



cAMPHunter™ Teriparatide Bioassay Kit

Qualified with Forteo®

95-0118Y2-00057 (2-Plate Kit)

95-0118Y2-00058 (10-Plate Kit)

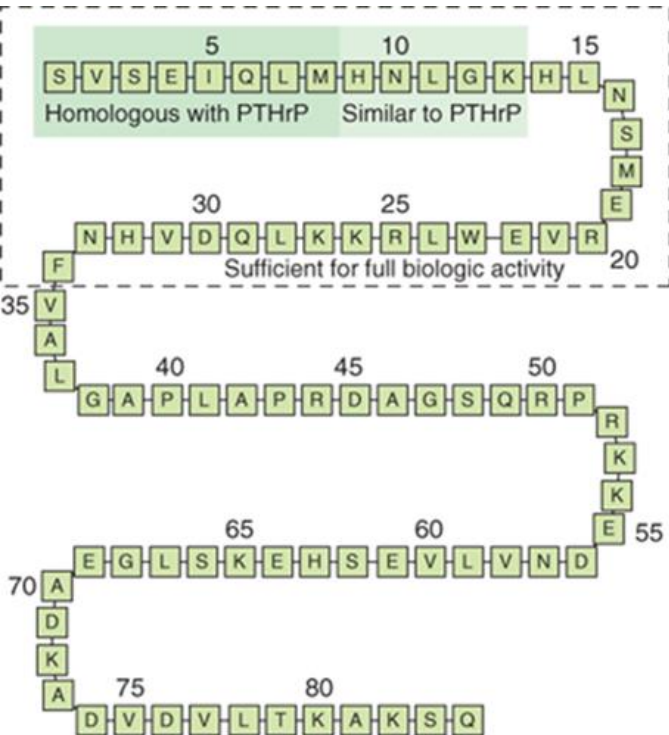
OUR EXPERTISE
IN YOUR HANDS.

DISCOVER
CONFIDENTLY.

Forteo[®] (Teriparatide)

For Treatment of Osteoporosis

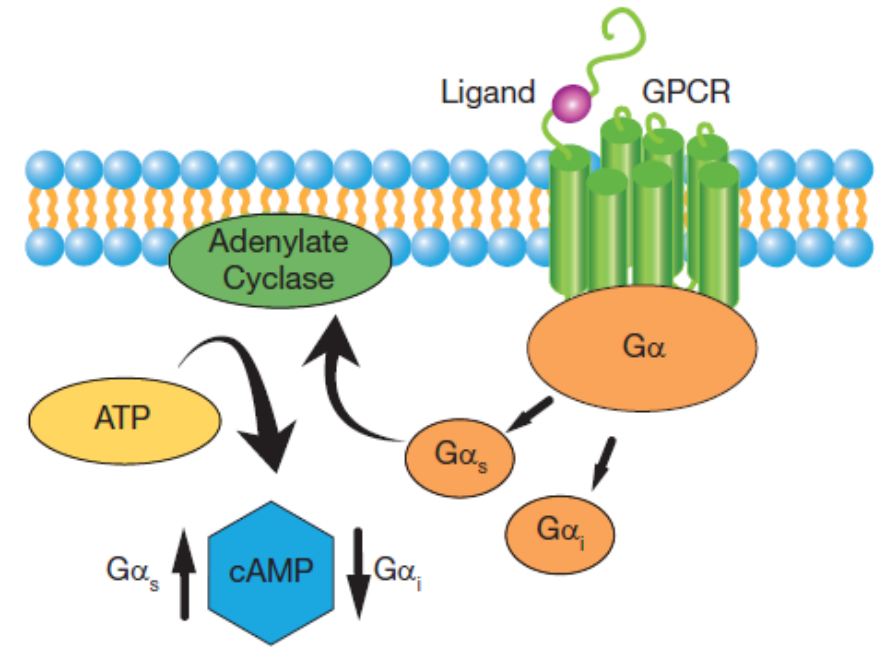
Amino Acid Sequence



Teriparatide

Mechanism of Action

GPCR cAMP Pathway



Source: Kim E. Barrett, Susan M. Barman, Scott Boitano, Heddwen L. Brooks: Ganong's Review of Medical Physiology, 25th Ed. www.accessmedicine.com Copyright © McGraw-Hill Education. All rights reserved.

cAMP Hunter™ Teriparatide Bioassay Kit

Kit Components

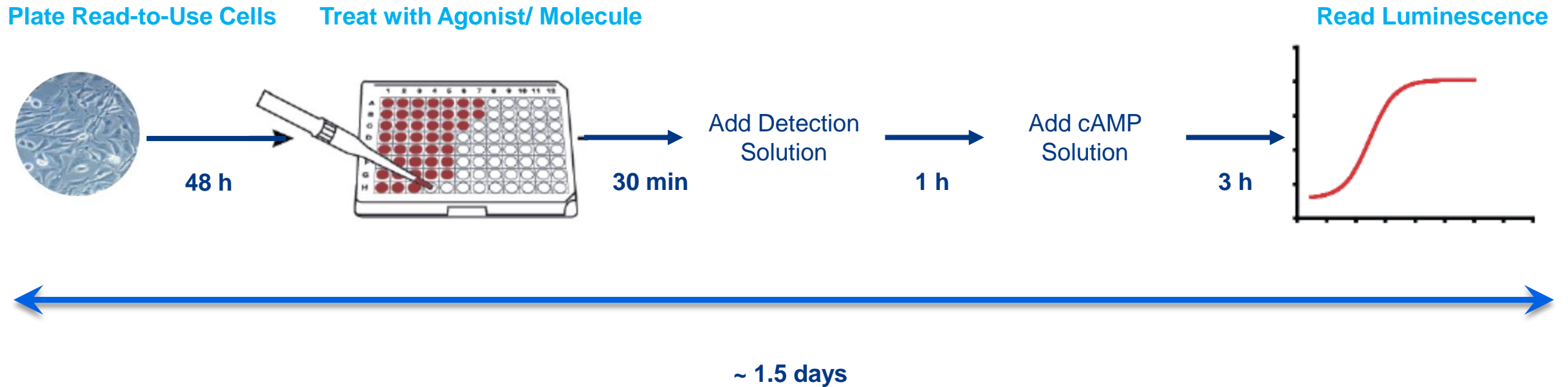
List of Components	95-0118Y2-00057	95-0118Y2-00058
cAMP Hunter CHO-K1 PTHR1 Bioassay Cells	2 vials	10 vials
cAMP Detection Kit		
cAMP Standard (250 µM) (mL)	0.2	1
cAMP Antibody Reagent (mL)	5	25
cAMP Lysis Buffer (mL)	7.6	38
Substrate Reagent 1 (mL)	2	10
Substrate Reagent 2 (mL)	0.4	2
cAMP Solution D (mL)	10	50
cAMP Solution A (mL)	16	80
Cell Assay Buffer (mL)	25	250
AssayComplete™ Cell Plating Reagent 2	2 X 20 mL	2 X 100 mL
Protein Dilution Buffer- B3	1 X 50 mL	2 X 50 mL
Control Agonist (PTH (1-34))	1 vial	1 vial
96-Well Clear-Bottom TC Treated, Sterile Plates w/Lid	2 plates	10 plates

Sample data

Teriparatide Bioassay Qualification

Bioassay Workflow

Simple, Homogenous and Rapid Protocol



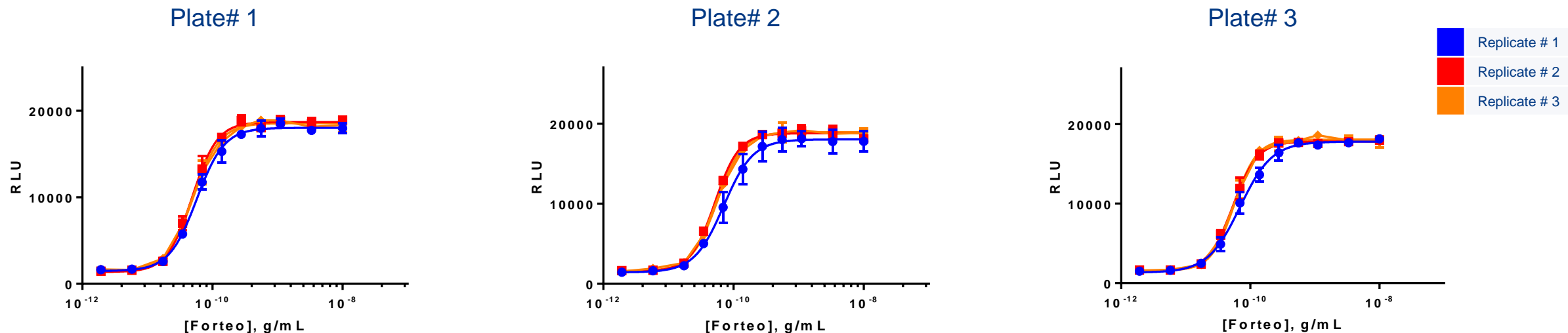
Teriparatide Bioassay Qualification with Forteo

Assay Parameters Assessed

- % CV between 8 full plate DRCs
- Plate uniformity: EC_{80} 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

Teriparatide Bioassay Qualification with Forteo

Plate to plate variability: 3 plates with full plate DRC - same day (Day 3)



Parameter	R1	R2	R3
S/B	12.0	12.9	12.5
Hill Slope	2.048	2.249	2.111
EC ₅₀ (pg/mL)	57.2	48.9	50.9

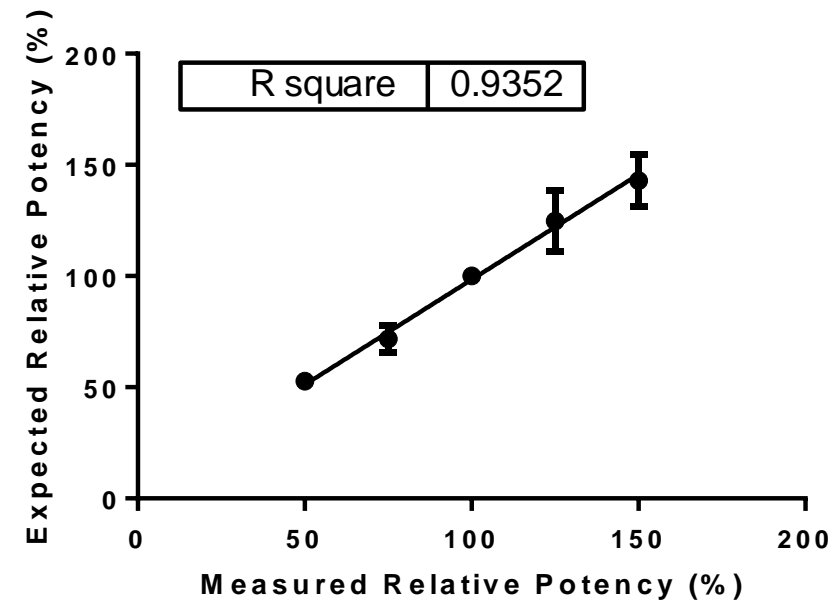
Parameter	R1	R2	R3
S/B	12.4	12.8	12.1
Hill Slope	1.929	2.333	2.217
EC ₅₀ (pg/mL)	70.6	51.9	55.9

Parameter	R1	R2	R3
S/B	11.3	11.7	12.1
Hill Slope	1.742	2.264	2.461
EC ₅₀ (pg/mL)	69.3	53.7	56

Teriparatide Bioassay Qualification with Forteo

Relative Potency, Linearity, Accuracy and Precision

Experiment	Expected RP (%)	Measured RP (%)	Average RP (%)	RSD (%)	% Recovery
1	150	134.3	142.9	11.9	95.3
2		151.3			
3		134.5			
1	125	138.2	124.8	13.8	99.8
2		125.6			
3		110.7			
1	75	83.3	71.8	6.1	95.7
2		67.5			
3		76.1			
1	50	49.4	52.8	NA	105.6
2		52.8			
3		53.2			



Accuracy: 100.4%
Precision: 9.9%

Teriparatide Bioassay Qualification with Forteo

Assay Robustness

Repeatability and Intermediate Precision (Inter-Plate)

Plate	Sample	S/B	%RSD, S/B	EC ₅₀ , pg/mL	Mean EC ₅₀ , pg/mL	%RSD, IC ₅₀
1	R1	12	3.6	57	52.3	8
	R2	12.9		49		
	R3	12.4		51		
2	R1	12.4	2.8	71	59.7	16.8
	R2	12.8		52		
	R3	12.1		56		
3	R1	11.3	3.4	69	59.7	13.7
	R2	11.7		54		
	R3	12.1		56		

Intermediate Precision (Inter-Day)

Day	EC ₅₀ , pg/mL	Mean EC ₅₀ , pg/mL	%RSD, IC ₅₀
1	78.8	71.9	17.7
2	79.6		
3	57.2		

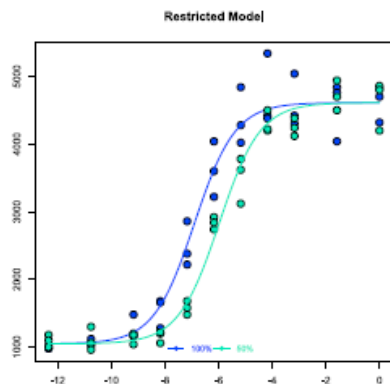
Intermediate Precision (Inter-Plate): 7.46%
Intermediate Precision (Inter-Day): 17.7%

Teriparatide Bioassay Qualification with Forteo

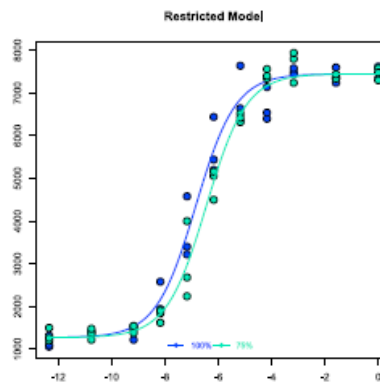
Parallelism and Potency Estimation (PLA):

Analyst 1

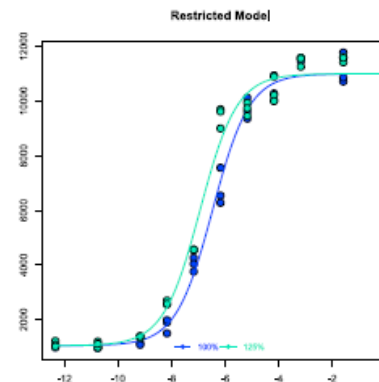
50%



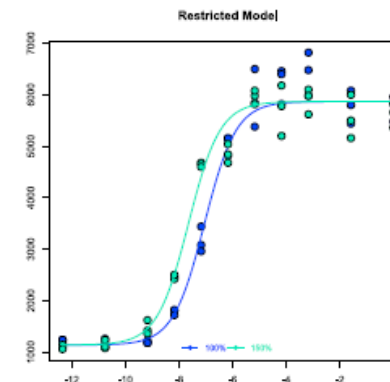
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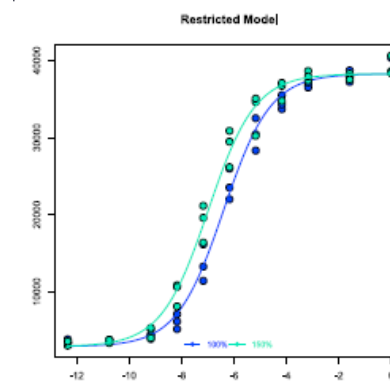
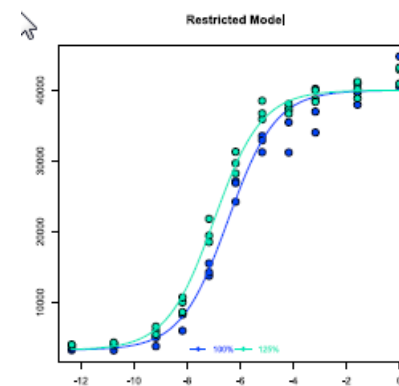
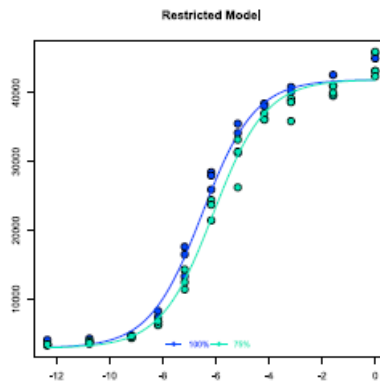
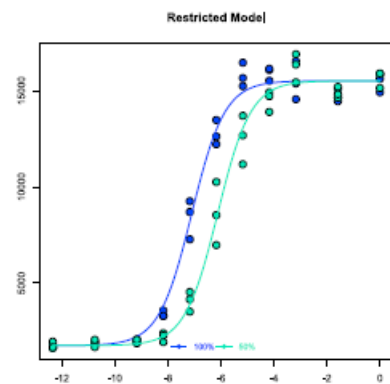
125%



150%



Analyst 2



● Reference ● Sample

Benefits for “Ready-to-Use” Bioassay Kits

Functional response based on drug MOA
Verified and Qualified with innovator 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 More Info, Questions or Technical Support



Web:

[Cell-Based Bioassays for Biologics](#)

Technical Support

For NA:

DRX_SupportUS@eurofinsUS.com

For Europe, Africa & Middle East:

DRX_SupportEurope@eurofinsUS.com

For Asia-Pacific:

AsiaPacificSupport@eurofins.com