A novel Islet Amyloid PolyPeptide ELISA for specific determination of IAPP in human samples

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PURPOSE

IAPP (Islet Amyloid PolyPeptide), or Amylin, is a peptide hormone co-secreted with insulin and plays a central role in glucose homeostasis, satiety signalling, and gastric emptying.

Altered IAPP secretion and aggregation lead to amyloid formation, which have been linked to beta-cell dysfunction and disease progression in type 2 diabetes, as well as in obesity-related and neurodegenerative disorders.

With rising global prevalence of obesity and type 2 diabetes there is an increasing scientific and therapeutic focus on IAPP biology and a growing demand for precise and reliable quantification of circulating human IAPP in biological samples.

METHOD

Rabbit monoclonal antibodies were specifically designed and characterised for selective detection of human IAPP.

A sandwich ELISA was developed to cover the expected range of circulating human IAPP concentrations.

Performance evaluation included assessment of specificity, parallelism and precision, and results were evaluated against predefined acceptance criteria for each parameter.

RESULTS

This assay is based on **a pair of rabbit monoclonal antibodies specifically designed and characterized for selective detection of human IAPP.** Sample volume is 50 µL, no sample pre-treatment is required, and total incubation time is 2 h 15 min. The measuring range is 0.412 – 100 pM (figure 1).

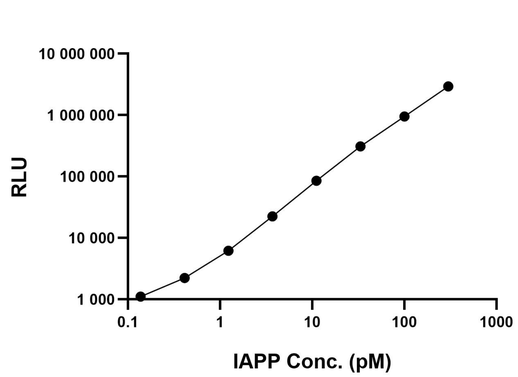

Figure 1. Standard curve of the IAPP ELISA.

Precision was evaluated across three runs using plasma samples in duplicates (table 1). Both intra- and inter-assay precision met predefined acceptance criteria.

Table 1. Assay precision.

Sample #	Sample Matrix	Average Conc. (pM)	Intra Run CV (%)	Inter Run CV (%)
1	P800	33.7	≤ 3.2	5.5
2	P800	19.9	≤ 0.8	6.7
3	P800	24.7	≤ 1.0	2.3
4	P800	22.0	≤ 4.3	4.2
5	EDTA	8.1	≤ 9.8	6.2

The assay shows **excellent analytical specificity**, by detecting all molecular forms regardless of C-terminal amidation status and minimal cross-reactivity to structurally related peptides (Table 2).

Table 2. Cross-reactivity.

	Tested Conc. (pM)	Cross Reactivity (%)
CGRP-α	100	<0.01
CGRP-ß	100	0.01
GLP-1	100	0.01
Glucagon	100	0.02
Insulin	100	0.01
Mouse IAPP	100	<0.01

Robust parallelism was observed in plasma matrix (Figure 2), confirming accurate quantification of endogenous IAPP with minimal matrix interference. CVs (%) between dilutions were below 6% for P800 plasma samples and below 22% for EDTA plasma samples. All samples except S3 1:4 and S4 1:8 were within ± 20 % recovery.

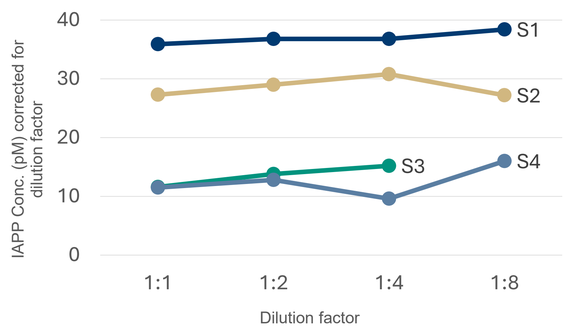

Figure 2. Parallelism demonstrated in two P800 plasma samples (S1 and S2) and two EDTA plasma samples (S3 and S4). S3 diluted 1:8 was below assay measuring range and therefore not included.

OBJECTIVE

The objective of this work was to develop and characterize a specific, sensitive and precise immunoassay for reliable quantification of IAPP in human samples.

CONCLUSION

This work presents a novel human IAPP ELISA enabled by **purpose-designed monoclonal antibodies**, delivering high sensitivity, specificity, and precision in human plasma.

Robust parallelism and minimal cross-reactivity ensure reliable quantification of endogenous IAPP, making the assay well suited for translational research and biomarker studies in metabolic and related disease areas.

The assay enables generation of high-quality, reproducible IAPP data, supporting confident biological interpretation and therapeutic research.

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