## Where Science Intersects **Innovation**



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Development

## **Empowering Scientists**

Ella is so much easier and so much less user-dependent than ELISA, and the ability to pick up even very low picograms of analyte per milliliter just blows other platforms out of the water."

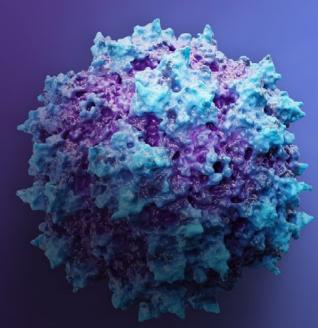


The Maurice is a one-stop solution to profiling proteins, with the only work being in sample preparation, the rest is handled by the automated workflow. The Maurice is definitely my favorite among all capillary electrophoresis methods."

- Julie Wei, Ph.D.
Associate Director, Analytical Development
Ultragenyx Pharmaceutical Inc.

The quantitative assays and short run times on Jess enable us to generate data faster and be more confident in our results."

- Tonmoy Sarkar, Ph.D. Senior Research Scientist TCG Lifesciences



## Streamline Viral Vector Development with:



### Speed

Get reproducible data faster with 90 min ELISAs, 3 hour Westerns or 15 min cIEF — all with hands-free operation, so you can win the race to approval.



## Scalability

Our platforms easily fit into your current workflows and adapt to your changing needs. No matter what throughput you need, results will be robust and reproducible, whether you're scaling up or scaling out.



## Low Sample Volumes

Save precious AAV and Lentivirus samples by leveraging the sensitivity of our platforms. Get the data you need with as little as 3  $\mu$ L of sample volume.



## Method Transferability

Be confident in your method performance and regulatory compliance by seamlessly transferring analytical methods between labs and across phases from discovery to manufacturing.



## Reproducibility

Our team of hands-free platforms provide you with consistent, highquality data by automating sample handling and processing.



### **Data Digitization**

Generate 21 CFR Part 11 compliant data for streamlined preparation of CMC packages for regulatory submissions.

# Next-Gen Tools for Rapid Viral Vector Development







## Single-Cell Western

Quantify vector transduction efficiency with single cell protein expression data directly in single cell lysates on Milo.

### **Simple Plex**

Get highly reproducible viral titer and HCP data in just 90 minutes. AAV and lentivirus.

#### **Simple Western**

The multi-attribute machine of choice to obtain up to six viral vector CQAs. Combines CE-SDS with amplified immune detection for highly sensitive, sample-agnostic, flexible assays.

#### Maurice

Late-stage characterization and quantitation workhorse with direct detection CE-SDS and imaged cIEF.

#### **Micro-Flow Imaging**

Get a grasp on your aggregation with imaged flow microscopy.

## How do these platforms address cell and gene therapy CQAs?

Critical Quality Attribute	Key Question	Attribute Detail	Simple Western	Simple Plex	Maurice
Identity	Do I have the right virus in this product?	Is my virus present in the sample?	<u> </u>	$\checkmark$	$\checkmark$
		Am I confident it is the right virus?	<u> </u>	<u> </u>	<u> </u>
Potency	How many viral particles do I have?	Physical viral titer	<u> </u>	<u> </u>	
	How well is my virus working?	Functional viral titer	<u> </u>		
	How much protein is expressed after treatment?	Protein Expression Potency	<u>✓</u>	<u>✓</u>	
	Are the VP ratios optimized to maximize infectivity?	Capsid protein ratio (VP ratios)	<u> </u>		<u> </u>
Purity	Are there any protein contaminants in my product?	Process-related impurities	<u> </u>	<u> </u>	<u> </u>
		Host cell-related impurities	<u> </u>	<u>✓</u>	<u> </u>
	Can you estimate the empty/full status of my sample?	Capsid Content (Empty/Full)	<u> </u>		✓
Stability	Does my viral product aggregate?	Aggregate formation			MFI
	Is my viral product stable?	Product stability			$\checkmark$

# Which platform is right for me?







Platform Specifications	Simple Western	Simple Plex	Maurice
Main Sample Type	Virus and tissue lysates, supernatants	Virus lysates, supernatants, and purified virus preparation	Virus preparation (>70% pure)
Assay Type	CE-SDS + immunoassay	Sandwich ELISA	CE-SDS or iclEF
Detection Modes	Chemiluminescence Fluorescence Total protein stain	Fluorescence	Absorbance & Native Fluorescence
Sample Volume	3µL	25µL	50µL
Assay Development	Single antibody – open platform	None – Fully validated kits	No antibody – open platform
Quantitative	$\checkmark$	$\checkmark$	$\checkmark$
Size Separation	$\checkmark$		$\checkmark$
Dynamic Range	3 to 4 logs	3 to 5 logs	3 logs
Detection Range (GC or VP/mL)	10° - 10¹²	10 <sup>6</sup> - 10 <sup>10</sup>	1011 - 1014



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