

The Eurofins Discovery PRODUCTS COMPANY

# cAMP Hunter® Semaglutide Bioassay

Qualified with Ozempic®

95-0062Y2-00175 (2-Plate Kit)

95-0062Y2-00176 (10-Plate Kit)

OUR EXPERTISE IN YOUR HANDS. DISCOVER CONFIDENTLY.

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# Semaglutide (Ozempic®)

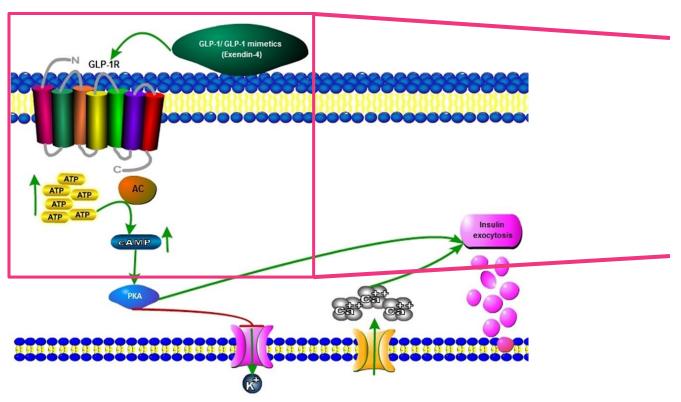


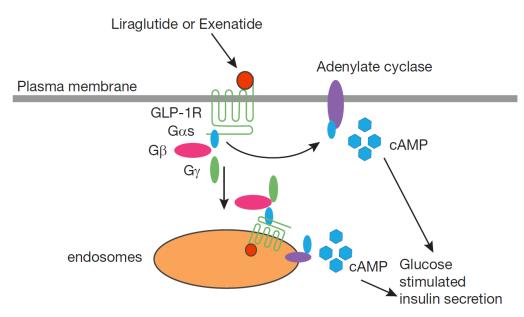
For Treatment of Type II Diabetes mellitus

### Mechanism of Action



### **Assay Principle**





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

# cAMP Hunter® Semaglutide Bioassay Kit



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### Kit Components

#### Materials Provided

List of Components	95-0062Y2-00175	95-0062Y2-00176
cAMP Hunter CHO-K1 GLP1R Bioassay Cells (3.75 x 10 <sup>6</sup> cells in 0.2 mL per vial)	2	10
AssayComplete™ Cell Plating 2 Reagent (100 mL per bottle)	1	2
AssayComplete Cell Assay Buffer (50 mL per bottle)	1	2
AssayComplete Protein Dilution Buffer B2 (50 mL per bottle)	1	2
Control Agonist (Human Exendin-4)	1 x 500 μg	1 x 500 μg
cAMP Detection Kit for Bioassays		
cAMP Standard (250 µM) (Bottle) cAMP Antibody Reagent (Bottle) cAMP Lysis Buffer (Bottle) Substrate Reagent 1 (Bottle) Substrate Reagent 2 (Bottle) cAMP Solution D (Bottle) cAMP Solution A (Bottle)	1 x 5 mL 1 x 7.6 mL 1 x 2 mL 1 x 0.4 mL 1 x 10 mL	1 x 1 mL 1 x 25 mL 1 x 38 mL 1 x 10 mL 1 x 2 mL 1 x 50 mL 1 x 80 mL
96-Well White, Clear-Bottom, TC-Treated, Sterile Plates with Lid	2	10

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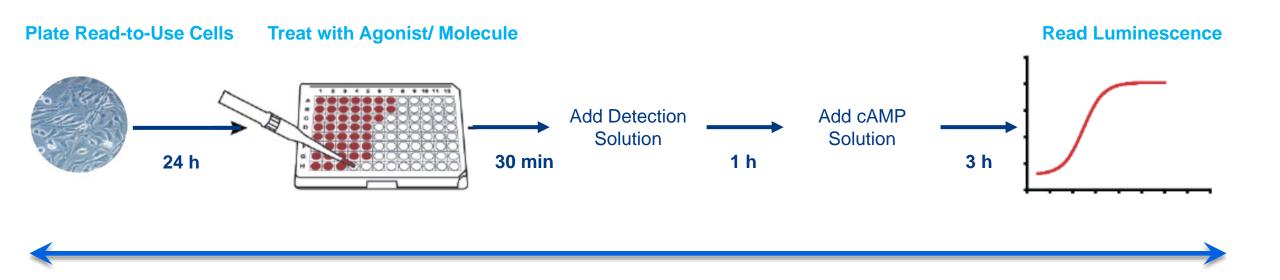
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Sample data

# Semaglutide Bioassay Qualification

### **Bioassay Workflow**

Simple, Homogenous and Rapid Protocol



# Optimized Semaglutide Dose Curve and Plate Layout For Assay Qualification

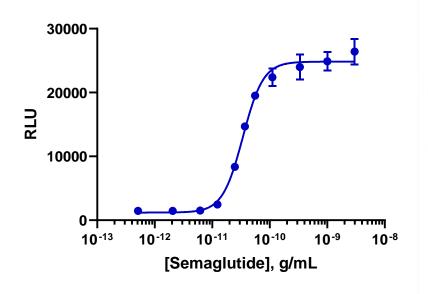


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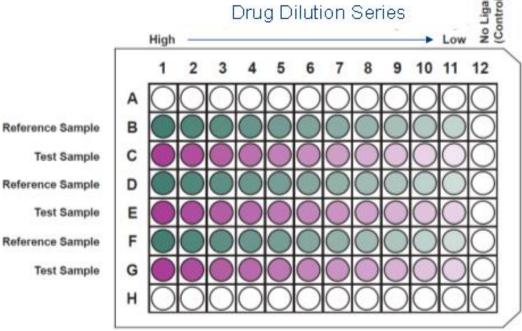
#### **Dilution Scheme**

Concentration, ng/mL	Diln Factor
3	
1	3
0.33	3
0.11	3
0.056	2
0.037	1.5
0.025	1.5
0.012	2
0.0062	2
0.0031	3
0.00078	4

# Representative Dose Curve (100%)



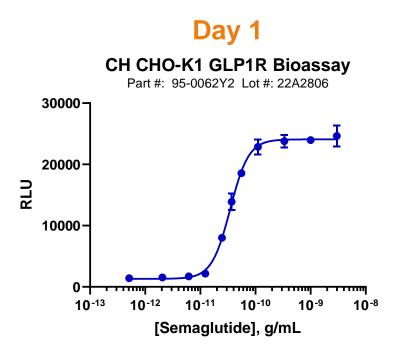
### **Plate Layout**

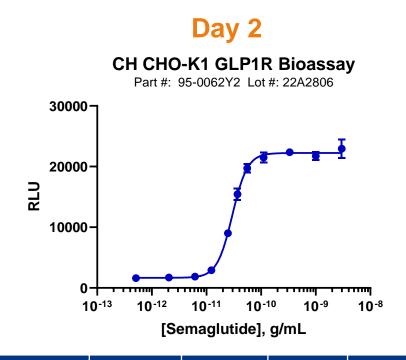


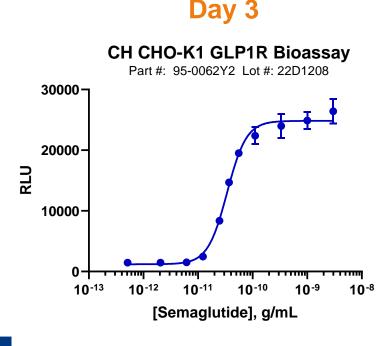
# Day-to-Day Repeatability with Semaglutide (Single Analyst)



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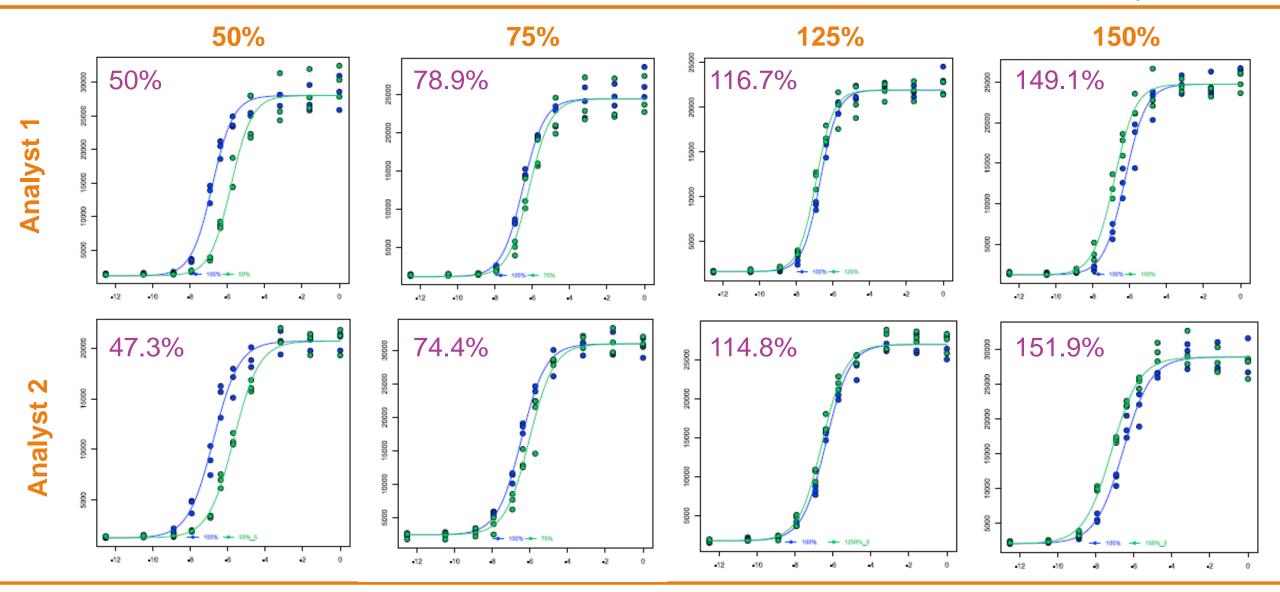
	Day 1	Day 2	Day 3	% RSD
S/B	15.8	13.9	16.3	8.3%
EC <sub>50</sub> , pg/mL	34.8	29.7	34.1	8.4%

Note: consistent data generated with two different bioassay lots

### Representative Relative Potency Data (4 Nominal Concentrations) curofins (Analyst 1 vs Analyst 2)



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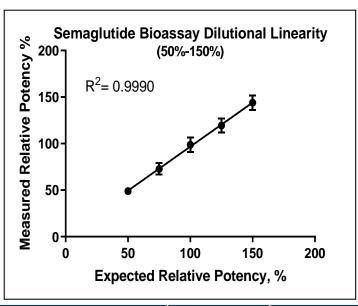
# Semaglutide Bioassay Qualification Data



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	Nominal RP, %	Analyst	Observed RP, %	Average RP, %	% RSD	Average % Recovery
	150	1	149.1	143.9	5.4	95.9%
		1	138.8			
	100	1	135.8			
		2	151.9			
		1	130.7		6.4	95.5%
	`125	1	116.7	110.4		
	120	1 115.2	119.4	0.4	95.5%	
		2	114.8			
		1	108		7.8	98.8%
		1	101.1	98.8		
	100	1	88.1			
		1	94.4			
		2	102.3			
		1	1 73.5		8.5 97.1%	07 10/
	75	1	79.0	72.8 8.5 48.9 3.9		
	73	1	64.3			97.176
		2	74.4			
		1	47.3			97.9%
	50	1	51.1		3.0	
		1	50		37.370	
	2	47.3				



Parameter	Value	Specification
Accuracy (Average % Recovery)	97%	100% +/- 20%
Repeatability	8.7%	≤20%
Intermediate Precision	≤8.5%	≤20%
Linearity (R <sup>2</sup> )	0.9990	≥0.95

Excellent accuracy, repeatability, intermediate precision, and dilutional linearity

# 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 More Info, Questions or Technical Support





#### Web:

Cell-Based Bioassays for Biologics

### **Technical Support**

DRX\_SupportUS@eurofinsUS.com