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Silicone Tech Advances are Key for In Vitro Device Manufacturers

Advances in silicone technology help in vitro device manufacturers respond to the demands of an accelerating market.

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Today, few industries are as innovative or technologically minded as medical devices, especially when it comes to in vitro diagnostics. In a market that is rapidly growing and changing, in vitro device manufacturers need to meet a key emerging demand for home testing and more rapid in lab analysis.

In vitro diagnostic medical devices (IVD) perform tests on biological samples, such as tissues, blood or urine, to determine the status of a person's health. From assays in a test tube or in a controlled environment outside an organism, IVD devices are used to diagnose, monitor, screen and assess predispositions to diseases and conditions. Unlike medical devices or pharmaceuticals, IVDs never come into contact with a person. There is a broad range of IVDs, from self-tests for pregnancy and blood glucose monitors for diabetics, to sophisticated diagnoses performed in clinical laboratories.

[i]According to an analysis by EvaluateMedTech, the in vitro diagnostics market will remain the number one medical device segment for the foreseeable future. It is expected to register a compound annual growth rate of nearly 6.1% by 2024 to give worldwide total sales of nearly $80 billion. Drivers in the growth of the in vitro diagnostics market include COVID-19 testing, the rise in chronic diseases, technological advancement to support preventative care, and an aging population across mature markets.

As the in vitro diagnostics market grows a couple of dominant trends are shaping it. The first is home testing to bring the diagnosis closer to the patient. This is helping doctors to detect problems earlier and treat conditions proactively, leading to an improved quality of life for patients. Provision of real-time results mean patients no longer have to wait days for information to come back from a lab, and they can often view their results online in the comfort of their home. Smaller, more sophisticated devices improve point of care as doctors can now perform analysis and treatment at the same time.

The second trend is for increased volume, speed, and precision of in laboratory testing, especially in response to the requirements of the COVID-19 pandemic where the PCR test has become one of the prevalent drivers of the molecular diagnostics market.

IVD devices contain a variety of polymer seals and components. Because of the biological nature of in vitro diagnostics, using the correct materials for these components is of the utmost importance. It is vital that materials do not contaminate a test or leach out when in contact with diagnostic fluid. The right material depends on the application, and it should provide the right combination of mechanical properties for the purpose of the component.

Liquid Silicone Rubber is a preferred material for seals and components in IVD. Being inert and bio stable, it is considered the gold standard in terms of biocompatibility and is non-reactive with other elements. It also demonstrates favorable physical and haptic attributes, good tensile strength, and

compression resistance. Different fillers match silicone compounds to specific applications and the material is easily molded, compressed into O-Rings or transformed into sheeting.

Liquid injection molding is a flexible process method, which lends itself to advanced multicomponent technology; the molding of plastic and silicone together in a single step. This results in a sanitary and robust part that eliminates assembly and improves the quality of a device. From a manufacturing efficiency standpoint, this cuts down on labor which enables skilled workers to focus on more value-added activities as opposed to fitting O-Rings into kits. This technology allows the manufacturing of components that cannot be produced in any other way and is ideal in the manufacturing of compact and user-friendly home test kits.

The Answer is in the Test (call out)

The simple O-Ring still plays an important part in many devices. As the COVID-19 pandemic put unprecedented pressure on healthcare systems, Trelleborg Healthcare & Medical supplied a leading diagnostics provider with O-Rings that effectively seal multiple patient samples per cycle, isolating COVID-19 test samples in a benchtop analytical platform.

Supporting laboratories in their efforts to detect and diagnose cases of COVID-19 more rapidly and effectively, the state-of-the art machine is capable of producing reliable test results in just two hours, thereby empowering healthcare providers to take faster action.

Microfluidics – A chip off the old block (Call out)

Microfluidics is an important tool for in vitro diagnostics. This method has been used in pharmaceutical research, biological analysis, and cellular analysis and is often referred to as “lab-on-a-chip.” Microfluidics conducts a quick specific test using a small sample and a chip. The chip goes into a piece of processing equipment, enabling testing and diagnosis for the presence of a virus. It can be done on site instead of being sent off to a lab.

Microfluidic devices are usually made of plastic engineered with tiny channels, valves, and pumps that can transport, mix, and analyze proteins, DNA, and other chemicals in body fluids to achieve the desired testing outcome. The fluid droplets form tiny hair-thin liquid streams which are precisely maneuvered to their intended destination by air pressure, electricity, or even sound. Once at the

destination they react with other chemicals, and ultimately yield clues about the presence of chronic disease or invisible pathogens.

By applying this technology to diagnostic procedures, doctors can improve test precision, run multiple analyses concurrently, and obtain samples with lower detection limits. Microfluidics technology depends on silicone sheeting. This comes into direct contact with the fluid tested and needs to be extremely precise, free from flash and must not contaminate the chip. Silicone acts as a pure background for microfluidics and satisfies biocompatibility requirements.

Conclusion

The in vitro diagnostics market has seen significant growth recently, partly driven by testing requirements for COVID-19 and also to fill a need for home testing. The latest polymer technologies are helping increase the accuracy and precision of tests and facilitate home testing kits and technology like microfluidics to treat problems proactively. This enables care providers to achieve real-time results, gain more information, and ultimately improve the quality of life for patients.

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[i] https://www.pwc.com/it/it/publications/assets/docs/pwc-IVD-market-trends-overview.pdf