MEDICAL

3 ways to improve performance in IVD applications

Key considerations for manufacturing in vitro diagnostic products

Throughout the COVID-19 pandemic, demand for in vitro diagnostic (IVD) testing solutions exploded as public health officials, health care providers, and others looked for faster, more cost-effective ways to achieve reliable diagnoses. With the value of these products proven beyond a doubt, the global IVD market has seen significant growth and was estimated at nearly $112 billion in 2021, according to Grandview Research. The outlook remains strong for the years ahead, and in the race to get products into market, many manufacturers have partnered with converters like Boyd who can improve the performance and manufacturability of critical materials and components.

IVD equipment requires extreme precision in the manufacturing process to ensure test kits function properly and all components are free of contamination. However, many IVD test kit designers and manufacturers aren't particularly concerned with how materials are converted, they simply want a reliable solution to their core challenges. The converting techniques and materials used have a significant impact on product performance, particularly for microfluidic diagnostic laminates, lab-on-a-chip devices, and polymerase chain reaction (PCR) testing applications. Meaning material selection and precise material conversion are critical processes for ensuring high quality and reliability.

Boyd has significant experience helping manufacturers enhance their IVD solutions, optimize total cost, and improve manufacturing efficiency in three main areas: cutting, bonding, and laminating. Learn how Boyd adds value and solves challenges in the IVD space using our industry-leading converting capabilities.

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Cutting

In vitro diagnostic solutions are often composed of multiple layers of engineered materials that must be converted to complex geometries with tight tolerances. While cutting materials to specified shapes may appear simple enough, the specific process used, precision, and quality control can have a profound impact on the integrity and reliability of IVD solutions. Precise sample fluid channels, for example, directly impact IVD test quality.

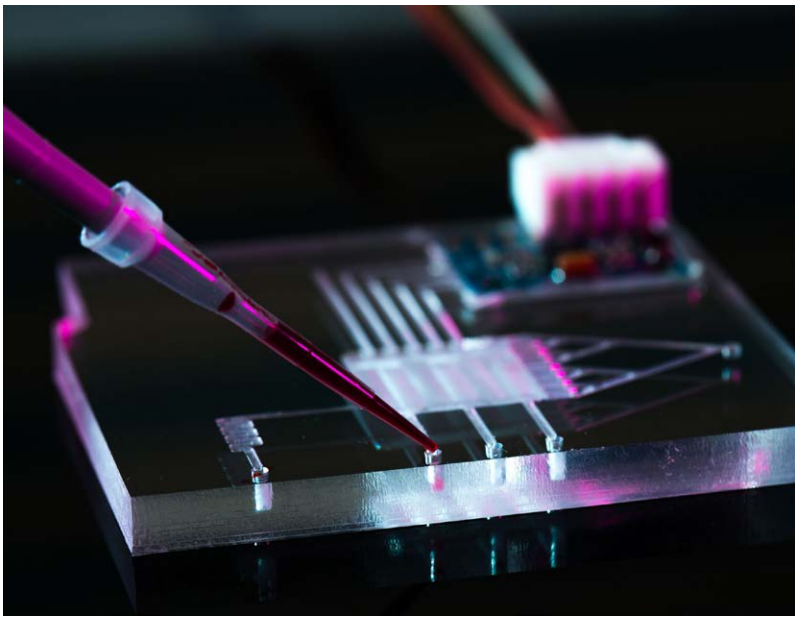
Manufacturers of IVD products have several primary options for cutting materials to improve manufacturability, quality, reliability, and performance:

Rotary die cutting — This process offers a wide range of integration possibilities with ultra-tight or zero-gap tolerances and registration control optimized for automated assembly systems. Rotary die cutting is ideal for high volume and high precision applications. Intricate shapes and details with world-leading manufacturing tolerance control are achievable in rotary die cutting.

Flatbed die cutting — Flatbed cutting utilizes steel-rule, horizontally oriented dies to convert raw materials. Flatbed die cutting is an ideal alternative for larger format components, thicker materials, and low-to-moderate volumes that may not be ideal for rotary converting processes.

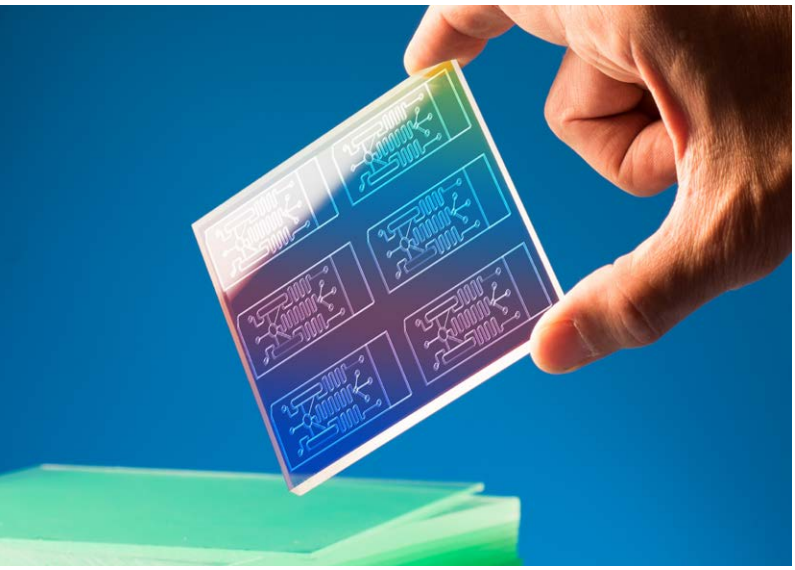
Water jet cutting — Converting materials into complex shapes with a high-power, precision water jet is optimal for low-to-moderate mass production volumes and thicker, highly compressible materials that may deform in traditional die cutting processes. Water jet cutting is CAD-controlled, meaning manufacturers have no tooling investment, making it ideally suited for affordable, quick prototyping.

Laser cutting — A precision-controlled laser can convert raw materials into complex shapes and is ideal for quick prototyping since it's die-less with no tooling cost. Laser converting is also optimal for thick or tough materials that may not be suitable for die cutting and for low-to-medium mass production volumes.



Boyd offers all of the above cutting options and has experience helping manufacturers match the ideal process for the intended application. For example, one of our partners was looking to enhance their microfluidic testing device that featured extremely small flow cells within a cartridge assembly. With such tight tolerances and the small size of the component overall, their engineers assumed their only option was laser cutting. However, with our precision die cutting, we were able to show that a die cut using traditional tooling could eliminate challenges with waste material removal and enhance overall device performance.

Switching from laser cutting to traditional tooling allowed the IVD manufacturer to achieve a higher edge quality within the flow cells without burning the substrate material. Traditional tooling also eliminated the small particles that are created in the laser cutting process, helping to minimize contamination within the testing apparatus. By making this simple switch in converting process, the manufacturer was ultimately able to achieve superior product performance while increasing manufacturing efficiency.



Bonding

To ensure the success of an IVD application, manufacturers need to select the right bonding adhesives that are durable enough to withstand the chemicals and fluids passing through the test without contaminating results or compromising adhesion. By using a combination of adhesives with hydrophobic or hydrophilic substrates and films, IVD designers and engineers can move or seal fluid in a controlled manner to mimic established lab practices on a microscopic scale in a small plate or test strip. Reflective materials like aluminum film and optically clear adhesives can also be added to assist in visual detection systems to further streamline the diagnosis process.

Adhesives commonly used for IVD applications include structural adhesives made from epoxy, acrylic, urethane, cyanoacrylate, and other materials. Pressure-sensitive adhesives (PSAs) like medical grade tapes from 3M are also used extensively for a variety of IVD applications. As a preferred 3M converter, Boyd has access to the best quality bonding adhesives on the market and our materials science experts help guide adhesive selection to find the ideal choice for a given application, helping to limit costs and improve product durability and performance.

Laminating

In vitro diagnostic products often call for precision medical laminates to enable highly accurate fluid flow that is protected from contaminants through microfluidic and PCR tests. In these instances, lamination integrity is critical to avoid contamination and ensure optimal product performance. PCR plates require an effective film or foil to safely contain and consistently preserve samples. PCR plate seals can feature reusable or permanent adhesives with strong or pierceable films.

Boyd's engineering team works closely with IVD design teams to select optimized materials that meet exacting application requirements. Boyd leverages close relationships with our medical material suppliers such as 3M to access the best fit material to meet each project's functional needs and cost targets. Boyd also has specialized processes to integrate microelectronic components into more advanced microfluidic diagnostic laminates for smart operation or device tracking.

We design ISO1385 compliant manufacturing processes to transform medical covers, lidding tapes, spacer tapes, adhesives, and substrates into functional microfluidic diagnostic laminates.

Cleanroom and high-volume manufacturing

The way materials are processed and converted is vitally important to the success of any IVD project. But equally important is where those products are being developed. Medical device manufacturers need access to cleanroom processing at high volumes to profitably create IVD products while meeting industry standards and regulations. Not only that, but manufacturing products closer to the point of use can allow for faster delivery, creating a competitive advantage.

This is where Boyd offers significant benefits to IVD product designers and manufacturers. We offer a variety of clean rooms ranging from Class 100 to Class 10K in our medical certified facilities with constant monitoring of critical parameters, ensuring a high level of cleanliness for sophisticated, precision products. We convert and pack products using numerous state-of-the-art manufacturing and assembly processes all within Boyd's clean room environments.

Boyd's ISO 13485 facilities take ISO 9001 quality controls to the next level with more thorough documentation and stricter process controls. Boyd adheres to ISO 13485 through each step of the solution life cycle from material sourcing, fabrication, and assembly to sterile kitting. To ensure we produce safe solutions, we utilize clean room environments, strict processes, and constant quality assessment in our work environments.

Our cleanroom facilities are available globally with scalable, replicated technology. We operate ISO 13485 certified cleanrooms in Oregon, Washington, and Tennessee in the United States, as well as in Germany, Singapore, Thailand, Mexico, and China. Our global reach means we can produce IVD solutions closer to where they're needed and mitigate logistical challenges that come from shipping materials, parts, or products to different global markets.

Converting processes make all the difference

The lengthy process of designing, developing, manufacturing, optimizing, and delivering IVD solutions to global customers is extremely complex. Within that complexity, it can be easy to overlook the little things like how materials are cut or laminated. But these foundational processes can have a significant impact on the overall quality and performance of IVD test kits and other diagnostic solutions. By taking time to reevaluate how materials are converted and where they are produced, medical manufacturers can improve products and achieve greater efficiency, ultimately leading to better business results.

Ready to start your next project?

Contact Boyd today to see how our converting capabilities and materials science expertise can help you deliver outstanding medical solutions.

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About Boyd

Boyd is a trusted partner for quality precision converting manufacturing. With over 90 years of customer-focused performance, Boyd's innovative, sustainable engineered material and thermal solutions make our customers' products better, safer, faster, and more reliable.