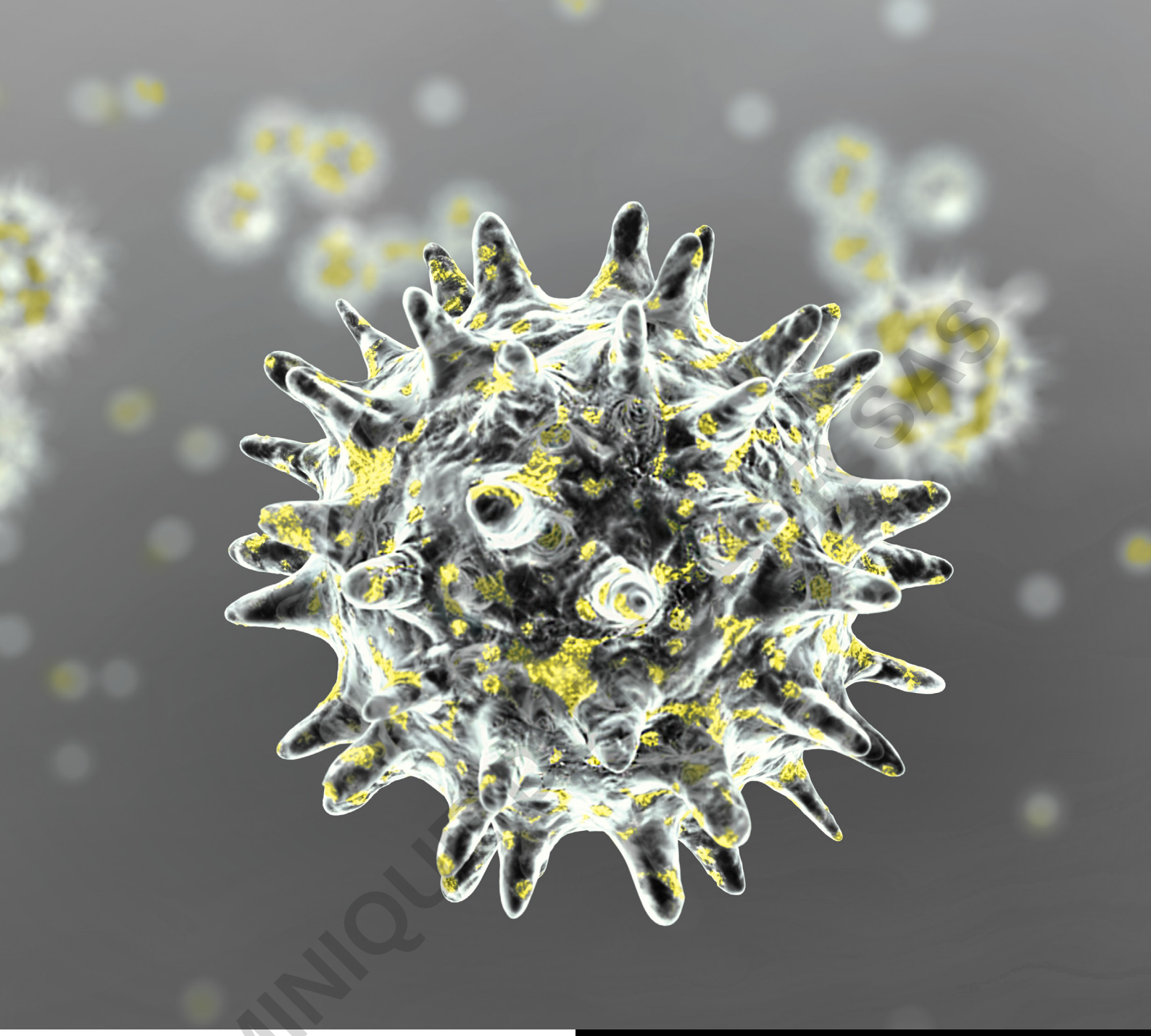


DOMINIQUE DUTSCHER SAS

Quality Control of Viral Vaccine and Viral Vector Production

Simplifying Progress

SARTORIUS

Growing in Importance

While inactivated or live attenuated vaccines dominate the market today, a new generation of viral vaccines known as recombinant viral vectors or virus-like-particles (VLPs) are in the pre-clinical and clinical development phases. Viral vectors are also widely used for gene therapy and oncolytic applications.

Quality Control of the Viral Vaccine and Viral Vector Production Process – Ensuring That Your Product Is Safe, Effective, and Pure.

Take a look at the example production process map, with the most important QC applications, and see where our products and services can help you overcome some of your quality control challenges from master viral seed (MVS) and master cell bank (MCB) all the way to final product release testing.

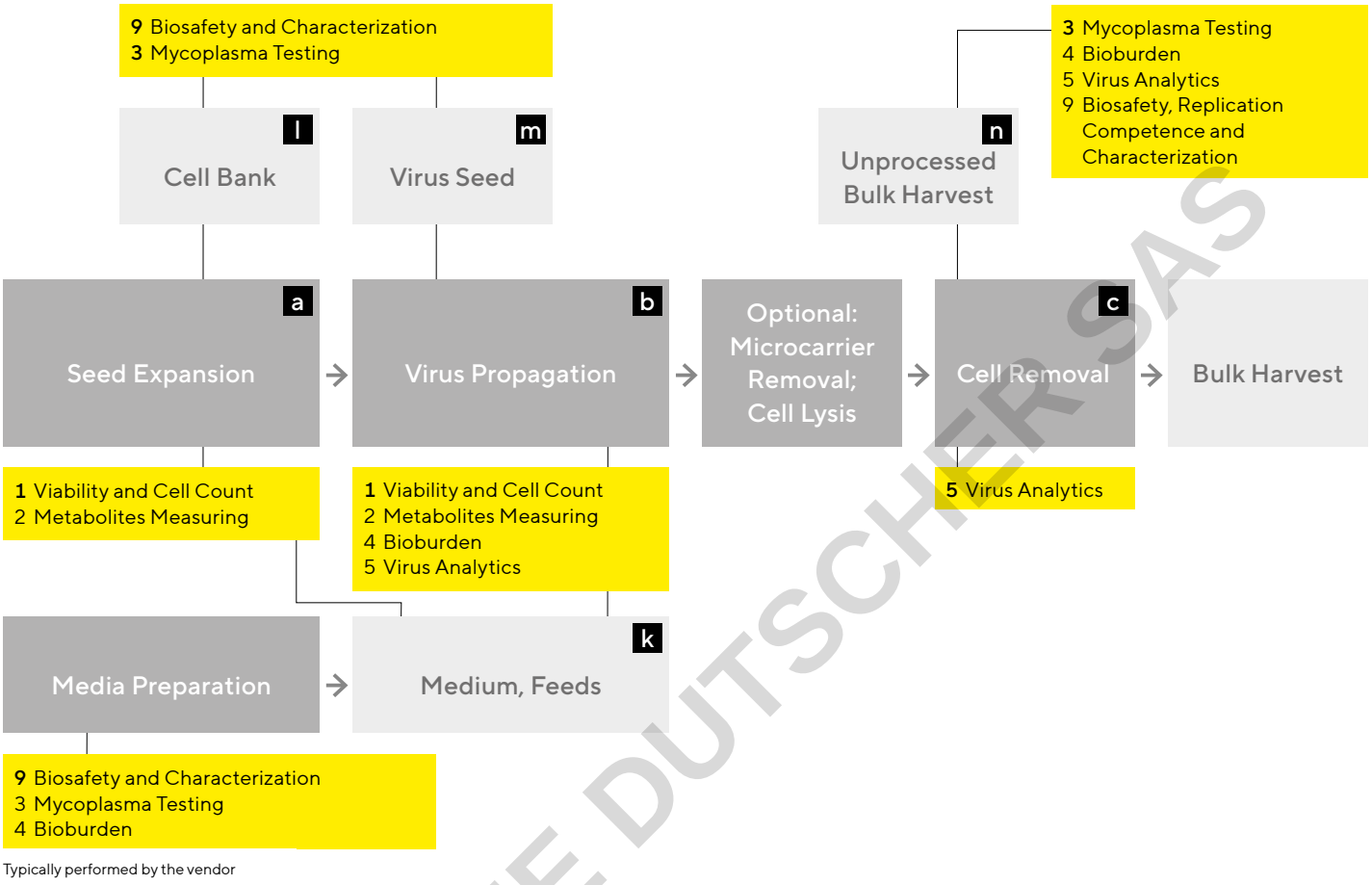


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Raw material testing **In-process control** **Final release**

Find out more
For more information, please visit sartorius.com

Sartorius QC Solutions



Typically performed by the vendor

DOMINIQUE DUTSCHER SAS

Your Application

1
Viability and Cell Count

Gives information about viable cell density in your cell culture; Allows automated cell bleed for perfusion processes or inoculation of seed trains.

Process Steps: a b

2
Metabolite Measurement

Gives information about the productivity, biochemical status, and lifecycle of your cells; Allows automated feed control based on glucose measurements.

Process Steps: a b

3
Mycoplasma Detection

Detect mycoplasma within three hours.

Process Steps: k l m n o p q

Sartorius Solutions

In-line monitoring and control of viable biomass in cell culture processes with BioPAT® ViaMass



On-line monitoring and control of glucose and lactate with BioPAT® Trace

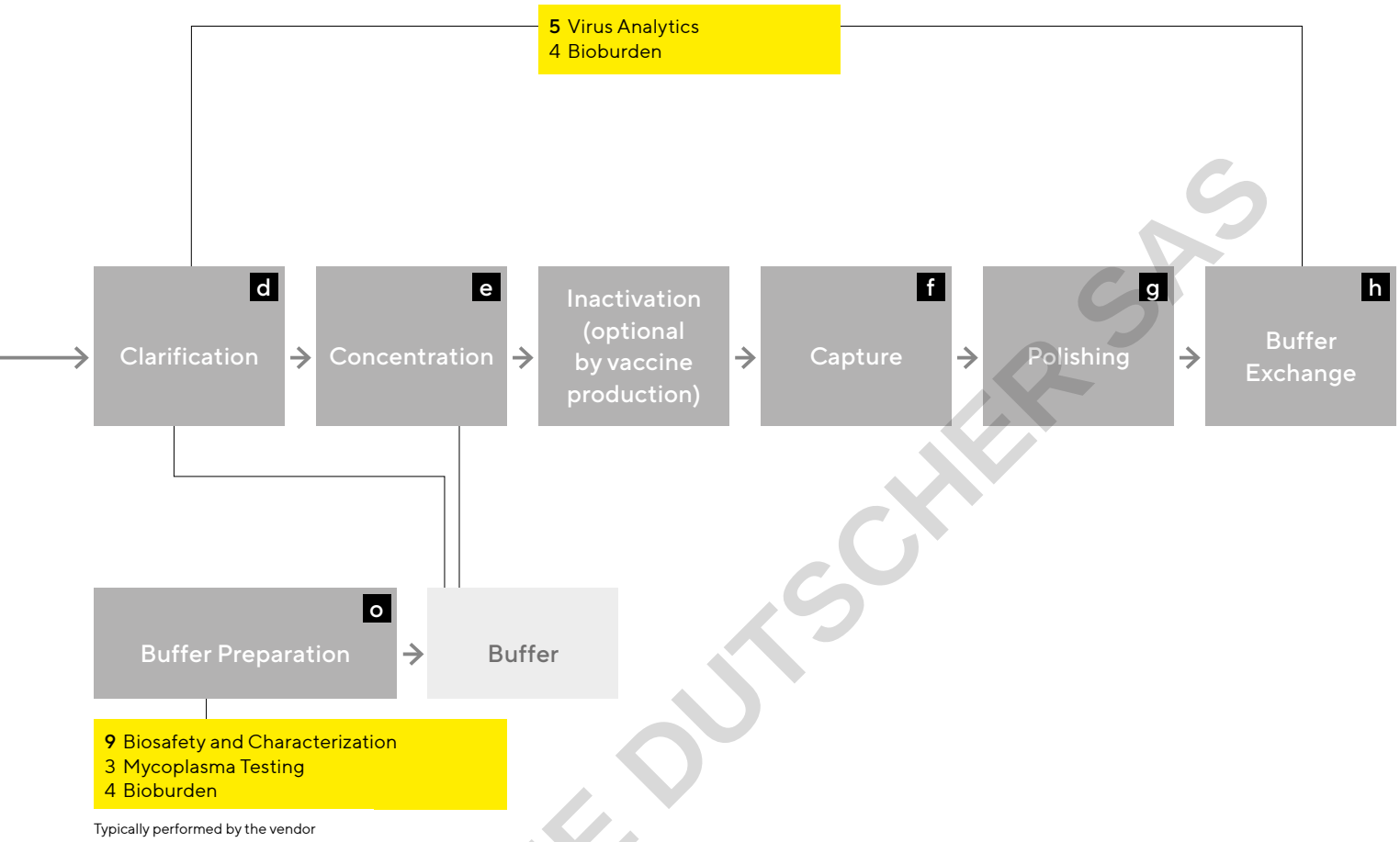


Fully automated control of the cultivation process

Microsart® Mycoplasma AMP qPCR kit – a rapid, reliable, and easy-to-use solution in compliance with international guidelines



Reduce time-to-result significantly



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4
Microbial Contamination Control | Bioburden Testing

Count the number of microbes in your sample using touch-free membrane transfer to agar.

Process Steps: b d e f g h i k n o p q

Microsart @filter and @media membrane filtration method for forceps-free and effortless membrane transfer



Minimize risk of cross-contamination

5
Virus Analytics

Real-time tracking of virus titer during growth, harvest, purification, and release allows process optimization and early detection of problems.

Process Steps: b c d e f g h i j n p q

Virus Counter® 3100 Platform rapidly and precisely quantifies total virus particles, providing results in minutes



Quantify a wide range of viruses and VLPs

6
Sterility Testing

Proof of sterility by membrane filtration method or rapid testing.

Process Steps: j

Batch release sterility testing with the Sterisart® NF canisters and Universal pump in compliance with international pharmacopeia

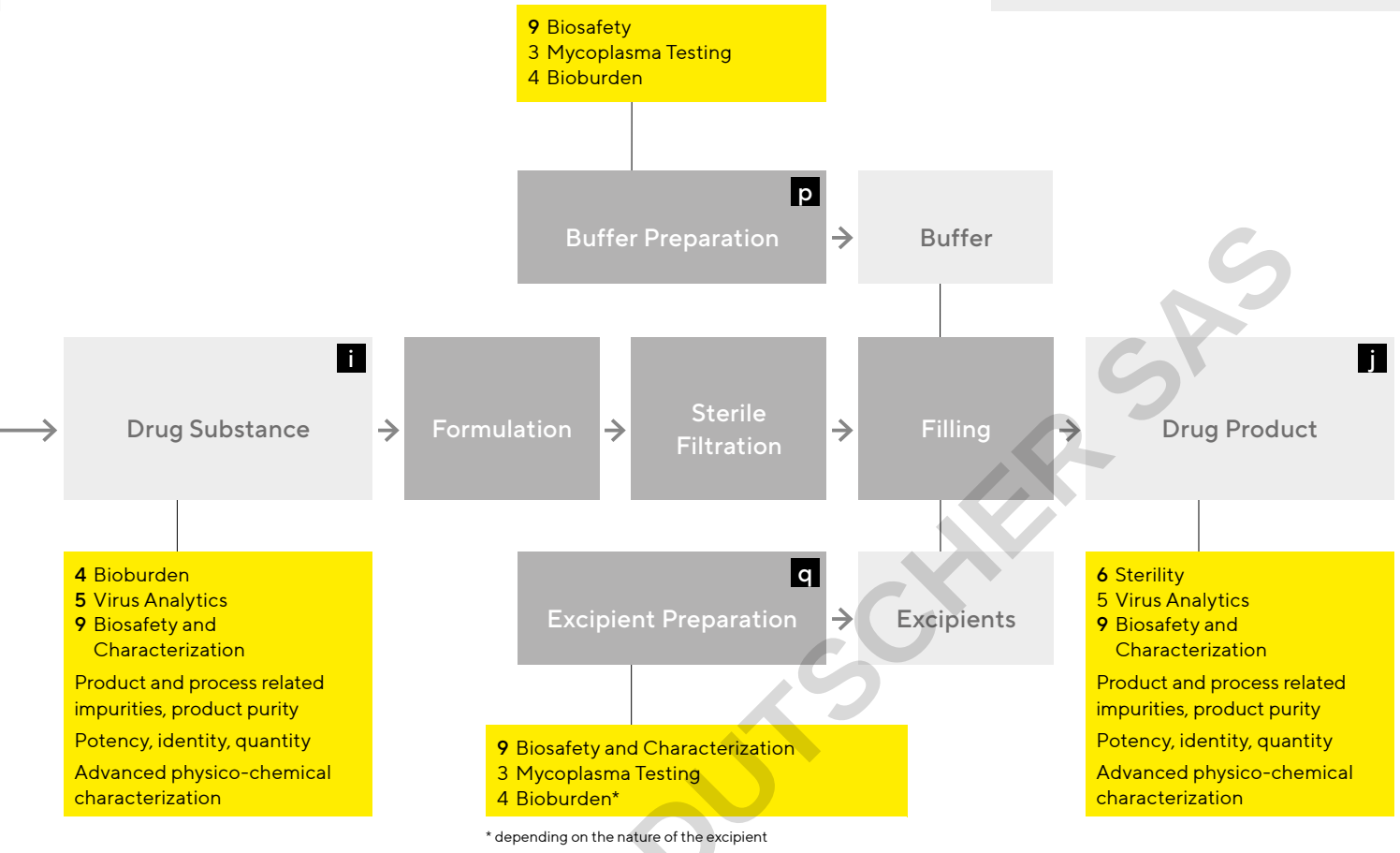


Easy handling and reliable test results

Rapid sterility testing based on qPCR



Know results in just 3 hours



* depending on the nature of the excipient

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7
Microbial Air Monitoring

Quantitative detection of airborne microorganism.

Process Steps: specified rooms, clean rooms and filling lines

8
Data Analytics

Analysis and interpretation of complex data.

Process Steps: throughout the manufacturing process

9
Biosafety and Characterization Testing Service

Sartorius Cell Line and Media Testing Solutions (CL&MTS) is a leading Contract Testing and Research Organization specializing in biosafety, biological activity, physico-chemical and structural analyses.

Process Steps: i j k l m n o p q

Active air monitoring with MD8 Airscan®—agar-free, continuous air monitoring



Ensure the most accurate data over an 8 hour period

Analyze and interpret complex data to efficiently develop new products, and control quality and costs



Identify efficiently critical process parameters

Endotoxin:
Chromogenic LAL test, compliant to USP and EP requirements

Virus testing:
Endogenous viral particles, adventitious virus, retrovirus assays, virus and vector shedding

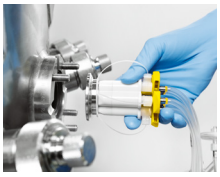
Product Impurities:
UPLC assays, SEC for aggregates stability studies

Process Impurities:
Residual Host Cell Proteins by ELISA, Residual DNA by qPCR

Release your final product safer and more cost-effectively

Planning for Quality Control Testing: Sample and Buffer Preparation

Contamination costs time and money. Improve the reliability of your analytical results and ensure speed-to-market by investing in appropriate contamination prevention products.





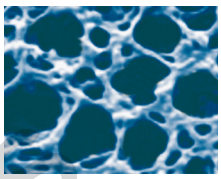
Sampling and Aseptic Fluid Transfer
TAKEONE® Aseptic Sampling System, MYCAP® Bottle Closures, and QUICK-SEAL® Aseptic Disconnect



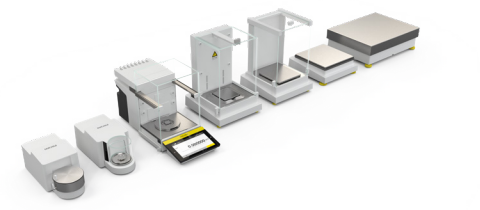


Clarification and Filtration
Sartoclear Dynamics® Lab V50 kits: Virus harvesting in one step. Kits combine a vacuum filtration unit, Sartolab® RF 50 with a 0.45 µm PES membrane, and a filter aid for clarification.





Concentration and Purification of Viruses
Vivapure® Virus Purification and Concentration Kits. Adenovirus Purification with AdenoPACK kits and Lentivirus Purification with LentiSELECT kits



Pharma Compliant Weighing
Cubis® III Premium Lab Balances. Sartorius's Cubis® III is designed to follow US FDA data integrity principles that require data to be accurate, legible, contemporaneous, original, and attributable (ALCOA). The Cubis® III balance, with pharma package, contains all the technical controls to support full compliance with common regulations.

See more Sample Preparation Solutions!
sartorius.com/en/applications/quality-control-testing/sample-preparation-qc

Service and Training
A comprehensive offering that includes qualified personnel, ensuring high-quality results and optimal operation.

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