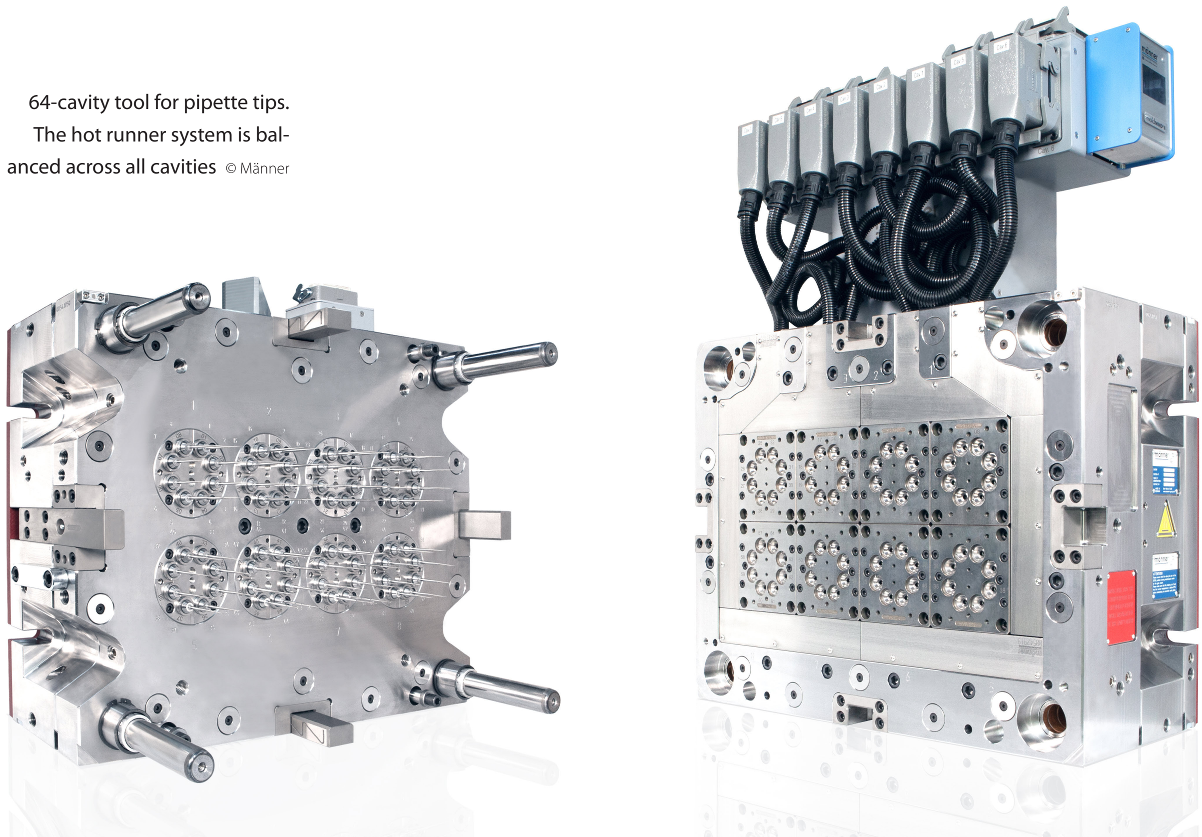
Mold Platforms for IVD Consumables

Strategic Approach through Classification according to Product Groups

In-vitro diagnostics is the examination, in laboratory vessels, of samples taken from the human body. The consumables required for this are manufactured in a production process that is subject to high requirements in terms of precision, quality and quantity, but also the complex cleanroom manufacturing environment. This has implications for the entire plant technology – especially toolmaking.



64-cavity tool for pipette tips. The hot runner system is balanced across all cavities © Männer

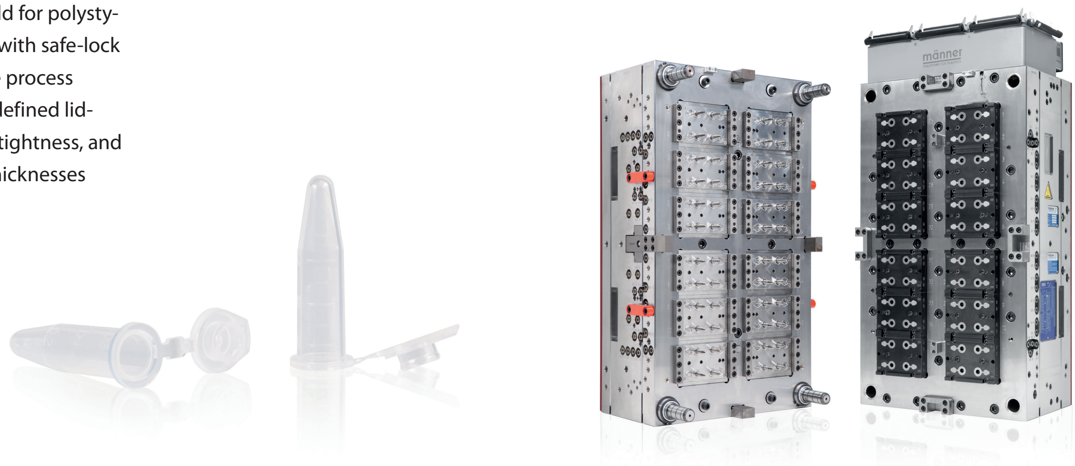
Medical technology plays an essential role in injection molding technology. This is due to demanding requirements in terms of availability, precision, quality, and high-volume production runs, in addition to complex manufacturing conditions such as a sterile environment or quality requirements enforced by GMP (Good Manufacturing Practice) regulations and the FDA (Food and Drug Administration). In-vitro diagnostics (IVD) pose unique challenges concerning machine and system technology, tools, and peripherals.

In-vitro diagnostics involve carrying out diagnostic and analytical procedures on samples such as blood or tissue that have been taken from the human body. These tests are generally conducted in laboratory glassware ("in glass" from Latin: in vitro). On the one hand, many of today's glass tubes are made of unbreakable polymers. On the other hand, there is no need for sterilization in the clinical environment when using disposable products taken from sterile packaging. The most critical requirement of IVD remains the absolute sterility of the parts involved in the reaction processes and diagnosis. This article focuses on the requirements for toolmaking.

Walking the Tightrope between Technical Feasibility and Value Creation

While the customary strategies for developing tools provide a decent basis, specific development expertise is necessary for in-vitro solutions. IVD consumables

Fig. 1. A 48-cavity mold for polystyrene reaction vessels with safe-lock lids. Challenges in the process include closure with defined lid-opening force, vapor tightness, and homogeneous wall thicknesses © Männer



are elaborate and highly varied, as units can be thin-walled, transparent, delicate, or have a complex shape. A typical requirement for in-vitro applications is very strict tolerances because functions such as dosing accuracy, snap-in catches, or seals are indispensable in diagnostics.

Consequently, there are unique specification profiles for toolmaking, including short cycle times, multiple cavities, highly polished, refined surfaces, sophisticated hot runner technology, integration of sensors, and automation systems.

The central requirement remains maximum precision combined with a high level of energy efficiency and output volume, in addition to low unit costs and minimal scrap rates. This condition always forces companies to strike a balance between technical feasibility, maximum process reliability, complex tool technology, and economic efficiency. The trade-off between these factors in IVD causes significantly higher demands compared with other industries.

In-vitro products pose strict process requirements that make it important to use a classification system for the product group in toolmaking. This leads to a platform strategy for mold design. Otto Männer GmbH, for example, has developed the following scheme:

- Group 1: pipettes;
- Group 2: sample and reaction tubes, cuvettes, or microcentrifuge tubes;
- Group 3: petri dishes, cell culture dishes, bottles, or plates;
- Group 4: deep-well plates, PCR plates, microtiter plates, racks, or cassettes.

A classification system like this provides the basis for the toolmaking strategy and serves as the blueprint for designing a production cell. Each group presents specific challenges in tool design. All of these applications can only be carried out in highly effective, automated production cells, causing high demands on the balanced interaction of machines, tools, and automation.

Challenges of Group 1 and 2 Applications

Pipettes (group 1) are functionally challenging, as liquids must be transferred in precise dosage volumes. Consequently, the requirements for precision tolerances and surface specifications are extremely important (**Title figure**). Hot runner systems play a crucial role in this process. The hot runner system developed by Männer, especially for pipettes, offers advantages such as the ability to control each individual cavity for precise balancing. The hot runner system is optimized for the specific properties of the polymer used, improving start-up behavior and the avoidance of "dead spots" in the runner channel.

Group 2 is geometrically less varied. Common features of reaction tubes include liquid volume and closure by means of a separate cap or a one-shot flip closure. The product characteristics of this group can include:

- Thermally resistant,
- injected scaling,

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Fig. 2. A 64-cavity tool for 2-ml reaction vessels made of polystyrene with separate closure. The multipoint nozzles used can be installed to save space © Männer

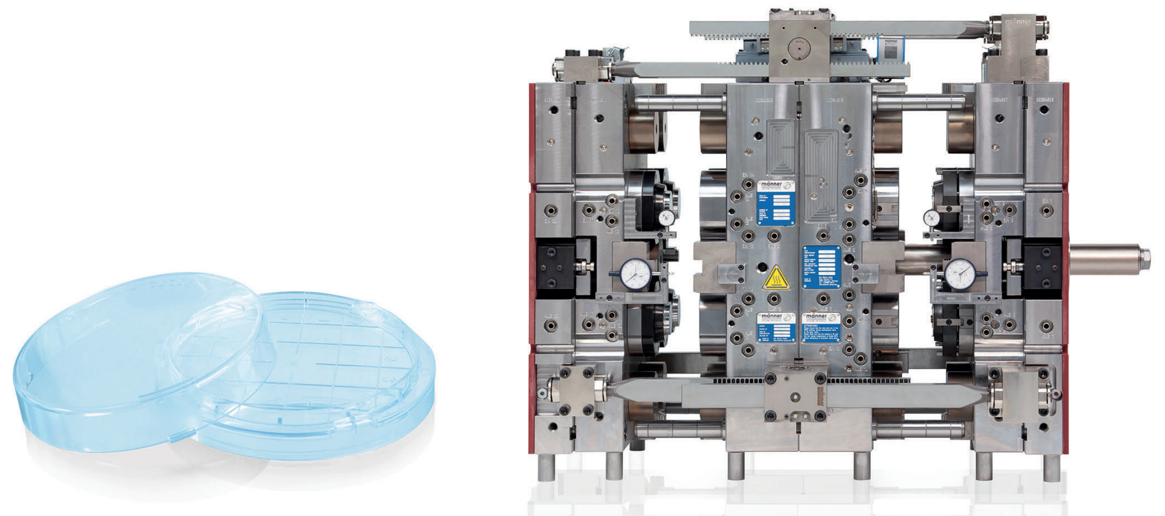

Fig. 3. 4+4 stack tool for contact trays. Cooling that closely matches contours can reduce cycle times by up to 25 % © Männer

- frosted label area,
- centrifugation stability,
- product meets IVD standard,
- CE certification,
- outstanding leak-tightness,
- purity standards,
- safe-seal cap.

Männer typically equips its tools with multi-point nozzles that can be installed in complex, space-saving high-cavitation molds. Molds featuring 24, 48, or 64 cavities are used to achieve the required output volume (**Figs. 1 and 2**). The surface finish plays an important role, as highly polished, refined mold surfaces ensure 1A part surfaces. Challenges that arise in this process include air entrapment in the sealing area, the safe-seal itself, vapor leak-tightness, the specified lid opening force, homogeneous wall thicknesses, and centrifugation stability.

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Challenges of Group 3 and 4 Applications

Regarding group 3, the primary demand is for petri dishes made of PS (polystyrene). Standard wall thicknesses are about 0.6 to 0.75 mm. Stack molds are common, with configurations ranging from 4+4 and 8+8, all the way to 16+16 cavities (**Fig. 3**). The challenge is achieving flatness of the base, high optical quality (from transparent to high-gloss), and a precisely defined fit of the lid and tray (particularly with contact trays). As a result, tolerances are extremely tight because the cover must lock securely and be easy to open and seal. The geometry is also complex because barely visible locking lugs connect the trays and lid. Coatings must ensure the best possible surface finish on the part in order to guarantee the quality of the tool.

Group 4 is quite diverse in terms of component sizes and geometries. The demand from laboratories and institutes is very high because these components are required in areas such as antibody tests and Sars-Cov2 tests. Microtiter plates are designed to accommodate large numbers of different pipette or tube sizes. Their function typically involves multiple replications of genetic material in vitro with identical conditions in each tube. By applying special materials and cooling that closely matches contours, cycle times can be reduced by up to 25 %. The split snorkel of the Männer hot runner system facilitates easy removal from the mold. The tool concept (**Fig. 4**) is used for 2– to 4-cavity molds.

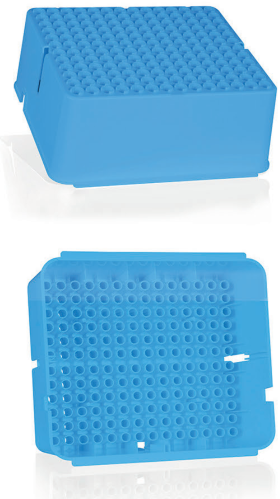
"Soft Factors" in Toolmaking

While process-optimized, state-of-the-art toolmaking is essential to adding value, servicing and life cycle support for the tools are also important for processors. This is due to the complexity of such high-performance tools that must remain available. In addition to mold validation, requirements, approvals, and materials testing, demand for online qualifications is increasing, especially in the wake of the coronavirus pandemic. In 2020, approximately 75 % of all validations were carried out online.

The Barnes Molding Solutions network provides a pool of 37 injection molding machines with clamping forces ranging from 700 to 5000 kN. The Test Center at Männer plays a central role, as half of its footprint is reserved for customer machines and systems.

Entire production cells complete with office space can be installed in closed areas in order to protect sensitive new developments. Extensive measurement technology, such as machines for optical and tactile testing, thermal imaging, hydrological measurement, high-speed camera systems, and flow-rate meters, is also available to customers.

Another service delivery factor is one-stop shopping. The approximately 40 design and application engineers at Männer oversee all stages of product develop-



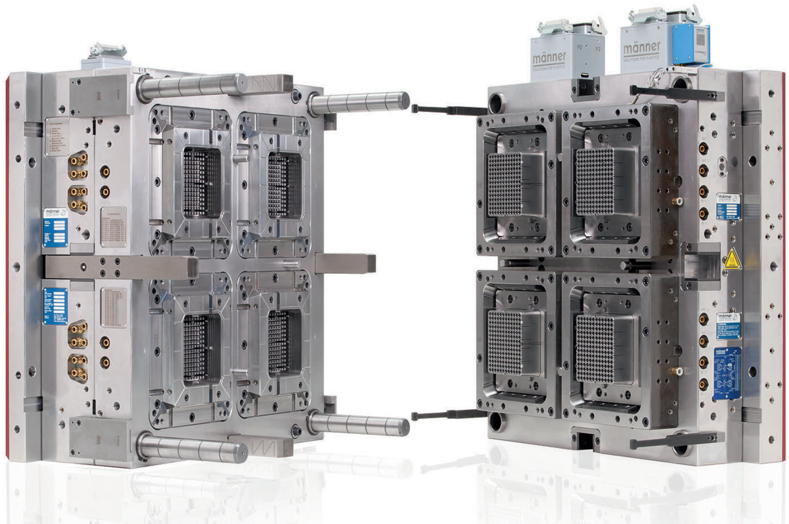


Fig. 4. A 4-cavity single-face tool for microtiter plates. The split snorkel of the hot runner system facilitates molded part removal © Männer

ment. As part of its project management, Männer matches customer teams with teams of engineers, addressing the complete development process:

- Design,
- part design,
- coordination of individual components,
- mold development and construction,
- production scheduling,
- interfaces for finishing, assembly, and automation,
- qualification, and
- after-sales service maintenance, service, parts subject to wear, upgrading.

From the customer's point of view, there is an additional condition for in-vitro products. With many providers operating globally at several production locations, identical products must be introduced into worldwide production in a decentralized way. The molding solutions group has five toolmaking locations for development, production, and life cycle maintenance in the USA, Europe, and Asia. The group relies not only on highly automated production but also on its employees' experience and technical know-how and uniform quality standards.

Global Reach, Local Alignment

Thus, in addition to the economic aspects of mold making – the lowest possible total cost of ownership (TCO) by using durable, low-maintenance, high-speed precision tools –factors such as short distances to local contacts and fast coordination are also decisive from the customer's point of view. Customer proximity and responsiveness, regional management, flexibility and time-to-market are the keywords for global, partnership-based collaboration in medical technology. ■

MCAM Presents KyronMAX Structural Thermoplastic Compounds

Expanded Resin Formulations

Mitsubishi Chemical Advanced Materials (MCAM), Mesa, AZ/USA, expanded the product line of its KyronMAX structural thermoplastic materials with new resin formulations to meet the requirements of applications in the medical, oil & gas, aerospace, automotive, and recreation market segments. The KyronMAX line is based around structural compounds which, according to the company, are the strongest compounds for the injection molding process in the world. These compounds can be used to replace steel in a structural component. The new materials are able to reach 414 MPa tensile strength. Metal replacement, particularly in automotive components, has become a part of OEMs lightweighting and sustainability programs, Dave Wilkinson, Technology Director for MCAM, says. "We've done studies on the savings of using KyronMAX compounds to replace metal. When you start taking weight out of the material you get a massive CO_2 reduction because you don't need as much fuel to power the vehicle." Additionally, KyronMAX technology enables very complex parts to be injection molded and retain the strength and mechanical performance of metal.

To the product presentation:
www.kunststoffe-international.com/a/article-314750

A bracket made of the new structural thermoplastic compounds © MCAM