CASE STUDY: COST SAVINGS OF RAPID BACULOVIRUS QUANTIFICATION

An ROI analysis demonstrates the significant benefits of replacing cumbersome plaque titer assays with a faster solution.

Since its first use in the 1980s, the utility of baculovirus to express proteins has grown in both scope and diversity. The ability to produce recombinant proteins at high levels, combined with the authentic post-translational processing required for eukaryotic function, provide an ideal combination. As is the situation with any virus-based product, however, viral quantification is a significant bottleneck throughout the development and commercialization of this technology. Traditional approaches can be divided into two major categories, those that determine particle number (such as electron microscopy) and those that establish infectivity (plaque titer). Although both provide valuable information, the cost and/or time to result for these methods can be substantial, leading to delays of days or even weeks.

Kempbio was interested in evaluating options for expediting their current process. As such, they investigated the use of the ViroCyt Virus Counter® as an alternative to traditional viral plaque assay for the quantification of their zero and first passage baculovirus stocks. While plaque assay requires about one week to determine viral titer, a Virus Counter measurement takes less than 10 minutes per sample, allowing Kempbio to initiate the next step in their process a full week earlier than is possible using viral plaque assay.

SAMPLES PER MONTH	25	50	100	250
Virus Counter Costs				
Instrument*	Contact info@virocyt.com for pricing			
Reagents	$1,500	$3,000	$6,000	$15,000
Labor	$6,000	$12,000	$24,000	$60,000
Plaque Assay Costs (prior to implementing Virus Counter)				
Instrument	$0	$0	$0	$0
Reagent Costs	$21,000	$42,000	$84,000	$210,000
Labor Costs	$30,000	$60,000	$120,000	$300,000
Residual Plaque Assay Costs (after implementing Virus Counter)				
	$12,750	$25,500	$51,000	$127,500
Net Benefit w/o Instrument Cost				
Year 1	$30,750	$61,500	$123,000	$307,500
Year 2	$61,500	$123,000	$246,000	$615,000
Year 3	$92,250	$184,500	$369,000	$922,500
Instrument Payback Period (in months)				
	33	17	8	3

* Instrument pricing varies by region

The resulting ROI analysis compares the direct costs of performing both methods in terms of initial investment, labor, and reagent costs based on information gathered from Kempbio. It assumes that 100% of the cost of the Virus Counter is incurred in Year 1. A hands-on time of 2 hours ($50/hr labor) and a $70 materials cost were used in the calculation of performing a viral plaque assay. For Virus Counter measurements, a conservative hands-on time of 4 hours for the analysis of 10 samples was assumed (~24 min/sample, $50/hr labor). In addition, it anticipates that 25% of the viral plaque assays conducted prior to implementing the Virus Counter will still be performed following adoption. The analysis was carried out for volumes of 25, 50, 100 and 250 samples per month.

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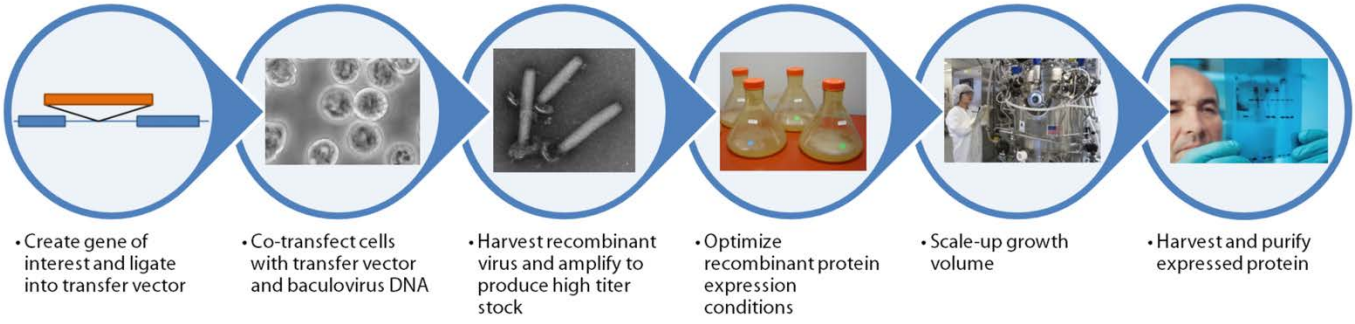
From an operations perspective, the cost-savings are immediate and scale quite dramatically with sample volume due to the higher per sample labor and reagent costs of the plaque titer assay. When the capital cost of the instrument is included in the analysis, the Virus Counter essentially pays for itself at 33.2, 16.6, 8.3 or 3.3 months following adoption, respectively. Several considerations not included in this analysis are:

- **Time Savings.** At points where a rapid time-to-result can facilitate advancing to the next step in the development process, the Virus Counter can significantly reduce overall development time, and thereby avoid the costs associated with delays.
- **In Process Control.** With such a rapid time to result, steps in the process where virus concentration would have been assumed rather than actually quantified, can now be easily measured without sacrificing precious time.
- **Outsourced Virus Quantification.** In certain situations, samples need to be sent out for quantification, adding significant cost and time.
- **Other Methods.** Although the plaque titer assay was the method used in this example, other approaches to virus quantification – such as TCID50, FFA, qPCR and TEM – also suffer from similar limitations.

Extending the advantages of rapid virus quantification permitted by the Virus Counter throughout the process of using baculovirus to express a therapeutic protein or vaccine can lead to even larger ROI. Determining factors such as multiplicity of infection, media conditions, and incubation periods prior to starting GMP production is essential in order to avoid significant problems during the actual run. Equally important is the increased process control derived from monitoring both the baculovirus amplification rate and the resulting protein expression during the large scale culture. Since the entire process may take many months and require the quantification of baculovirus at numerous time points, the cost and time savings afforded by the Virus Counter accumulate quickly.



With this in mind, it is surprising that many in the field still rely on cumbersome methods such as plaque titer or quantitative PCR, or worse, choose not to track virus yield and therefore essentially operate in the dark, hoping that the system will perform as expected. Since there are not only millions of dollars at stake, but the lives and well-being of patients relying on drugs and vaccines generated by baculoviruses as well, adopting and implementing the Virus Counter along the continuum from early research though production is a simple and highly cost-effective solution.

Virus Counter® 2100

- ✓ Quantify virus samples in minutes, not days or weeks
- ✓ Accurate, precise, reproducible
- ✓ Quantitative and non-subjective
- ✓ Provides a complete picture of viral preparations

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