
# Virus Counter® Platform

## Rapid, Direct, Biologically Relevant Virus Quantitation

Simplifying Progress

SARTORIUS

# Accelerate and Optimize Your Process Development With the Virus Counter® 3100 Platform

The Virus Counter® 3100 platform is purpose built to rapidly and precisely quantify total virus particles in process development and manufacturing.

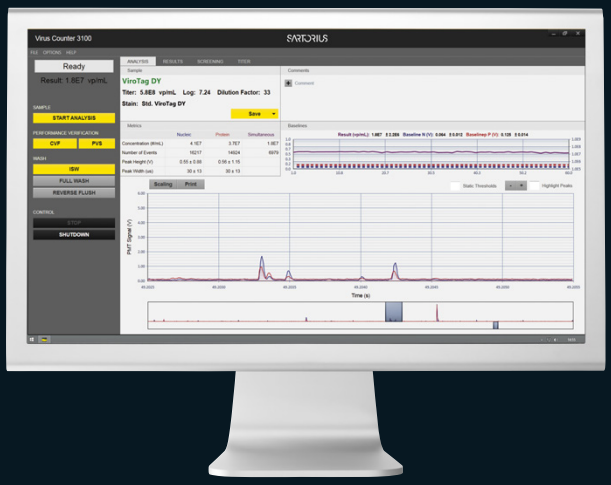
- Accelerate development times with real-time virus titer insights for vaccines and viral therapies
- Improve product yield by optimizing development and manufacturing processes
- Increase product safety and quality by in-depth sample characterization.

**The Virus Counter® system features**

- Unrivaled speed with titer results in less than one hour compared to days and weeks of traditional methods
- Quantification of total virus particles with high precision and confidence
- Ready-to-use, specific and flexible quantification solutions
- Ease-of-use with simple, no wash assays and software guided sample analysis

**The Virus Counter® instrument detects and measures viral particles in a fluid stream.**


**Integrated software directs instrument function and data analysis.**




**Virotag® Assay Kits label virus particles using simple, no-wash assays.**

# Total Virus Particle Count Matters

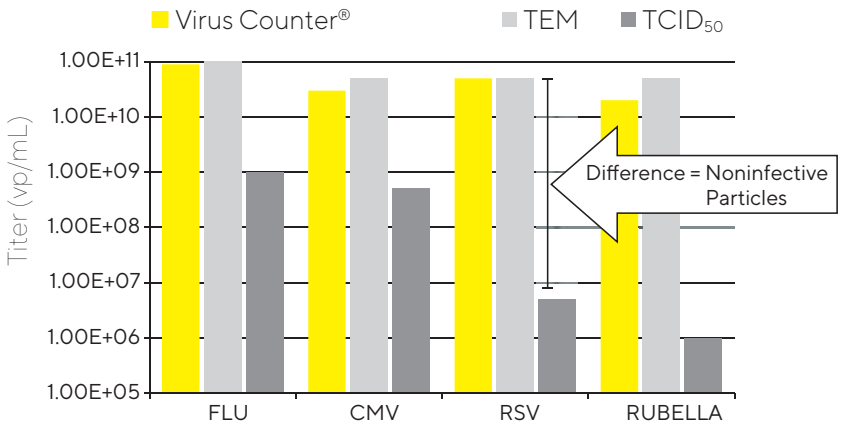
The Virus Counter® platform is in use by leading companies, regulatory agencies, and research institutes around the world. Why? A growing body of evidence demonstrates that noninfective particles are of biological importance and can impact both *in vitro* and ***in vivo*** studies. Infectivity and total virus counts are essential for in-depth sample characterization.

## Comparison of Infectious Titers With Total Particle Count

Samples of Influenza H1N1 (FLU), Cytomegalovirus (CMV), Respiratory Syncytial Virus (RSV), and Rubella Virus (Rubella) were measured by 50% tissue culture infective dose assay ($TCID_{50}$) Virus Counter® platform, and quantitative transmission electron microscopy (TEM).

Total particle counts determined by either TEM or the Virus Counter® platform were not statistically different. Titers determined by $TCID_{50}$ measured values 2 – 3.5 orders of magnitude lower.

These results highlight the relative abundance of noninfective particles across multiple virus types.




*"Given the potential toxicity of the adenoviral particles themselves, CBER recommends that patient dosing be based on particle number."*

Guidance for Human Somatic Cell Therapy & Gene Therapy
FDA Centers for Biologics Evaluation & Research

*"The Virus Counter has a short assessment time, requires minimal sample preparation, is easy to use, is a relatively inexpensive platform, and assesses the quantity and quality of viral materials."*

Sanofi Pasteur

# Rapid and Precise Virus Quantification

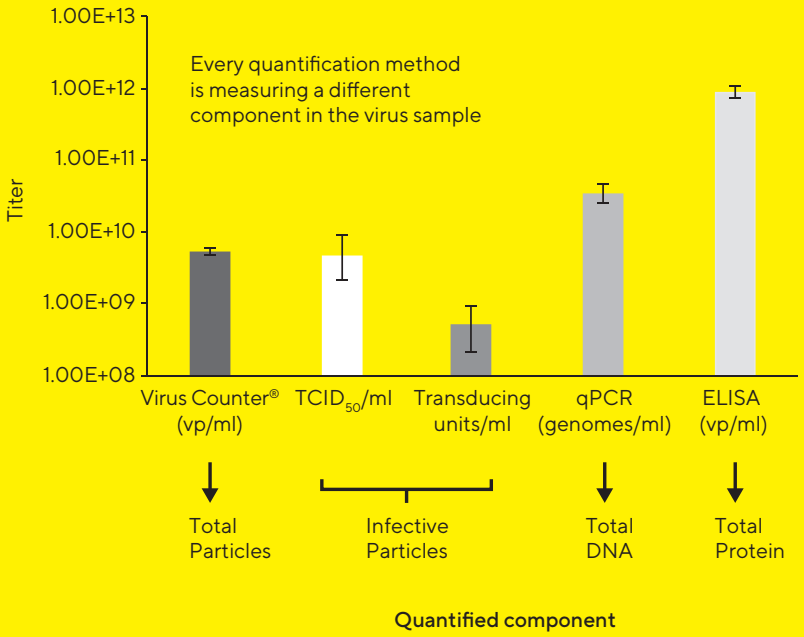
Quantitative detection of individual virus particles is a critical issue for safety and efficiency for many applications. Due to limitations of conventional techniques this issue remained challenging, until now.

| Technique | Detection principle | Reproducibility | Time | Labor | Cost per sample |
|---|---|---|---|---|---|
| **Virus Counter® platform** | **Viral Particle** | **Excellent** | **Minutes** | **Low** | **$** |
| Plaque Assay | Infectivity | Poor | Days | High | $ |
| $TCID_{50}$ , $LD_{50}$ | Infectivity | Poor | Days | High | $ |
| qPCR | Nucleic Acid | Excellent | Hours | Mod | $$$ |
| ELISA | Viral Protein | Good | Hours | Mod | $ |
| HPLC | Viral Protein | Excellent | Days | High | $$ |
| Viral Flow Cytometry | Viral Particle | Excellent | Hours | High | $$$ |
| Transmission Electron Microscopy | Viral Particle | Excellent | Weeks | High | $$$ |

The Virus Counter® platform provides excellent reproducibility at a lower cost per sample in minutes, not hours or days, compared to other detection methods.*

$LD_{50}$ (Lethal dose, 50%), qPCR (quantitative polymerase chain reaction), ELISA (enzyme-linked immunosorbent assay), HPLC (High-performance liquid chromatography)

* The table is adapted from Pankaj Kumar, Methods for Rapid Virus Identification and Quantification, MATER METHODS 2013;3:207, 10.13070/mm.en.3.207, with the permission of the copyright owner Labome (www.labome.com).



# Virus Counter® Reagent Kits

## Virotag® DY Kits

With the Virotag® DY reagent kits, viral genomes and viral envelope proteins are stained with a combination of two fluorogenic dyes. When fluorescent emission is simultaneously observed in both channels, this 'simultaneous event' is counted as one intact particle.

- Detects a wide range of viruses
- Optimized for enveloped viruses
- Compatible with single- and double-stranded DNA and RNA viruses

## Virotag® AB Kits

The Virotag® AB reagent family utilizes a fluorescently labeled, high-affinity antibody which binds to a unique viral epitope. Virotag® AB reagents are detected on a single channel. Quantification of viruses using Virotag® AB reagents is independent of the presence of nucleic acid.

- Highly specific detection reagent
- Detection of total viral particles
- Quantification of virus like particles (VLP)
- Enumeration of both enveloped and non-enveloped viruses.

## Virotag® Kits

**Virotag® AB reagent Kits**

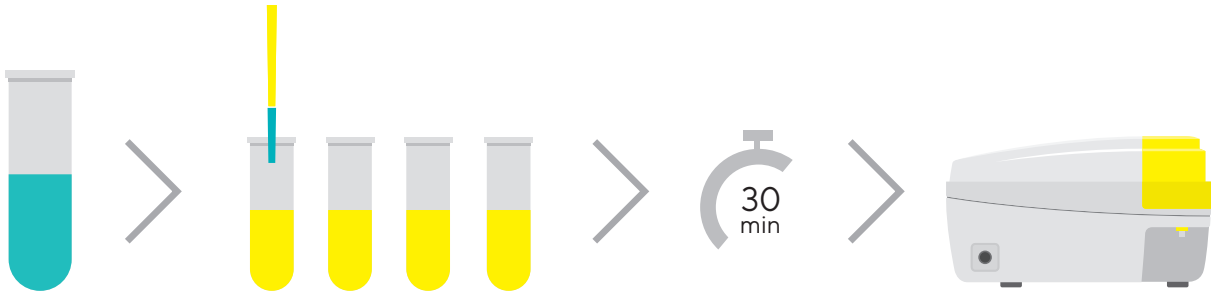
- AAV2-3 for Adeno-Associated Virus Serotypes 2, 3
- BCVB for Baculovirus
- VSVG for pseudotyped viruses such as Lentivirus or BacMam
- INVA for Influenza A seasonal flu virus
- INVB for Influenza B seasonal flu virus

**Virotag® DY reagent Kits**

- DY ENV for enveloped viruses

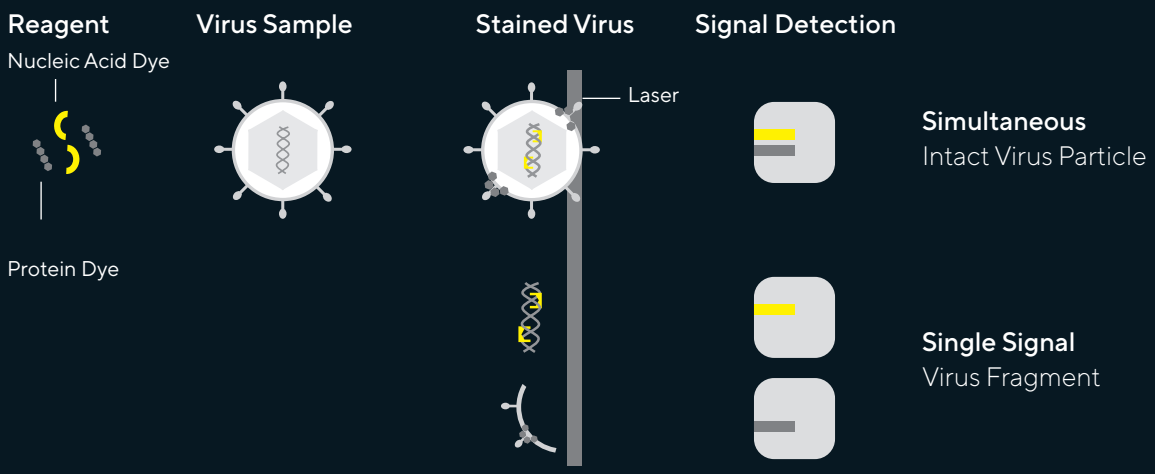
## No Wash Assay

Both Virotag® DY and Virotag® AB labeling systems use a rapid, no-wash workflow.




Mix Reagent | With Virus Sample | Incubate | Analyze

## Virotag® DY Reagent – Virus Sample Staining Principle



*"We have basically stopped running plaque assays on our P0 and P1 virus stocks because the accuracy of the titers obtained with the Virus Counter® leads to better virus amplifications than those obtained using plaque assay titers. The instrument saves one to two weeks on our virus production timeline and it is very helpful to know within a day or two that a transfection or co-transfection has yielded virus particles."*

Kempbio

*"Virus Counter® results significantly correlated with both plaque assay and qRT-PCR. These results demonstrated that the VC is an easy, fast, and consistent method to quantify filoviruses in stock preparations."*

USAMRIID

# Research Areas

## Viral Vaccines

Due to surging demand for a wider range of vaccines, the industry needs to evolve from traditional, time-consuming methods to new, more efficient approaches.

Virus quantitation represents a rate-limiting step at many stages of vaccine development and production, for both egg and cell culture.

## Protein Expression

Therapeutics produced using Baculovirus expression system include viral vectors for gene therapy and personalized immunotherapy, vaccines such as subunit proteins, and VLPs. Baculovirus-mediated expression of recombinant proteins is a complex, multistep, time-consuming process.

Virus quantitation has been an especially notable source of delays, since many methods require days or weeks to complete.

## Virotherapy

Virotherapy is an emerging application that involves engineering viruses for viral vectors used for gene therapy, oncolytic therapeutics and viral immunotherapy.

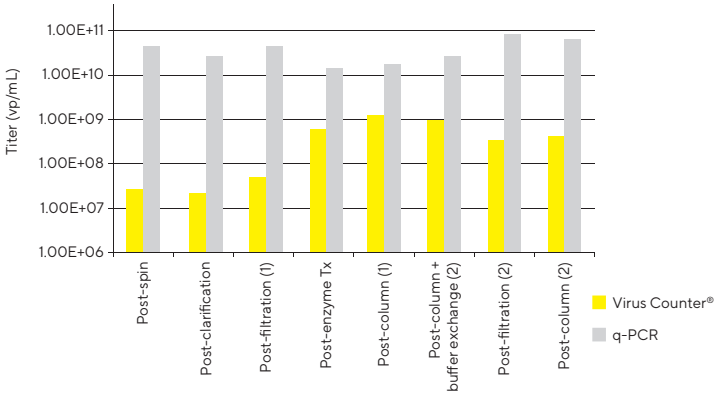
The quantitation of viral vectors during growth, harvest, purification, and release using current methods like qPCR and absorbance readings are highly variable, resulting in over- or underestimation of particles present at any given step.

This compounds the risk associated with administering too little (no therapeutic effect) or too much (adverse immune response) product to patients.

# The Virus Counter® Platform is Specifically Designed to Enable Rapid Virus Quantitation in Each of These Three Research Areas:

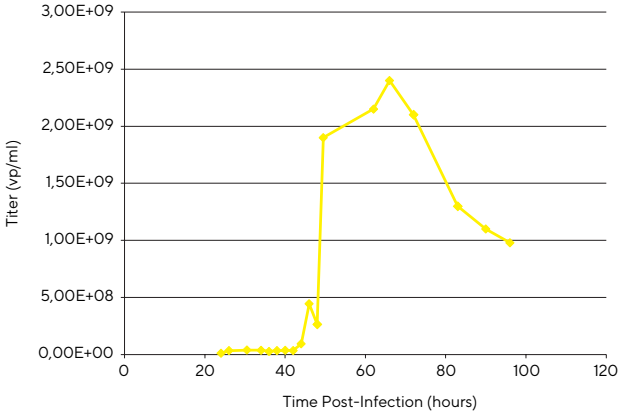
## Virus Counter® platform in viral vaccine manufacturing

- Real-time insights into virus titer during the bioprocess allows optimization of each processing step
- Increased viral vector yield by comparing growth conditions and recovery during process development




## Virus Counter® platform in the field of protein expression

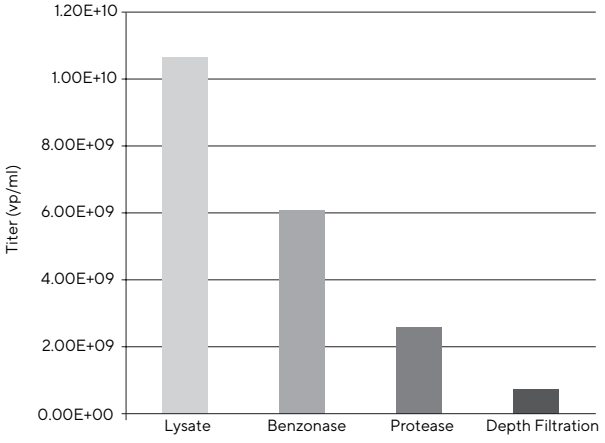
- Optimize protein expression yields and shortened timelines by harvesting with pinpoint precision
- Early identification of problems during manufacturing can reduce loss of time and money




Birch A, Allen H, Kennefick K, Gugel A, Kemp CW. Rapid and effective monitoring of baculovirus concentrations in bioprocess fluid using the Virocyt Virus Counter. BioProcess J, 2014; 13(2): 32–9. http://dx.doi.org/10.12665/J132.Kemp

## Virus Counter® platform in virotherapy development

- In-depth characterization of total particle concentration in final product increases safety and efficiency
- Rapid and accurate determination of biologically relevant readout- total virus particle counts



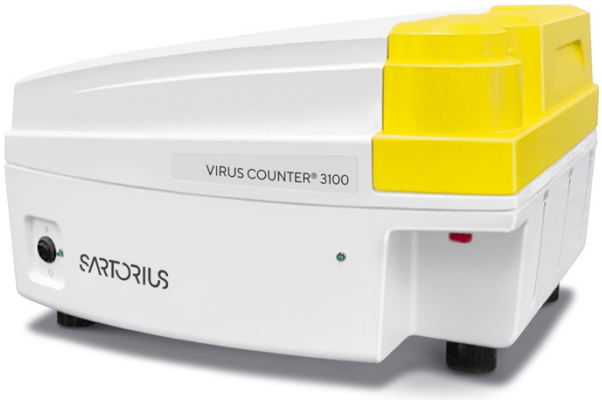

Artinger M. Virotherapy process optimization. BioProcess J, 2015; 14(1): 26–9. http://dx.doi.org/10.12665/J141.Artinger

# The Virus Counter® Platform is Versatile

The number of viruses and VLPs quantifiable by the Virus Counter® platform is continuously growing and includes viruses that impact human health (e.g., Influenza); viruses used in expression systems (e.g., Baculovirus); viruses used in veterinary science (e.g. Canine Distemper Virus), and viruses used in gene and cell therapy (e.g., Adeno-associated Viruses 2, 3, 5 and Lentivirus).

## Virus Counter® Instrument Specifications

- Dimensions (W × D × H): 43.2 cm × 51.9 cm × 27.9 cm (17″ × 16.5″ × 11″)
- Weight: 13.2 kg (29 lbs)
- Linear dynamic range of $5 \times 10^5$ vp/ml – $1 \times 10^9$ vp/ml
- Enveloped and non-enveloped virus detection
- Detection of large (Baculovirus, 30 to 60 x 250 to 300 nm) and small (AAV, 20 nm) viruses




Learn why leaders in vaccine development, protein expression, and viral therapeutics choose the Virus Counter® 3100 Platform as their tool of choice for virus quantitation.
Please visit: www.sartorius.com/virus-analytics

The Virus Counter® Platform is for research use or further manufacturing use only – not for use in therapeutic or diagnostic procedures. They are not for in vitro diagnostic use nor are they medical devices. Drug manufacturers and clinicians are responsible for obtaining the appropriate IND/BLA/NDA approvals for clinical applications.

**Germany**
Sartorius Stedim Biotech GmbH
August-Spindler-Straße 11
37079 Göttingen
Phone +49 551 308 0

**USA**
Sartorius Stedim North America Inc.
565 Johnson Avenue
Bohemia, NY 11716
Toll-Free +1 800 368 7178

For further contacts, visit
www.sartorius.com


Order No.: 1000055747
Status: 01 | 2021