



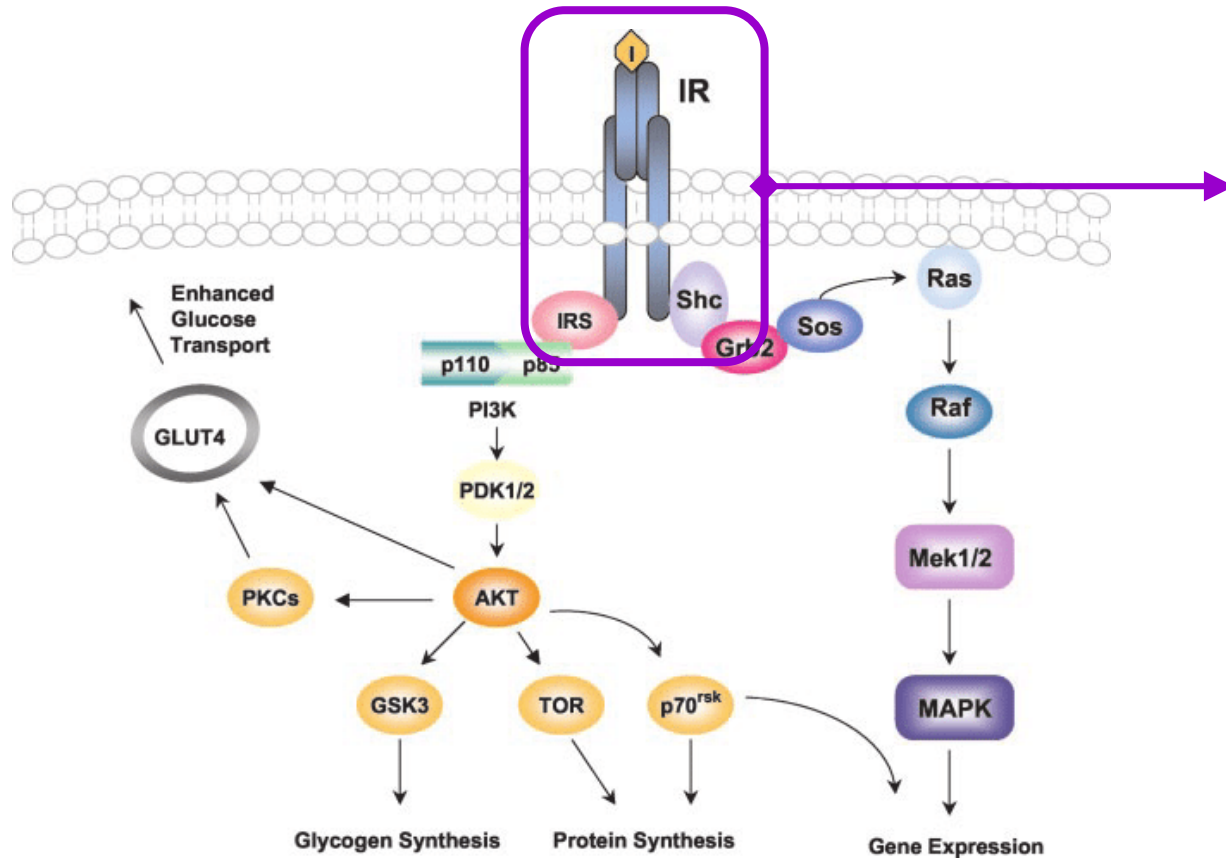
PathHunter[®] Qualified Insulin Bioassay Kits

Insulin, Insulin Glargine, Insulin Lispro

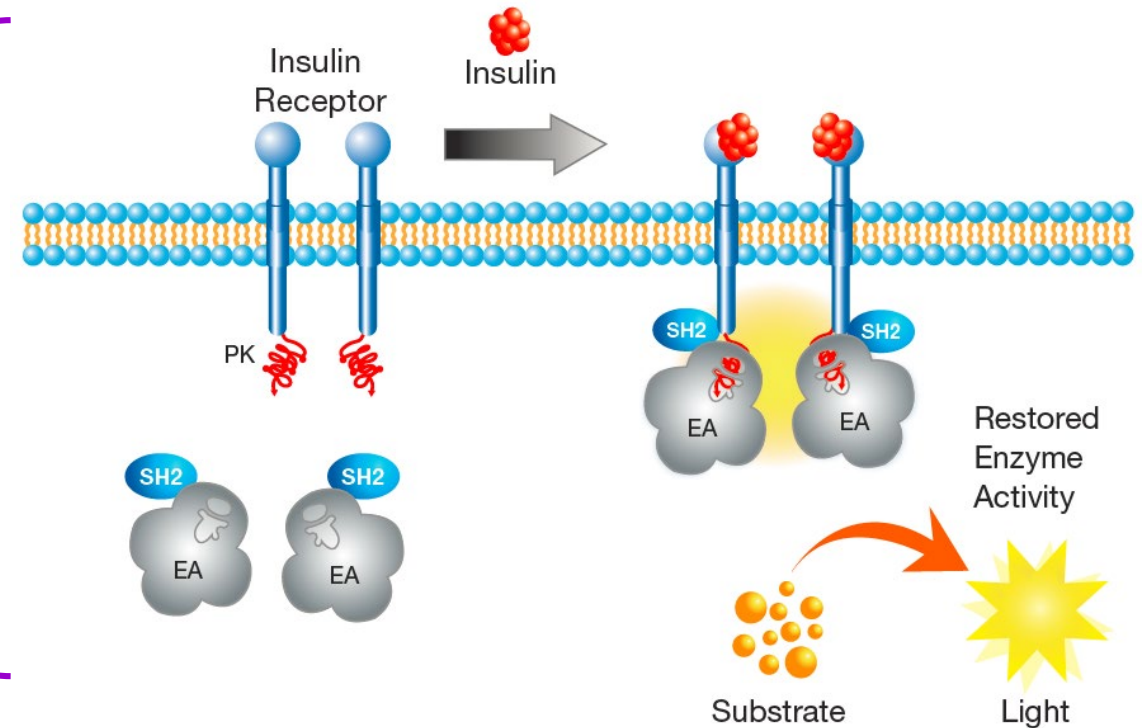
OUR EXPERTISE
IN YOUR HANDS.
DISCOVER
CONFIDENTLY.

Insulin Drugs' Mechanism of Action

Molecular MOA



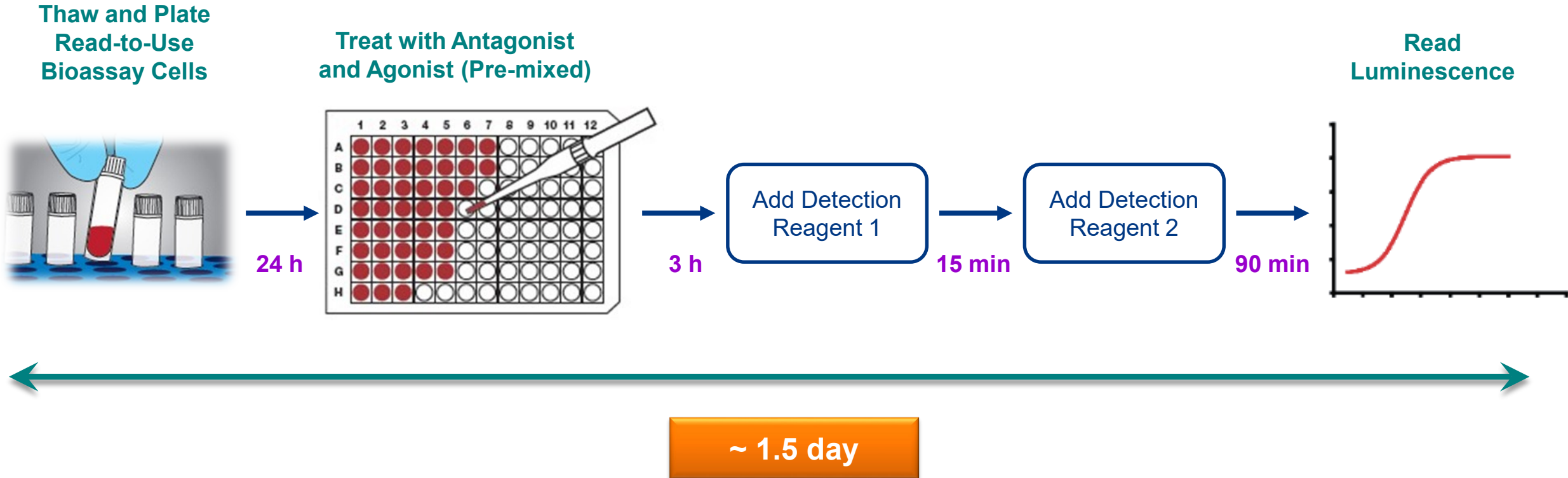
Assay Principle



Source: Murray K. Molecular & Cellular Proteomics, 2003. 2(6):399-404

Bioassay Workflow - Get Results within 2 Days

Simple, Homogenous and Rapid Protocol



Assay Parameters Assessed

- % CV between 8 full plate DRCs
- Plate uniformity: EC_{80} and IC_{80} (of drug and stimulus) across entire plate
- Plate-to-Plate variability: 3 plates with full plate DRCs run on 3 days
- Slope consistency
- Relative potency across range of 50-150%
- Parallelism of relative potency data from two operators
 - Assay developer
 - Assay qualifier

Qualified with USP Insulin

Insulin Bioassay

[93-0466Y3-00007](#) (2-Plate Kit)

[93-0466Y3-00008](#) (10-Plate Kit)



Insulin Lispro Bioassay

[93-0466Y3-00009](#) (2-Plate Kit)

[93-0466Y3-00010](#) (10-Plate Kit)

Insulin Glargine Bioassay

[93-0466Y3-00011](#) (2-Plate Kit)

[93-0466Y3-00012](#) (10-Plate Kit)

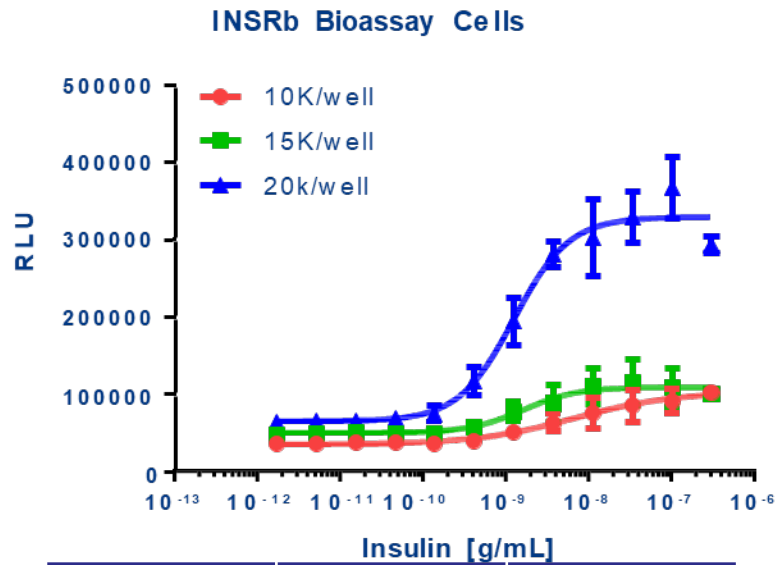
List of Components	93-0466Y3-00007	93-0466Y3-00008
PathHunter U2OS INSRb Bioassay Cells	2 vials	10 vials
PathHunter Bioassay Detection Kit		
• Detection Reagent 1 (mL)	2	10
• Detection Reagent 2 (mL)	8	40
AssayComplete™ Cell Plating Reagent 5	2 X 100 mL	4 X 100 mL
Control Agonist (Insulin)	1 vial	1 vial
96-well Clear-Bottom TC Treated, Sterile Plates w/lid	2 plates	10 plates

List of Components	93-0466Y3-00009	93-0466Y3-00010
PathHunter U2OS INSRb Bioassay Cells	2 vials	10 vials
PathHunter Bioassay Detection Kit		
• Detection Reagent 1 (mL)	2	10
• Detection Reagent 2 (mL)	8	40
AssayComplete™ Cell Plating Reagent 5	2 X 100 mL	4 X 100 mL
Control Agonist (Insulin)	1 vial	1 vial
96-well Clear-Bottom TC Treated, Sterile Plates w/lid	2 plates	10 plates

List of Components	93-0466Y3-00011	93-0466Y3-00012
PathHunter U2OS INSRb Bioassay Cells	2 vials	10 vials
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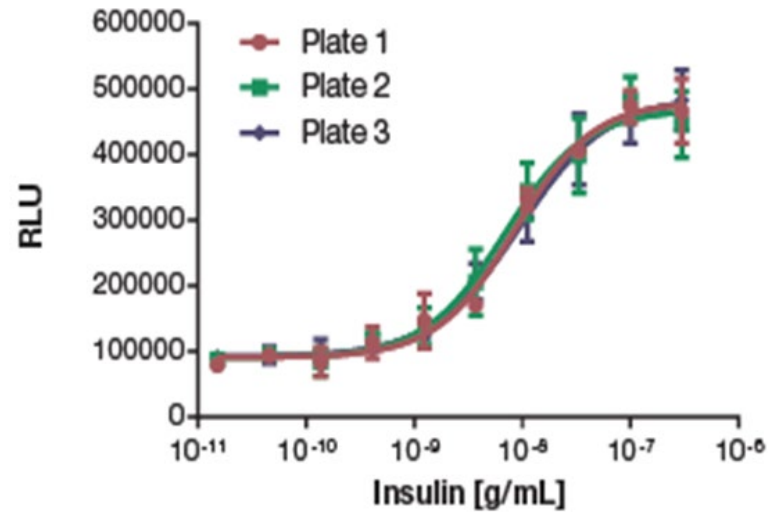
Insulin Bioassay: Optimization & Characterization

Seeding Density Titration

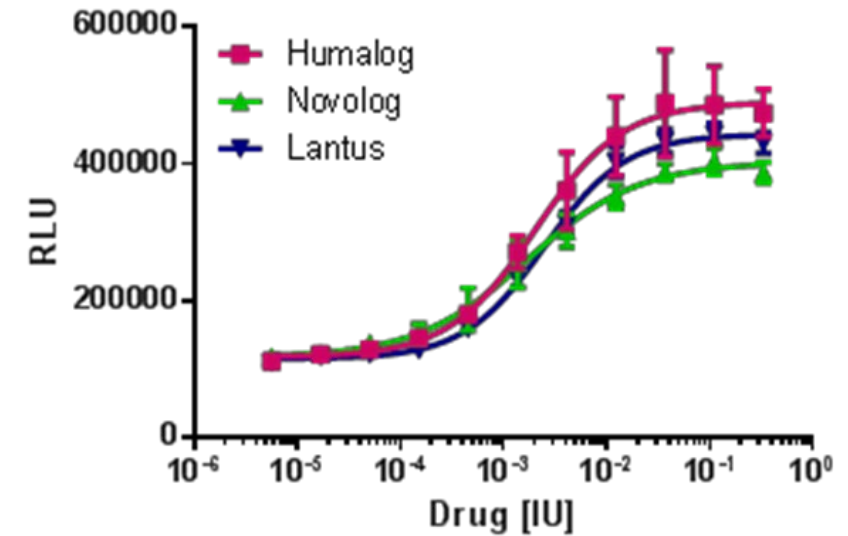


Cells per well	EC ₅₀ (ng/mL)	S:B Ratio
10,000	6.72	2.8
15,000	1.60	2.2
20,000	1.25	4.5

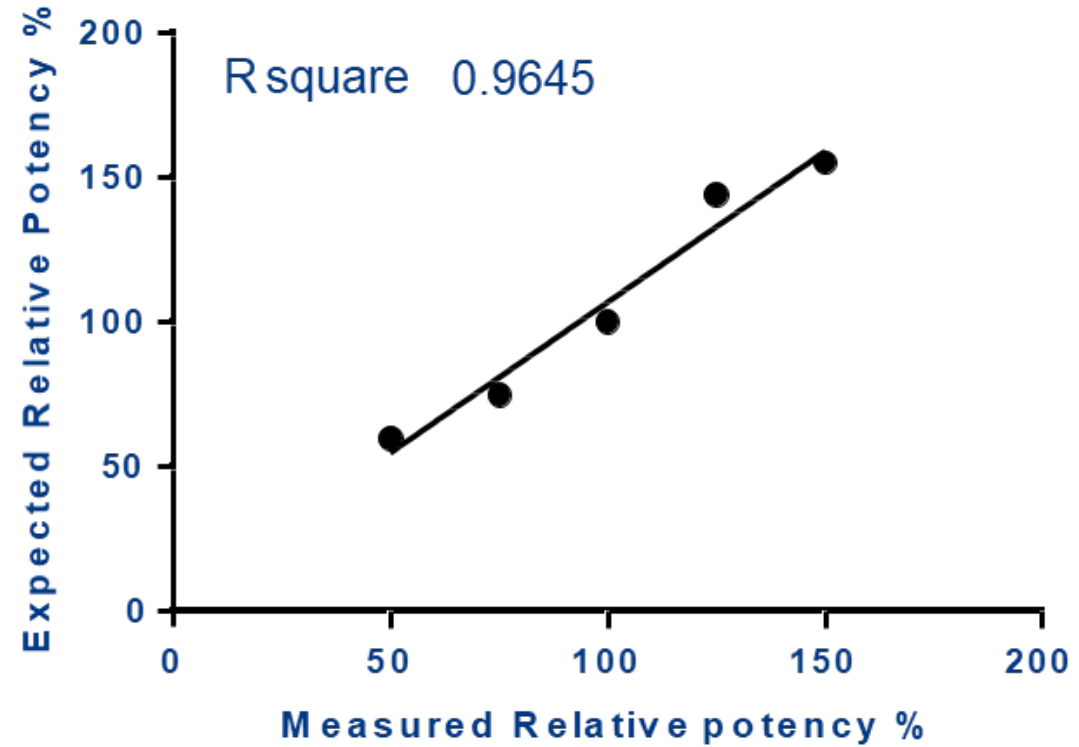
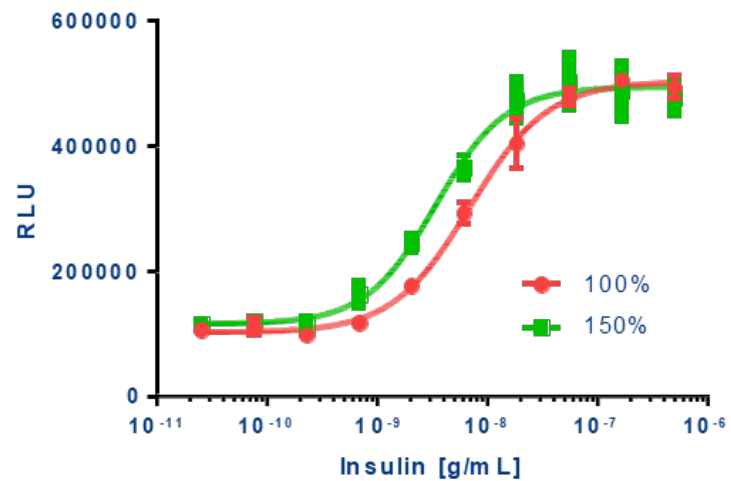
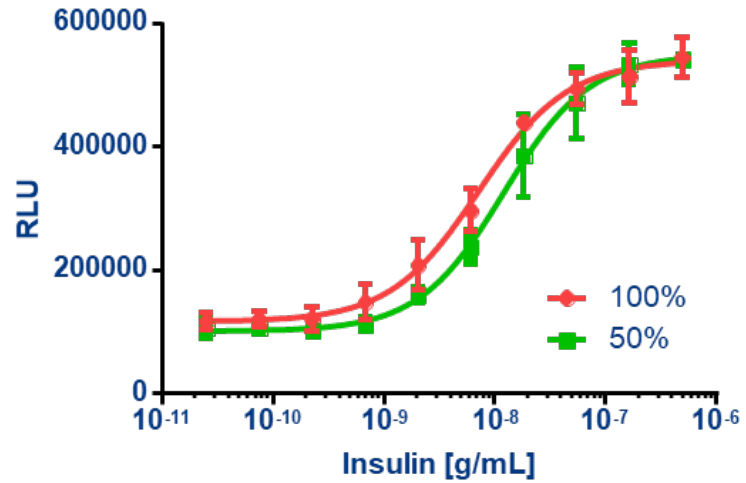
Plate-to-Plate Reproducibility



Compatible with Several Insulin Products

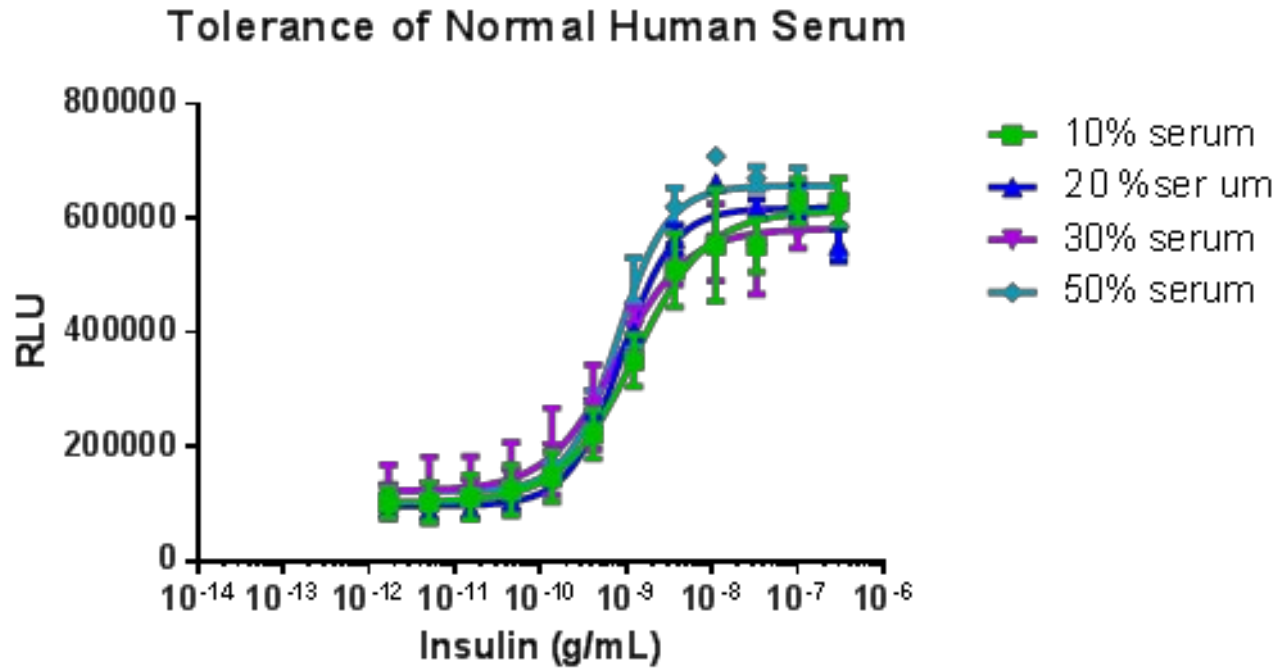


Insulin Bioassay - Relative Potency & Linearity



Insulin Bioassay Matrix Tolerance

Compatible for Detection of Neutralizing Antibodies



Serum (NHS) Concentration	EC ₅₀ (ng/mL)	S:B Ratio
10%	1.25	6.2
20%	0.88	5.9
30%	0.78	5.0
50%	0.796	4.9

Benefits for “Ready-to-Use” Bioassay Kits

Functional response based on drug MOA

Verified and Qualified with innovator’s marketed drug

Simple protocol; Rapid results

Specific and Sensitive assay

Highly reproducible

High tolerance of matrix components (serum & plasma)

Readily Implement with Optimized kit

- Frozen ready-to-assay cells
- Bioassay Detection Reagents
- Cell Plating Reagent
- Dilution Buffer
- Control Agonist
- Tissue Culture-Treated Plates



For More Info, Questions or Technical Support



Web:

[Cell-Based Bioassays for Biologics](#)

Technical Support

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