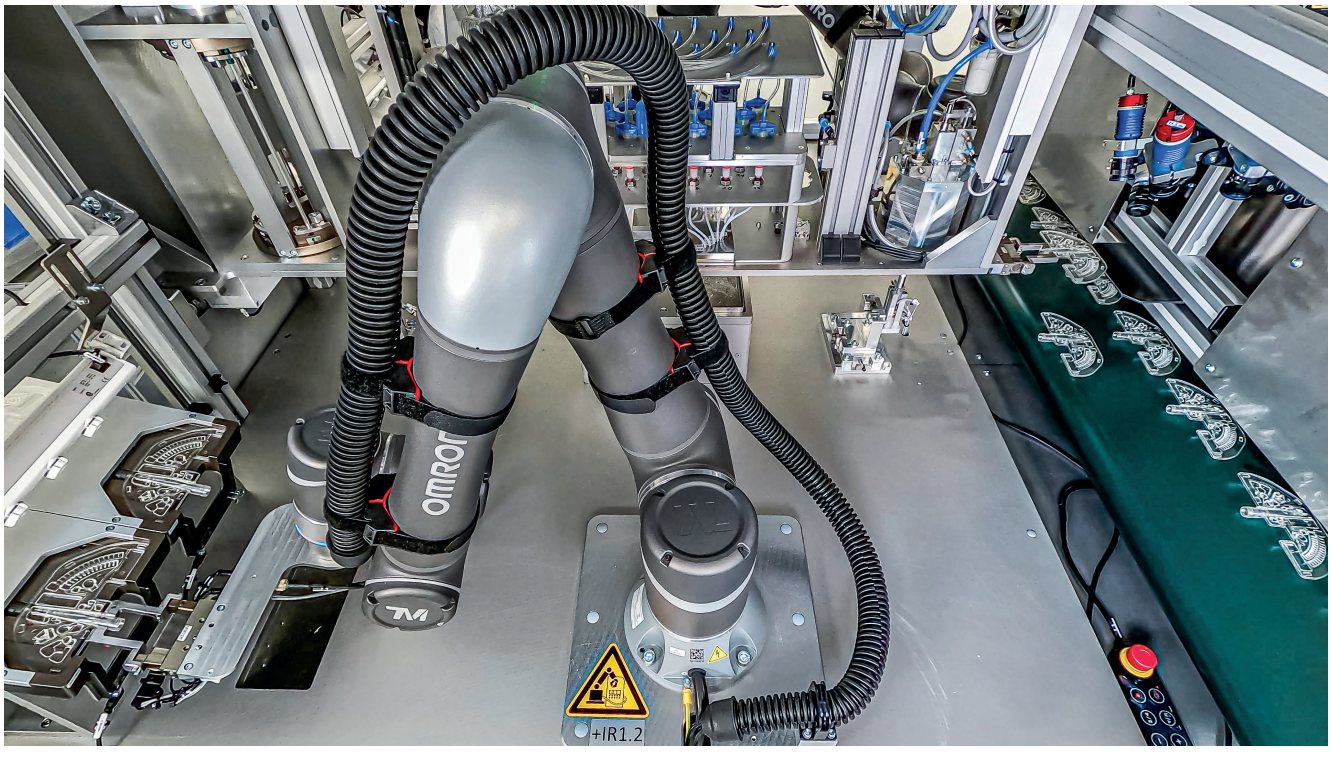
An All-Round Winner

High-Tech Production of Life-Saving Disks for Fast Analysis of Dangerous Germs

RKT has been manufacturing plastic products for medical and industrial technology for 45 years. Discs for the rapid analysis of multi-resistant hospital germs are a lighthouse project within the sophisticated product portfolio.



A six-axis robot picks the molded parts out of the mold under an inert gas atmosphere and conveys them into the cleanroom for further processing and packaging © Medienproduktion Holzer

As a one-stop system service provider, RKT Rodinger Kunststoff-Technik GmbH based in Roding, Germany, a subsidiary of Alfmeier Präzision SE, supports its customers with expert information and activities along the entire value chain. Everything from development and design, mold construction, injection molding and finishing up to quality control, assembly and contamination-free packaging – all comes from a single source. To this end, the company not only uses Allrounder injection molding technology, but also makes intensive use of Arburg's know-how in application and service technology.

Diagnostic discs, manufactured by RKT for start-up company Spindiag from Freiburg im Breisgau, Germany, are a current and outstanding example from the field of medical technology. With this product, it will soon be possible to rapidly determine, within a maximum of 30 min, by smear analysis whether a patient is infected with multi-resistant hospital germs. Whereas complex laboratory analysis is required at present, the disc provides an immediate result. This will allow for quick decisions regarding the admission of patients, which can be vital for survival.

Channels Measured in Microns

The requirements for components and quality assurance are very demanding as a result. The Spindiag discs have recesses and contours to hold the respective laboratory chemicals. Such complex geometries are a specialty of RKT. "These products feature microfluidic channels in the micron range," emphasizes Dr. Dieter Pfeifle, Business Development Manager at RKT. "We process COP and COC plastics, which are relevant to medical technology, as inert materials with high light transmission values in an inert gas atmosphere to prevent oxidation."

During the new product's initial phase, the discs are produced on an electric Allrounder 470 A with a clamping force of 1000 kN, which is docked to a large ISO 8-equivalent cleanroom. The machine is equipped with a laminar-flow box, a laminar airflow system and a single hot runner master mold from RKT with inserts. The molded parts are removed by a six-axis robot and transported into a

Here, a disk is filled with a spherical freeze-dried reagent (lyophilisate)
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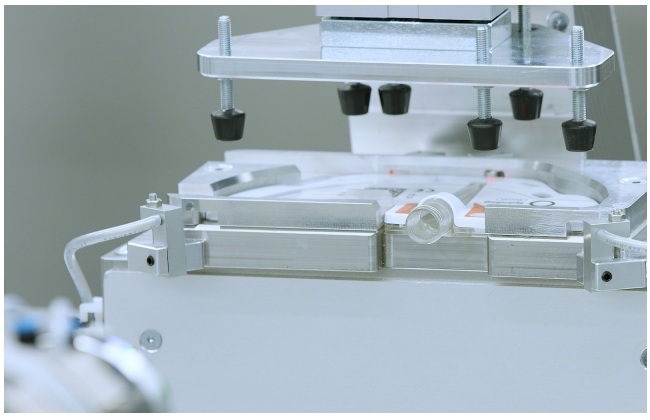

A cover is clipped onto the disk (the circular sample inlet at the front) to protect the film © Medienproduktion Holzer

smaller cleanroom with air lock system and access control, which is located within the ISO 8-equivalent cleanroom. It meets the requirements of cleanroom class 7 according to ISO 14644–1 and also has to be free of contamination and without any foreign DNA entry (free of analytes). In this cleanroom environment, the parts are fed into a Bagmatic tubular bag machine, which double packs the parts free of contamination (bag-in-bag).

For further processing, they are then transported to another ISO-7 cleanroom, which is also located in the ISO-8 equivalent large room. Here, a worker removes the disks from the bags and feeds them to a production line. A robot now moves the components through individual stations, including a micropipetting unit, a drying oven and a thermobonding station, where chemicals are introduced by pipette, dried and atmospherically sealed with a plastic film. A lid is then applied to protect the film, the unit is sealed in an aluminum bag and packed outside the cleanroom in secondary packaging ready for shipping.

Own Department for Process Development

According to Andreas Persch, Head of Sales and Projects, the sophisticated work process itself has proven to be the most economical for the customers. "We generally build our entire production lines according to customer requirements," Persch continues, adding that RKT has created a dedicated Process Development department for this purpose.

RKT has collaborated with Arburg since it was first founded in 1974. All machines of the manufacturer from Lossburg, Germany, are equipped with linear and six-axis robotic systems and can remove the molded parts according to cavity. Some of the machines are integrated in a clean area (ISO-8 equivalent) or operate into an ISO-7 cleanroom. As Andreas Persch says: "Such close connections ensure first-class service and competent application technology advice, enabling us to jointly realize new ideas." ■

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Service

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