TECHNICAL BRIEF:
Delivering Accurate Lateral Flow Diagnostic Test Results with Integrated Active Material Science Technology

Situation

Diagnostic tests are a critical component of patient care, enabling health care professionals to diagnose disease and recommend appropriate treatment. In particular, the surge in the development of new COVID-19 test kits and the pandemic-related supply chain challenges led to increased demand for consumer-friendly, at-home testing solutions. With diagnostics companies racing to secure EUA approval from the FDA, assuring the most accurate test results possible is critical to gaining that approval quickly and helping slow the spread. Additionally, as these companies are now selling tests directly to consumers, assuring delivery of the most accurate results possible provides a competitive advantage in gaining market share.

Challenge

Lateral flow diagnostic assays require the use of dry form reagents which can be inactivated or desensitized prior to use by exposure to moisture and humidity during storage. This can affect test integrity, negatively impact "signal to noise" ratio, a key factor in delivering reliable results, reduce positive test line retention, and even limit shelf life. To protect against environmental exposure and mitigate these risks, diagnostic test device developers often include a non-integrated, drop in desiccant sachet inside the device's packaging (Figure 1). While this can help with reducing moisture exposure, this approach can introduce a secondary risk of contaminating the device reagents with desiccant particulates during storage, which can affect device functionality. A desiccant sachet also complicates the manufacturing process, increasing both time and cost of production, and resulting in a larger overall packaging footprint. There is a need for an integrated solution to ensure diagnostic tests are stored in an ideal microclimate to protect device integrity and reduce the risk of device contamination while optimizing the manufacturing process.

Figure 1: Standard Desiccant Sachet

Solution: Active Material Science Technology

Aptar CSP Technologies' active material science solutions deliver a proven, customizable and seamlessly integrated method for protecting diagnostic test kit stability while improving signal to noise ratio and positive test line retention to maintain test accuracy. The proprietary 3-Phase Activ-Polymer™ technology is extruded into a flexible film format (Activ-Film™ material) and integrated into the diagnostic test strip for both a standalone dipstick format or within a cassette (Figure 2). Alternately, Activ-Film™ can be applied to the foil pouch containing the diagnostic cassette or dipstick. The Activ-Film™ material is custom formulated to adsorb tailored amounts of moisture, scavenge oxygen or VOCs, or provide a combination of active protection. In this form, the Activ-Film™ material provides a stable, non-reactive, non-corrosive material that delivers the ideal microclimate needed to protect the diagnostic device, without leaving behind particulates that might interfere with device performance as is possible with drop in desiccant sachets.

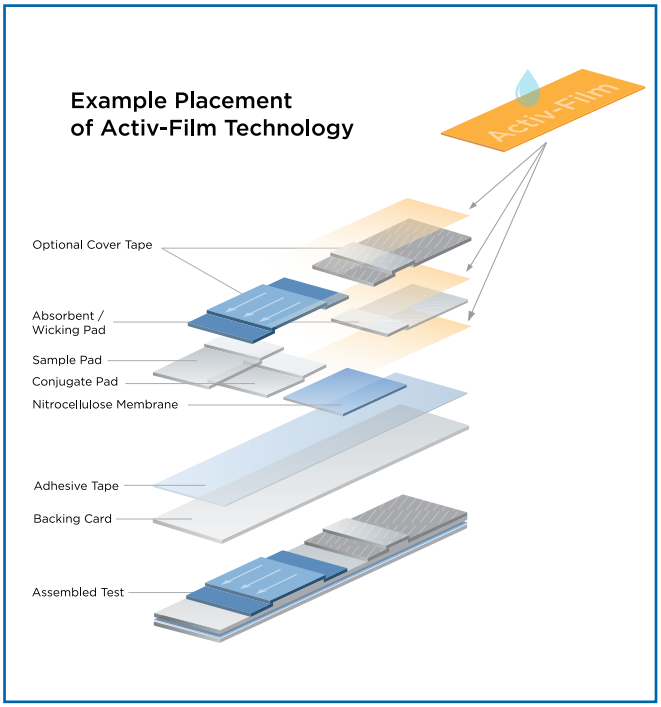

Figure 2: Concept Rendering of Potential Activ-Film™ Integrations for Dipstick or Cassette

Activ-Film™ material is produced in various sizes to accommodate any lateral flow dipstick, cassette or packaging design. The tailored, highly-engineered process delivers an optimized active packaging solution to meet the stability needs of specific diagnostic test kits. In the following data, we will illustrate how integration of Activ-Film™ technology into a lateral flow test improves device stability over the control.

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DATA REVIEW:

Impact of Integrated Activ-Film™ Technology on Lateral Flow Test Device Stability

The graphs to the right illustrate the impact of integrating the Activ-Film™ material into a diagnostic test dipstick. This study evaluated the average positive test line retention over time in two different lateral flow tests over a period of weeks when stored at 45°C.

Figure 3 shows performance of Influenza tests both with and without integrated Activ-Film™ material. The Y axis reflects the percentage of tests in the study with positive test line retention, which is an indicator of device stability. Over the full 14+ week test period, the device with the integrated Activ-Film material consistently outperformed the control, with a particularly pronounced impact during the first 9 weeks that was then sustained for the duration of the test period.

Figure 4 uses the same methodology to explore the impact of integrated Activ-Film in a strep test. Again, the devices with integrated Activ-Film™ technology delivered improved positive test line retention over the control during the 8 week testing period, with a notable difference in the early weeks of storage when the positive test line retention for the control dropped precipitously.

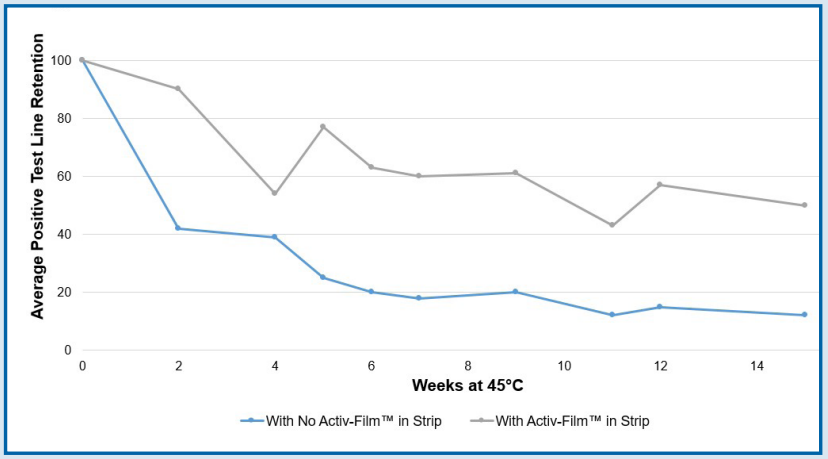

Figure 3: Influenza Test Device Stability
(With Integrated Activ-Film™ Technology vs. Control)

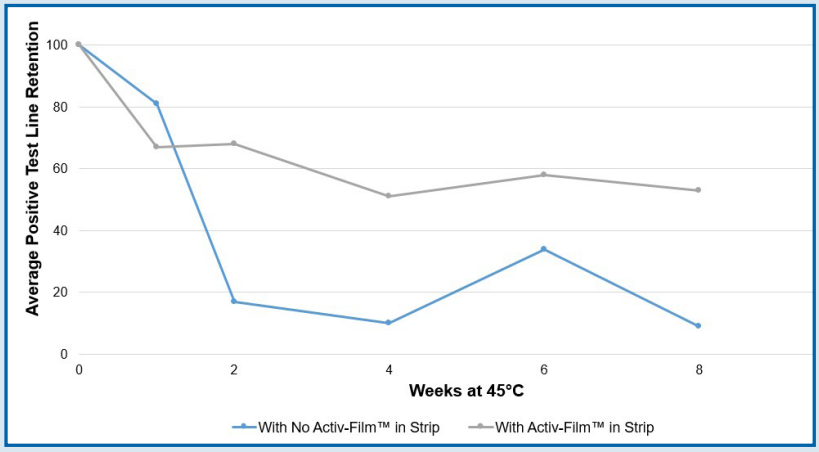

Figure 4: Strep Test Device Stability
(With Integrated Activ-Film™ Technology vs. Control)

Conclusion

Leveraging active material science technology to protect diagnostic test kits is a cutting-edge method for ensuring test result accuracy. The custom-formulated solutions deliver a controlled microclimate to mitigate risks associated with relative humidity impacts on diagnostic components and reduces “signal to noise” ratio, leading to more consistent test results. By minimizing moisture ingress that can degrade test integrity over time, the technology enhances stability, preserving shelf life and maintaining performance. Lastly, the ability to eliminate drop in desiccant sachets results in both operational efficiencies and an improved, intuitive user experience. There is no risk of dusting, breakage, or particulate damage during processing, no labor costs or reduced manufacturing downtime associated with inserting a drop in desiccant solution, and a decrease in overall packaging footprint.