

CRITICAL CONSIDERATIONS WHEN MOLDING DIAGNOSTIC CARTRIDGES

The molding of diagnostic cartridges, lateral flow components, and intricate microfluidic devices requires expertise in mold design, injection molding, and in-vitro diagnostic device manufacturing to ensure the successful production of high-quality, validated, and scalable components. When molding diagnostic cartridges there are several key considerations to incorporate into your project scope:

- 1. Material Selection** – Select a medical grade material suitable for the diagnostic application – a medical USP Class VI material or lipid resistant material. The material should have good dimensional stability, chemical resistance, and transparency if visual requirements are necessary.
- 2. Mold Design** – Design the mold to ensure accurate and consistent replication of the diagnostic cartridge. Specify uniform cooling and heating channels for dimensional control. Select gate type and location for low shear and apply sufficient draft angles for easy release and to avoid stress during ejection.
- 3. Tooling Considerations** – Choose the appropriate mold tooling based on the required volume and the complexity of the cartridge. Consider factors such as the number of cavities, cooling channels, and mold material to optimize production efficiency.
- 4. Parting Line and Gate Design** – Determine the appropriate location for the parting line and gate in order to minimize flash and ensure proper mold fill. The gate should be strategically placed to prevent trapped air or flow interruptions.
- 5. Tolerances and Surface Finish** – Consider the tolerances and critical dimensions required to ensure proper functionality, as well as the surface finish requirements for the cartridge's main contact points and flow characteristics.
- 6. Venting** – Incorporate appropriate venting to allow air and gases to escape during molding. Insufficient venting can result in cosmetic defects, voids, or haziness on the surface which can impact light transmittance during diagnostic testing.
- 7. Processing** – Maintain proper hygiene and machine maintenance within the molding process for low fluorescence by frequently cleaning screw and barrel, maintaining low shear and resistance time, eliminating interruptions, and de-gassing the polymer before processing.
- 8. Assembly Compatibility** – If the cartridge assembly requires additional components, ensure that the molded parts are designed to facilitate easy assembly and integration with other elements such as sensors, electronics, or membranes.
- 9. Quality & Regulatory Compliance** - Validate the molding process for robustness and prove repeatability & reproducibility of the process for a reliable, quality product. As diagnostic cartridges are intended for medical or regulated application, ensure compliance with all relevant standards, such as ISO 13485 and FDA guidelines.
- 10. Cost Optimization** – Evaluate the cost effectiveness of the molding process by considering factors such as tooling costs, material efficiency, cycle time, and the potential for scalability into large scale production.



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