

Solutions for Lateral Flow Assays and IVD Manufacturers

Solutions to Help Your Diagnostic Target Analyte Shine



The diagnostic industry plays an essential role in healthcare, not only by providing essential tools to clinicians, but also by supplying a range of at-home testing solutions. Recently, the field has been shifting from curative to preventative diagnosis, with a greater emphasis on personalized offerings.

To meet aggressive milestones and tough standards for performance, there is a need for continued innovation in the field as well as solutions that streamline the development and quality control workflows.

Sartorius is globally recognized for an expertise in biotherapeutics, including solutions for in vitro diagnostics kit (IVD) manufacturers. We can help you:

- Design a standardized sample preparation protocol before diagnosis with tailored lab instruments and consumables
- Get optimal performance characteristics on your lateral flow rapid tests with consistent and homogeneous UniSart® membranes
- Monitor and trace your critical Quality Control parameters
- Accelerate your analyte discovery steps, development and production

Customized Preparation of Patient Samples

- Liquid handling instruments with embedded workflows to standardize a strictly defined protocol
- High purity, DNase, RNase, endotoxin -free pipette tips available in bespoke packaging formats
- Privately labelled filtration and ultrafiltration devices, with volumes and membranes tailored to optimize specific sample preparation steps



UniSart® Membranes for Lateral Flow Assays

- Outstanding inter- and intra-lot consistency allowing constant test production parameters between lots
- Smooth and defect-free membrane surface leading to increased yield in test manufacturing
- High sensitivity membrane, requiring a minimal amount of biomarker
- Complete lot traceability over the entire manufacturing process, from mixing of the raw materials to the final slit roll
- 100% controlled by backlight inspection
- ISO 9001 certified manufacturing, REACH compliant



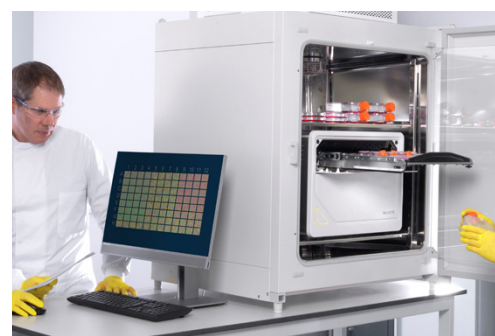
Quality Control of Target Analyte

- Label-free Bio-Layer Interferometry (BLI) technology with Octet® enabling direct detection of specific receptor proteins, ligands, antibodies and other analyte specific reagents (ASRs). Optional 21 CFR Part 11 software available along with installation and qualification (IQOQ) and performance qualification (PQ) kits.
- Cubis® II Pharma Compliant Weighing and sample management solutions, designed to follow data integrity principles and regulations such as ALCOA principle, FDA's (21 CFR Part 11) and EU's (Annex 11).
- Microsart® family for Microbial enumeration with touch- free membrane transfer



Analyte Specific Reagent Discovery & Optimization

- Identification of antibodies with Incucyte® S3 Live-Cell Immunocytochemistry Assay and Incucyte® Fabfluor-594 Antibody Labeling
- Protein quantification and kinetics characterization with Octet® Bio-Layer Interferometry (BLI) Detection Systems for Label-Free detection
- Cultivation and media optimization for optimal growth and protein production with Ambr® 15 Cell Culture Bioreactor



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