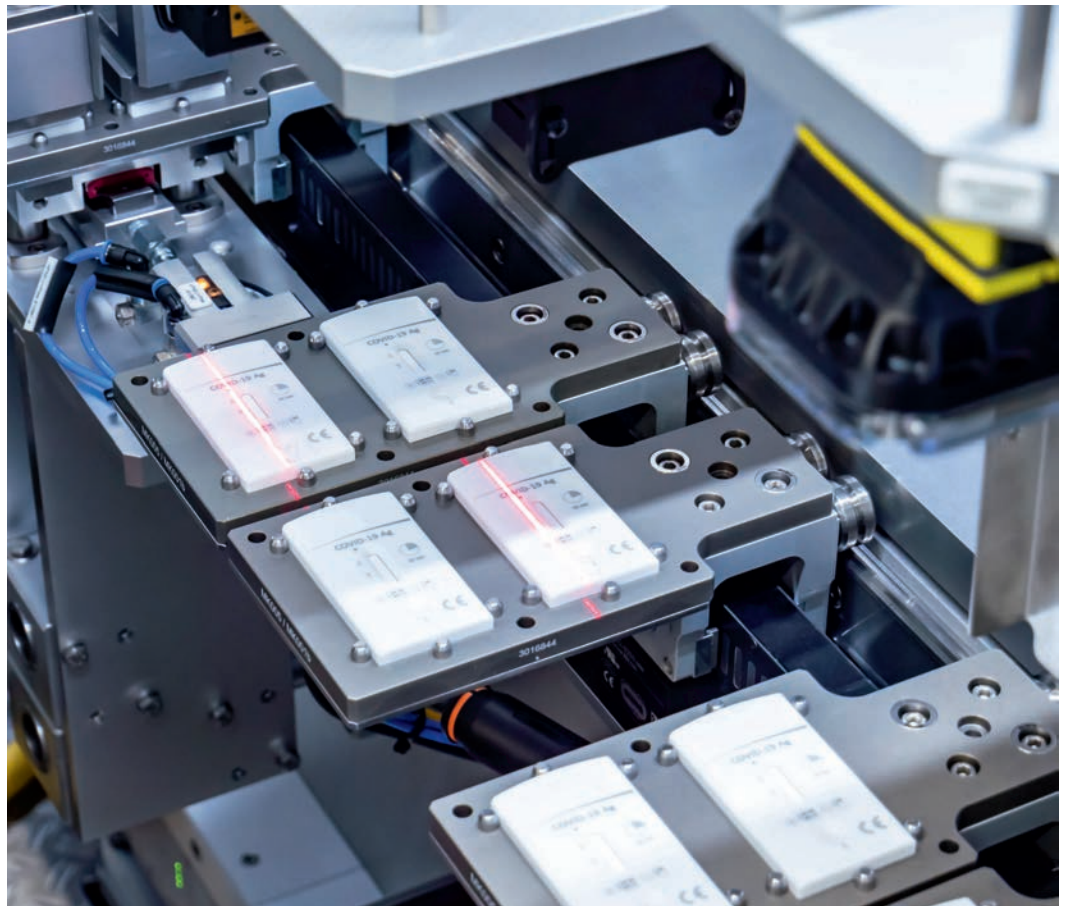
Sanner and MA micro automation Bring Rapid Test Production Back to Europe

Too Fast for the Human Eye

Current developments indicate: supply chains have become fragile and near-shoring or reshoring is regaining importance. Many companies have successfully demonstrated that with fully automated production, many products, including rapid medical tests can be produced in Germany just as cost-effectively as in the Far East. Sanner and automation specialist MA micro automation create attractive conditions even for smaller batch sizes. An assembly cycle time of 750 milliseconds per test is a help in achieving this manufacturing capability.

Final inspection of the finished test cartridges. Thanks to the cooperation of Sanner and MA micro automation, various design and labeling requirements can be realized.

© MA micro automation



The laboratory landscape in Germany is diverse. Highly competent small and medium-sized companies develop test strips including analysis equipment for detecting a wide variety of substances. Covid test kits are just one example. Point-of-care (PoC) diagnostic devices are also relevant for detecting diabetes, pregnancy or illicit drug use. Production of test cartridges alone is not profitable for many laboratories due to the demand

for small quantities, which is why they often buy standard products from Asia and assemble them there as well. But if production volumes of many smaller customers were combined and supported by a highly efficient assembly line, it would be just as easy and more profitable to manufacture in Europe. Doing so would provide simpler logistics, better quality monitoring and private labeling of products. Sanner GmbH, Bensheim,

Germany, is a renowned provider of plastic primary packaging for pharmaceuticals, medical consumables including point-of-care tests and in vitro diagnostic devices. MA micro automation GmbH, St. Leon-Rot, Germany, designs and builds complex automation solutions to support medical device manufacturing. Both companies are now combining their expertise to advance the insourcing (in this case also reshoring) of rapid tests.



Cutting station: it makes individual test strips from card material and automatically sorts out faulty parts. © MA micro automation

The basis for this is utilization of MA micro automation's Ceres POC system, which can assemble test cartridges with up to three test strips – in just 750 ms per cartridge. Sanner can now offer customized or standard cartridges, which can accommodate the needs of many customers. The precise fit of component parts is important in order to achieve an effective lateral flow, the uniform spreading of a test sample along the reagent coated test strip.

Sanner has been an expert in the field of precision injection molding for years and has used their in-house competence to develop a test device and housing design according to customer specific functional requirements. Design and reliable production of this component guarantees the functional capability required to deliver precise test measurement results.

Sophisticated Assembly Process

Components of rapid test devices, the plastic upper and lower housing parts plus test strips, undergo a complex manufacturing process. Injection molded and packaged in bulk, the cartridges are loaded into feeders to be separated, oriented and fed into the assembly line. Up to three cutting modules are docked with the line to convert sheet stock material into test strips. The latter is available in cards of about 300 mm length and, depending on the product type, are cut into 60, 80 or 95 mm widths. After prior visual inspec-

tion to confirm reaction agent or test chemical is applied everywhere, the cutting modules cut the cards into individual test strips with any faulty raw material automatically ejected by the system.

Cutting is followed by precise feeding of test strips into lower cartridge parts and subsequent "on the fly" vision inspection to confirm correct positioning. This is done using 3D scanning technology. Upper parts are still needed to complete the assembly. While component parts purchased from Asia provide dimensional accuracy sufficient for manual assembly, typically they are not suitable for trouble-free operation of a high-performance assembly machine. In-house production of all cartridge components by Sanner solves this problem.

Visual Individualization of Tests

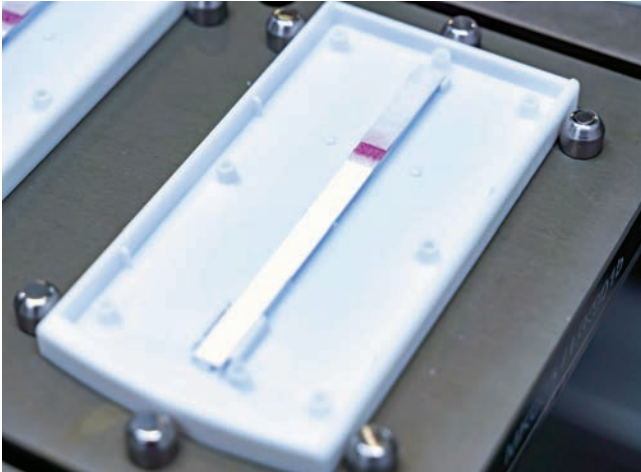
The next step in the manufacturing process involves a special feature of the whole concept: the visual individualization of test devices. Conventionally, products like these are marked by pad printing processes. However, this technology always requires complex setup of a new template when a production type is changed causing significant downtime between batch runs. Instead

of pad printing, the Ceres POC, uses two programmable laser writers to mark products. They can produce a variety of label configurations in short cycle times and are simply switched from one program to the next when a version change is to take place. In practice, this means that each laboratory can accommodate its own labeling requirements including a logo. To change production over from one customer's production order to the next, only a change of test strip card material and activation of a specific laser program. In this way, smaller production volumes can add up to a larger run make test production in this country more efficient and profitable. Most laboratories require quantities ranging from a few hundred thousand to five million tests per year.

A closely controlled press force combines the upper and lower parts to form a finished test cartridge. Subsequent inspection checks monitor whether everything has been assembled correctly. The last vision inspection verifies correct labeling and then the finished tests leave the machine via a conveyor belt leading to a primary packaging. At this point, in addition to the test cartridges, drying agents and any necessary pipettes can be added and contents can be welded in bags. »



Assembly time 750 ms: the rapid transport of individual parts – here the lower shells – is the prerequisite. © MA micro automation



Lower shell with inserted lateral flow test strip.

© MA micro automation



Inline process testing ensures product quality at all times.

© MA micro automation

Info

Text

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Service

For more information about the system manufacturer and user:

www.micro-automation.de
www.sanner-group.com

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A PDF file of the article can be found at
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80 Tests in 60 Seconds

The Ceres POC works so fast that the human eye can hardly follow: the system produces 80 tests in 60 s. Numerous optical tests integrated into the assembly process guarantee all products are of the highest quality. MA micro automation has the necessary in-house know-how, so that image processing, IT and mechanical design of automation equipment complement each other. The company is one of the world's leading providers of automation technology and special machinery construction and currently employs around 200 people at three locations in Germany, Singapore and the USA. They create systems for patient-oriented applications (PoC tests), in vitro diagnostic consumables (such as pipette tips) and the production of disposable contact lenses. Sanner is the world market leader in the field of desic-

cant packaging and is also a sought-after provider of individual product development services and contract manufacturing for customers in the fields of medical technology, diagnostics and pharmaceuticals. The Sanner Group is characterized in particular by a very high quality standard in production, no matter whether it is a gray- or cleanroom, as well as a high OTIF level (on time in full) of 99 % and thus a high delivery reliability. Founded in 1894, the company has around 600 employees and operates production sites in Germany, France, Hungary and China. Sanner has been producing rapid tests for some time, but the minimum quantity production volumes required so far have often been too high for small and medium-sized laboratories. Due to the extremely flexible yet high throughput capability of Ceres POC from MA micro automation, this is now changing. ■