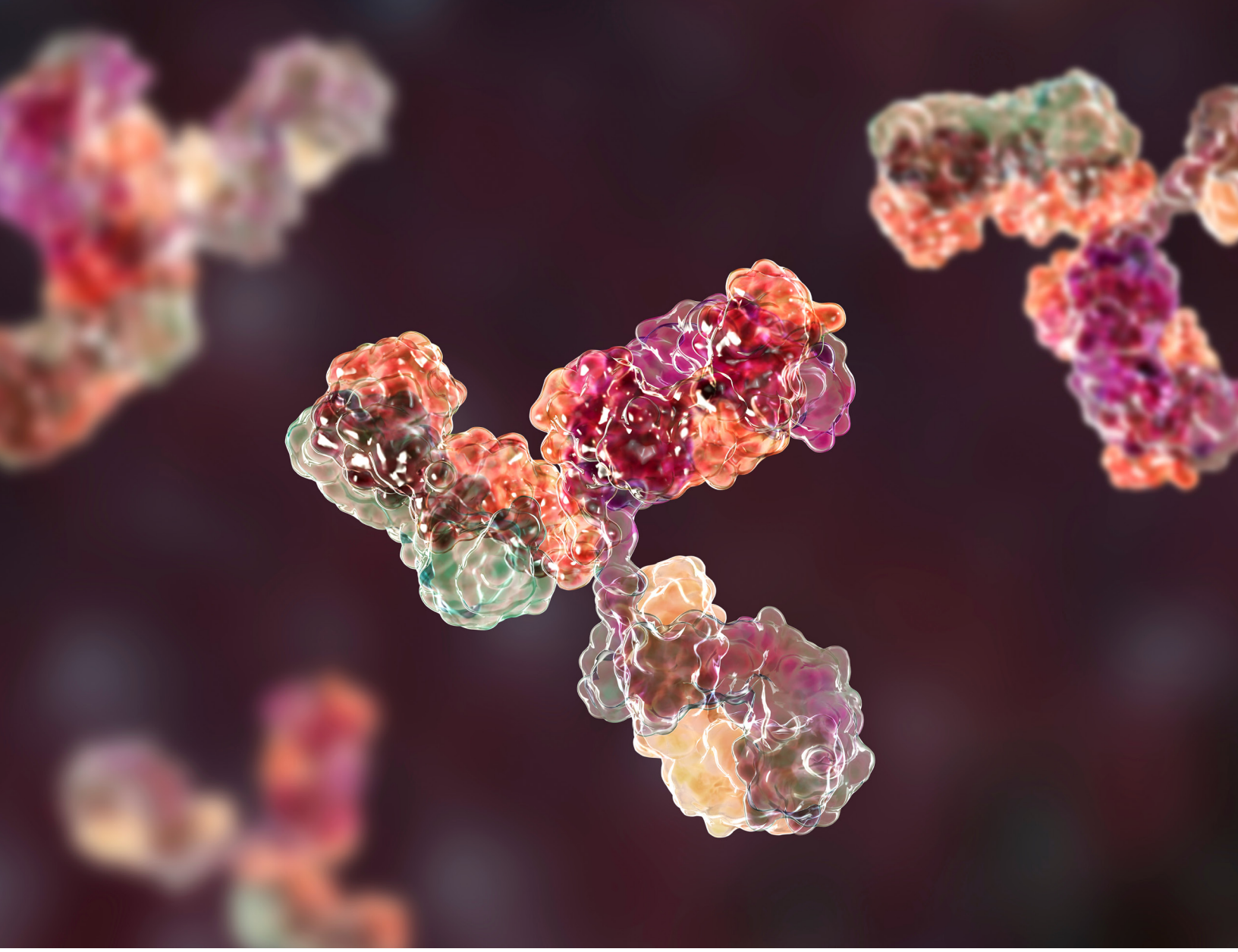


Expedite & Simplify IgG Quantification

With the Valita Titer Gen III Assay in an automation-friendly 96-well format

ACCELERATING *answers*

BECKMAN COULTER Life Sciences

The next generation in IgG quantification - results in minutes, not hours

The high-throughput Valita Titer Gen III assay enables measurement of 96 samples in < 15 minutes—with a simple, 3-step workflow that can be automated easily on a liquid handler.

- High-throughput measurement via 96-well plates
- Results in < 15 minutes
- Excellent correlation (R^2 < 0.99) with established methods such as HPLC and BLI
- Detection range of 0.5-100 mg/L for standard, Fc-fusion and bispecific IgG

Compare the Valita Titer Gen III assay with other IgG quantification assays:

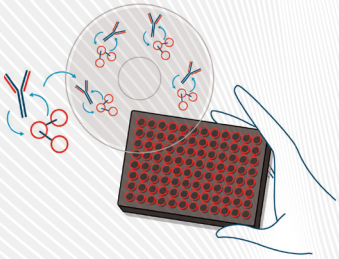
	Valita Titer Assay	BLI	ELISA	HPLC
Assay Time	15 mins	1 hour	5 hours	10 hours
Sample prep	none	none	cell centrifugation	cell centrifugation and protein purification
Reagents	1	>2	>6	2
Steps	add, mix, read	>3	>20 steps	>5
Costs	$	$$$$	$$	$$$

Applicable in any IgG Quantification Workflow

Discovery → Developability → Clonality → Productivity → Scale-Up → Production

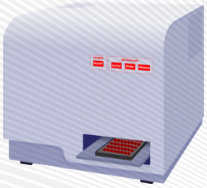
In the development and production of monoclonal antibodies, one of the most critical parameters to monitor is IgG titer.

The Valita Titer Gen III assay enables fast, easy assessment of IgG titer throughout the workflow, facilitating early detection of high-producing clones. It requires no sample preparation or additional reagents, and can be performed in three simple steps:



Add fresh media & IgG sample and mix

Incubate for 5 minutes at room temperature



Measure IgG using fluorescence polarization on a standard plate reader

Specifications

- Functional range of 0.5-100 mg/L
- Excellent correlation (R^2 < 0.99) with established methods such as HPLC and BLI
- High accuracy and precision, with > 96% accuracy and < 1.2% relative standard deviation (RSD)
- Format: 96-well plate
- Cell robustness: Up to 15 x 10^6 cells/mL
- Binding Human IgG 1,2,4 and rabbit IgG, Fc-fusion proteins, and bispecific antibodies
- Fluorescent label: Excitation max = 485 nm, Emission max = 520 nm

Benchmark data confirms correlation with conventional IgG measurement methods

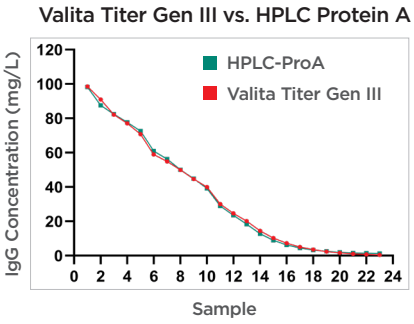


Figure 1. Comparison of measured concentrations of IgG for Valita Titer Gen III assay and HPLC-ProA across 24 samples, ranging from 0.5 to 100 mg/L.

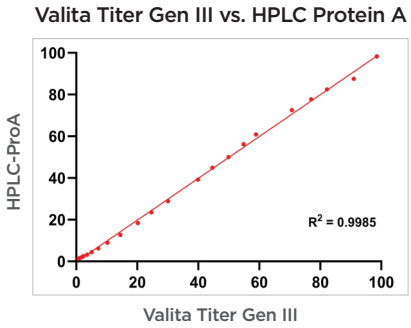


Figure 2. Simple linear regression of Valita Titer Gen III assay versus HPLC-ProA. The red line represents the best-fit line, and the R^2 value shows the strength of the relationship between the two technologies.

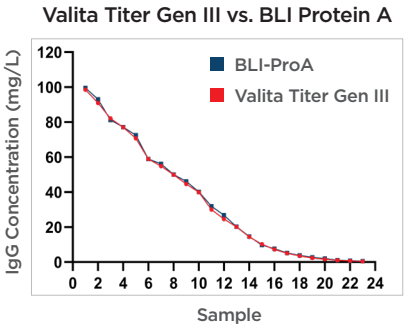


Figure 3. Comparison of measured concentrations of IgG for Valita Titer Gen III assay and BLI-ProA across 24 samples, ranging from 0.5 to 100 mg/L.

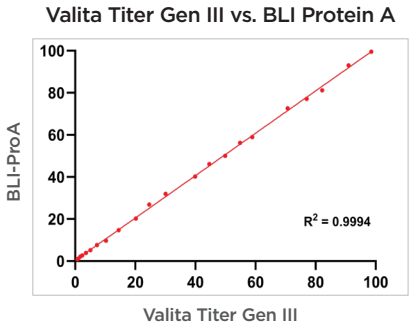


Figure 4. Simple linear regression of Valita Titer Gen III assay versus BLI-ProA. The red line represents the best-fit line, and the R^2 value shows the strength of the relationship between the two technologies

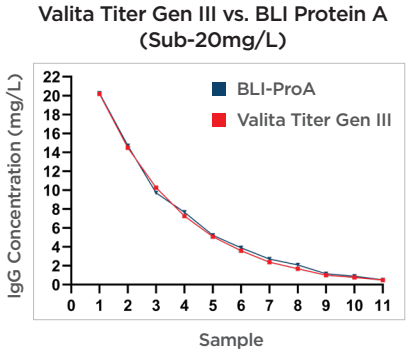


Figure 5. Comparison of IgG concentrations measured with Valita Titer Gen III assay and BLI-ProA in the sub-20 mg/L range across 11 samples.

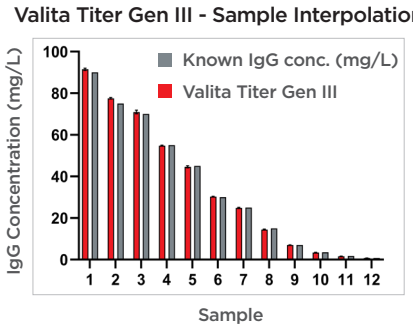


Figure 6. Comparison of known IgG concentrations versus Valita Titer Gen III assay output results. The bar chart shows the average interpolated concentration from 3 replicates, with error bars representing the standard deviation. Average recovery = 98.9%, average standard deviation = 0.29 mg/L and average %CV = 2.1% across the entire range.

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Not intended or validated for use in the diagnosis of disease or other conditions.

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