



cAMP Hunter[®] Exenatide Bioassay

Qualified with Byetta[®]

95-0062Y2-00101 (2-Plate Kit)

95-0062Y2-00102 (10-Plate Kit)

OUR EXPERTISE
IN YOUR HANDS.
DISCOVER
CONFIDENTLY.

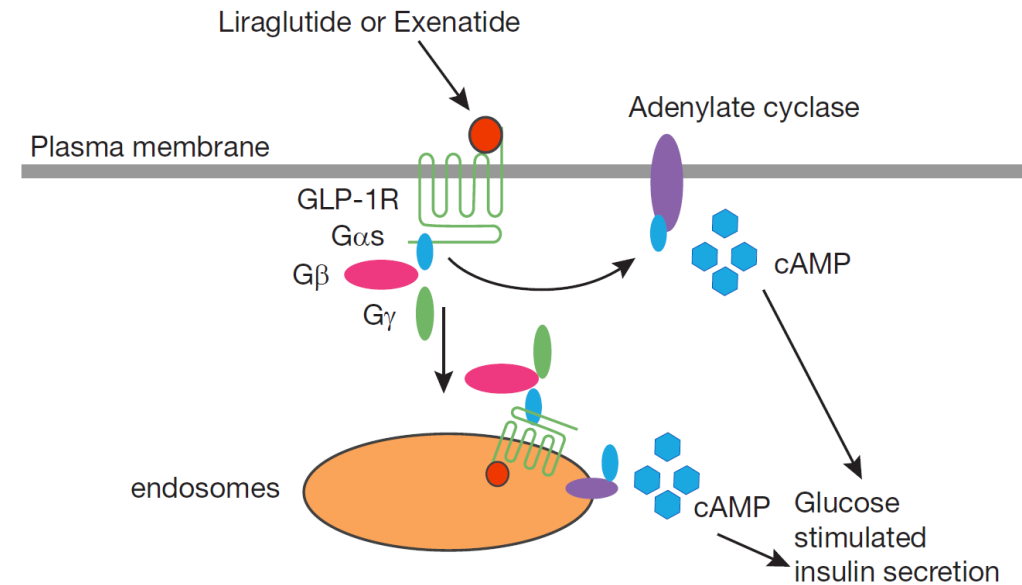
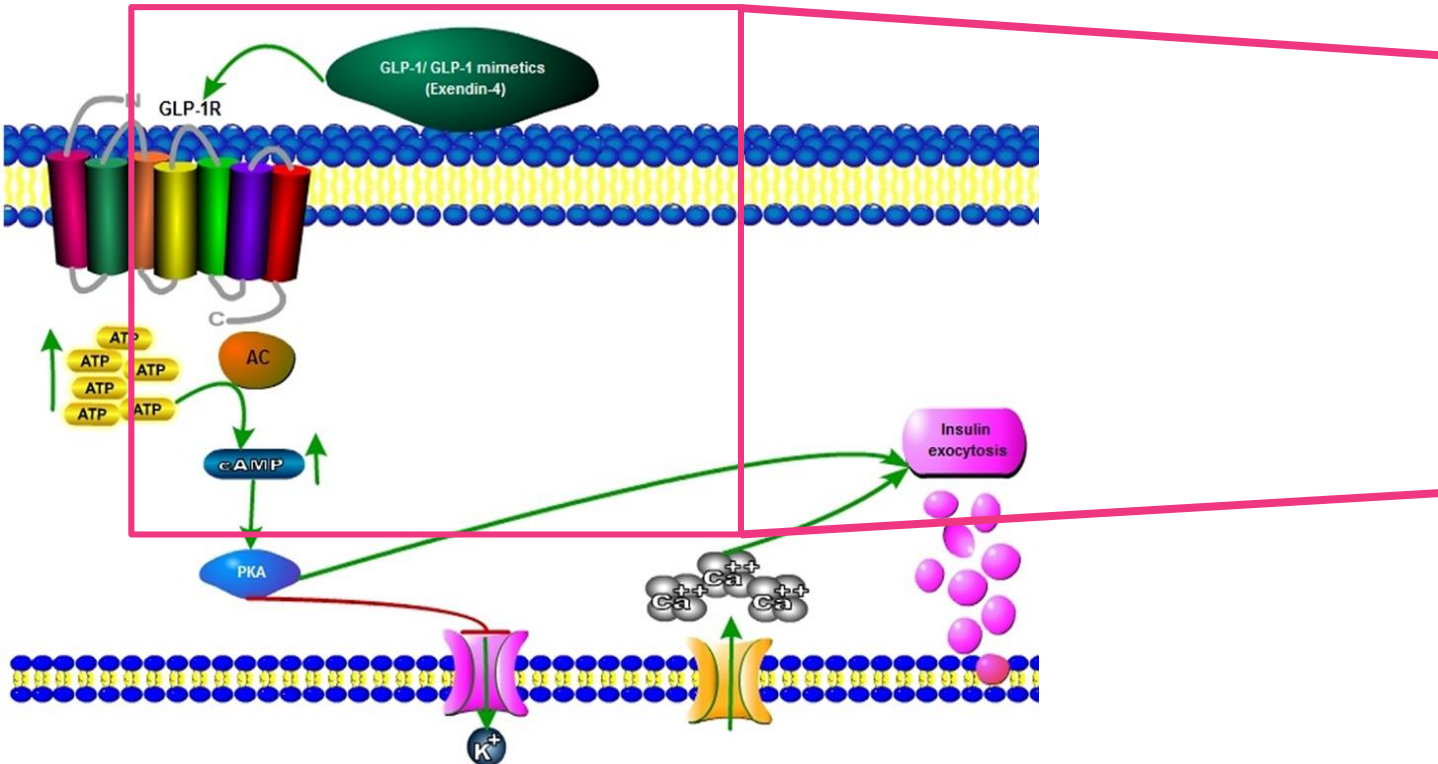
Exenatide (Byetta®)

For Treatment of Type II Diabetes mellitus

Mechanism of Action



Assay Principle



Source: Sebastião et. al., *Front. Endocrinol.* (2014); 5, 110

cAMP Hunter[®] Exenatide Bioassay Kit

Kit Components

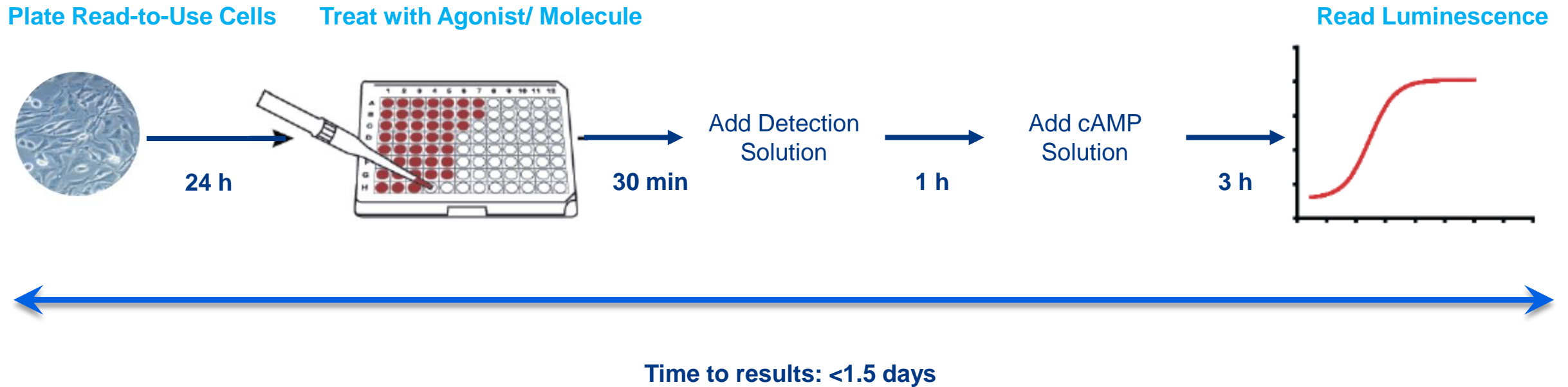
List of Components	95-0062Y2-00101	95-0062Y2-00102
cAMP Hunter CHO-K1 GLP1R Bioassay Cells	2 vials	10 vials
cAMP Detection Kit for Bioassays		
cAMP Standard (250 µM) (mL)	0.2	1
cAMP Antibody Reagent (mL)	5	25
cAMP Lysis Buffer (mL)	7.6	38
Substrate Reagent 1 (mL)	2	10
Substrate Reagent 2 (mL)	0.4	2
cAMP Solution D (mL)	10	50
cAMP Solution A (mL)	16	80
Cell Assay Buffer	1 X 50 mL	2 X 50 mL
AssayComplete™ Cell Plating Reagent 2	1 X 100 mL	2 X 100 mL
Protein Dilution Buffer- B2	1 X 50 mL	2 X 50 mL
Control Agonist (Exendin-4)	1 vial	1 vial
96-Well Clear-Bottom TC Treated, Sterile Plates w/Lid	2 plates	10 plates

Sample data

Exenatide Bioassay Qualification

Bioassay Workflow

Simple, Homogenous and Rapid Protocol



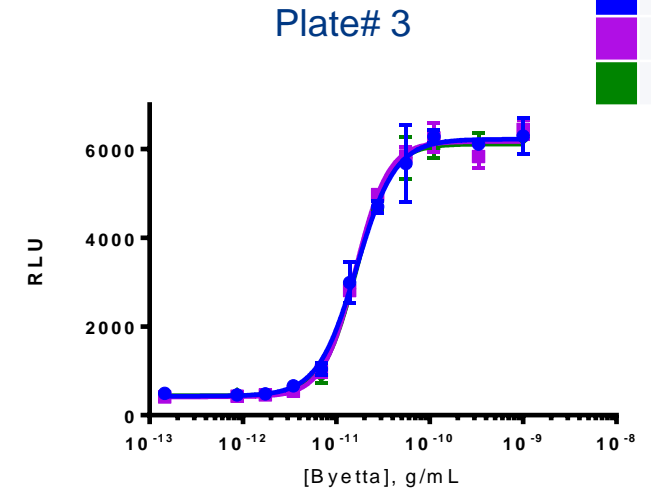
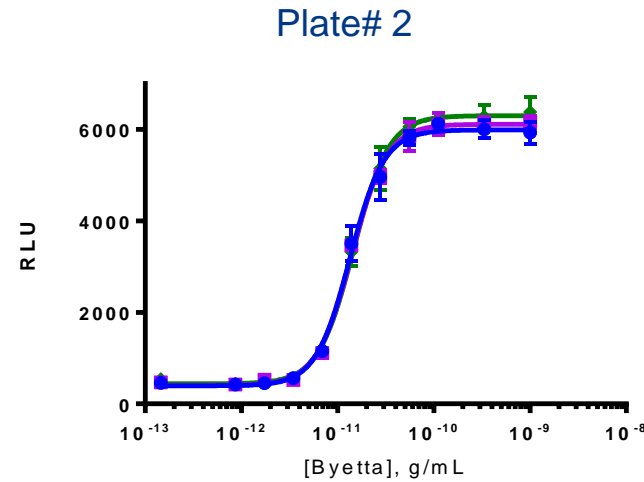
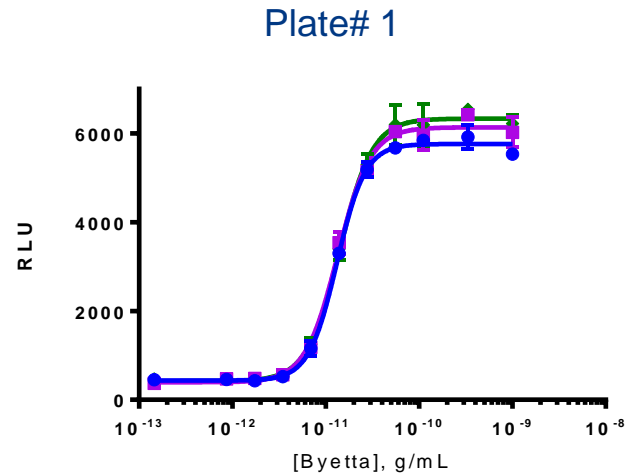
Exenatide Bioassay Qualification with Byetta®

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

Exenatide Bioassay Qualification with Byetta®

Plate to plate variability: 3 plates with full-plate DRC - Same Day



Parameter	R1	R2	R3
S/B	14.1	14.3	13.9
Hill Slope	2.867	2.482	2.464
EC ₅₀ (pg/mL)	13.21	13.47	14.11

Parameter	R1	R2	R3
S/B	13.6	14.3	14.2
Hill Slope	2.447	2.363	2.370
EC ₅₀ (pg/mL)	13.47	14.01	14.61

Parameter	R1	R2	R3
S/B	13.4	13.7	11.6
Hill Slope	2.097	2.466	2.415
EC ₅₀ (pg/mL)	16.49	16.11	16.37

Assay Robustness

Repeatability and Intermediate Precision (Inter-Plate)

Plate	Sample	S/B	%RSD, S/B	EC ₅₀ , ng/mL	Mean EC ₅₀ , ng/mL	%RSD, EC ₅₀
1	R1	14.1	1.4	0.013	0.014	3.4
	R2	14.3		0.014		
	R3	13.9		0.014		
2	R1	13.6	2.7	0.014	0.014	4.1
	R2	14.3		0.014		
	R3	14.2		0.015		
3	R1	13.4	8.8	0.017	0.016	1.2
	R2	13.7		0.016		
	R3	11.6		0.016		

Intermediate Precision (Inter-Day)

Day	EC ₅₀ , ng/mL	Mean EC ₅₀ , ng/mL	%RSD, EC ₅₀
1	0.030	0.029	18.8
2	0.023		
3	0.034		

Intermediate Precision (Inter-Plate): 2.9%
Intermediate Precision (Inter-Day): 18.8%

Exenatide Bioassay Qualification with Byetta®

Parallelism and Potency Estimation (PLA):

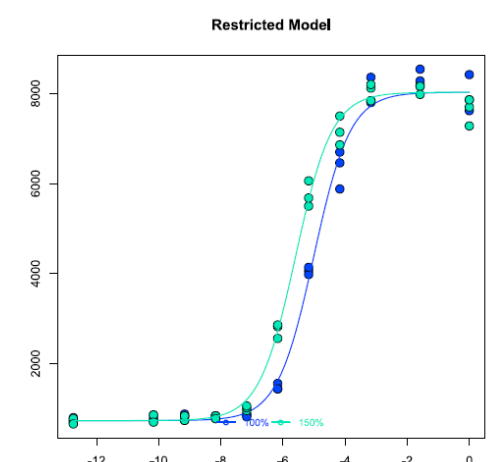
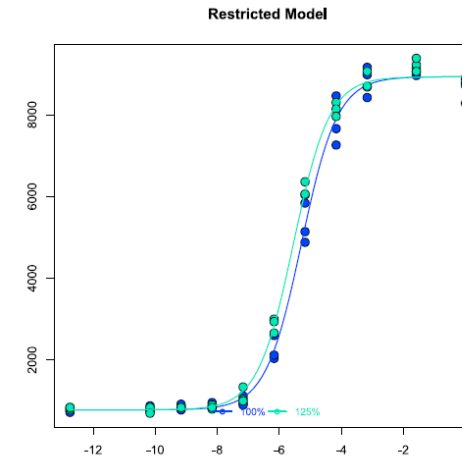
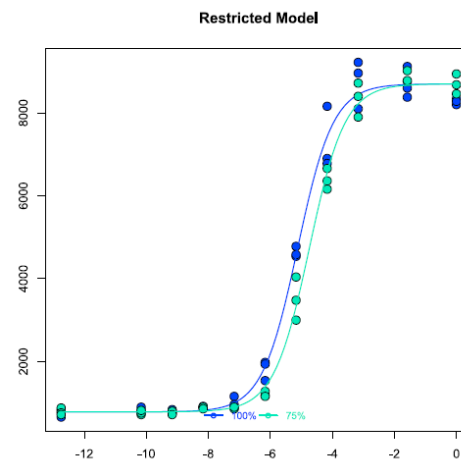
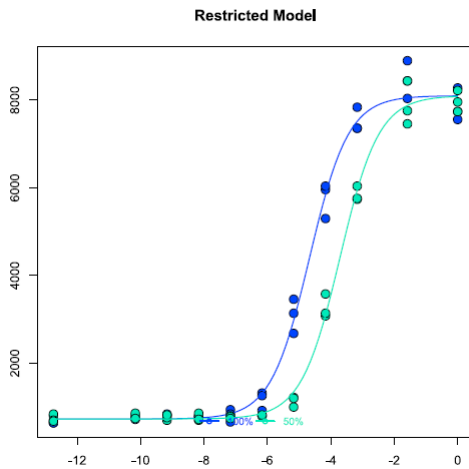
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75%

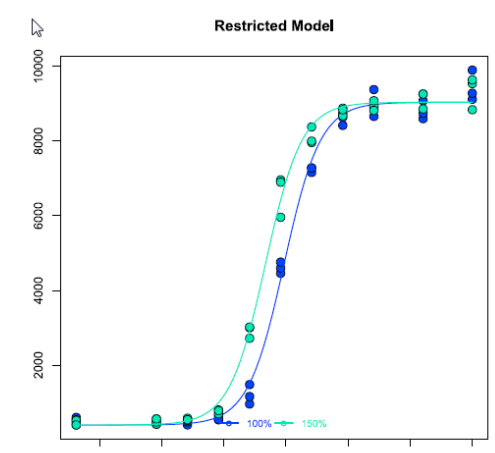
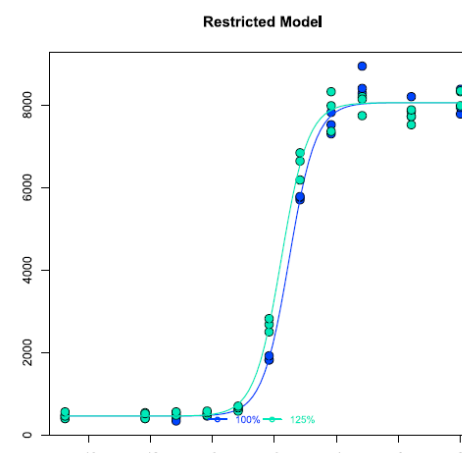
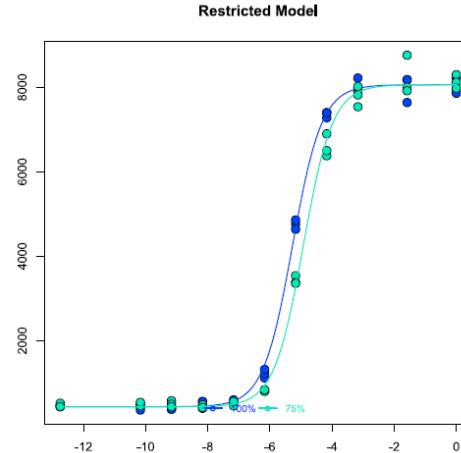
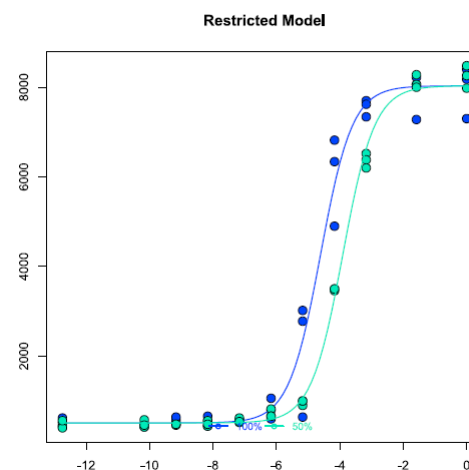
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150%

Analyst 1



Analyst 2

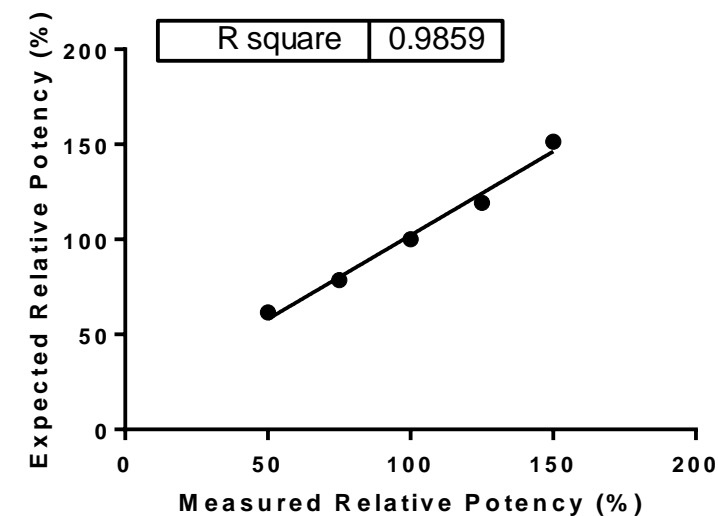


● Reference ● Sample

Exenatide Bioassay Qualification with Byetta®

Summary: Accuracy, Precision and Dilutional Linearity (2 Analysts)

Expected RP (%)	Exp #	Analyst #	Measured RP (%)	Average RP (%)	% RSD	% Recovery
150	1	1	147.5	154.4	9.56	96.5
	2	1	168.5			
	3	1	150.1			
	4	2	151.4			
125	1	1	119.5	119.6	2.54	104.5
	2	1	122.8			
	3	1	116.6			
	4	2	119.3			
75	1	1	76.9	76.3	3.20	99.3
	2	1	71.6			
	3	1	78			
	4	2	78.6			
50	1	1	48.8	51.8	6.90	102.9
	2	1	45.5			
	3	1	51.5			
	4	2	61.5			



Accuracy: 100.8%

Precision: 5.2%

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

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 Additional Information or Technical Support



Web:

[Cell-Based Bioassays for Biologics](#)

Technical Support

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