

Ensuring the Quality of Biologics at the Point of Care: Lessons from Insulin Therapy

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**IN
SPIRE
LAB.**

beyond.
diagnostics



Diabetes

A global health crisis. Insulin is essential for millions.

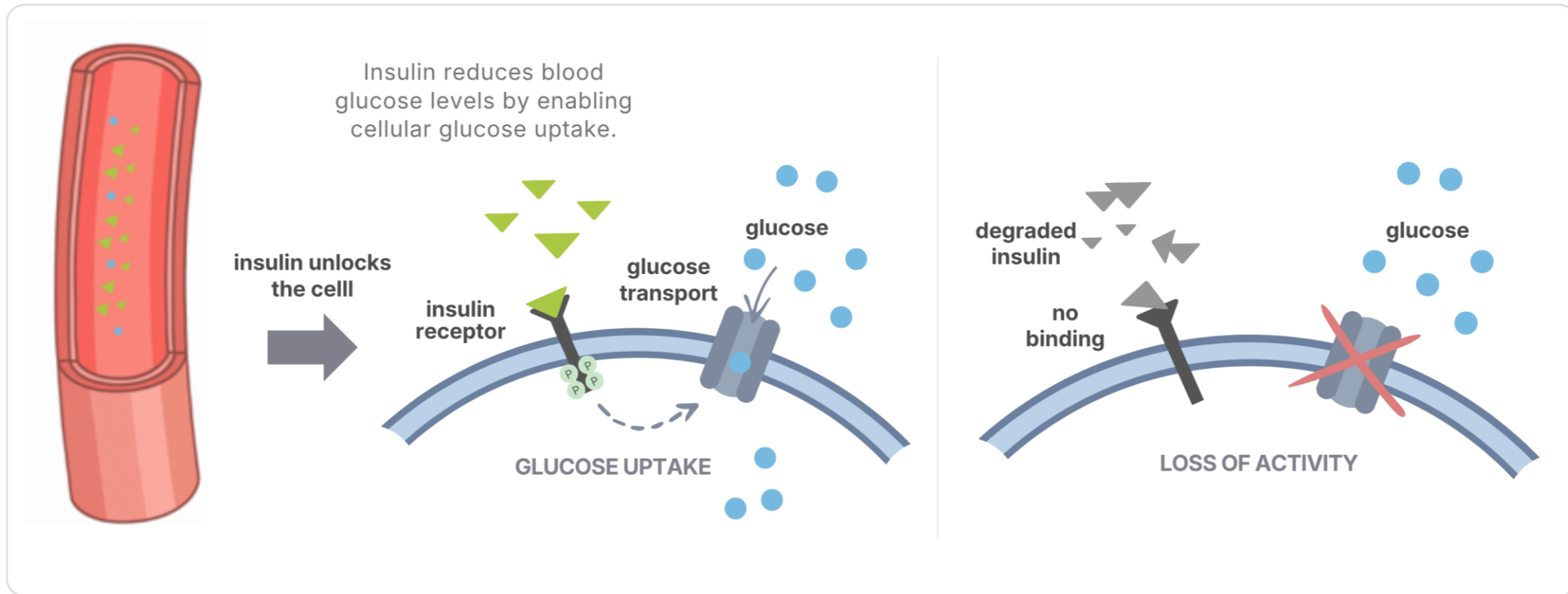
590M People
live with
diabetes (PwD)
globally.

Exogenous
insulin is the
essential
therapy.

100M PwD rely
on insulin
therapy.

The Protein Hormone Insulin

Intact insulin 3D structure reduces blood glucose levels by enabling cellular glucose uptake.



Diabetes and Insulin in Everyday Life

Temperature exposure challenges devices, therapy, and insulin quality.

Left in hot car-
efficacy was
reduced by 50%.

If I've been on the beach for
a day, the insulin will not
bring my BG's down as usual.

During insulin treatment, have you ever
suspected a difference in insulin activity?

75% YES 25% NO

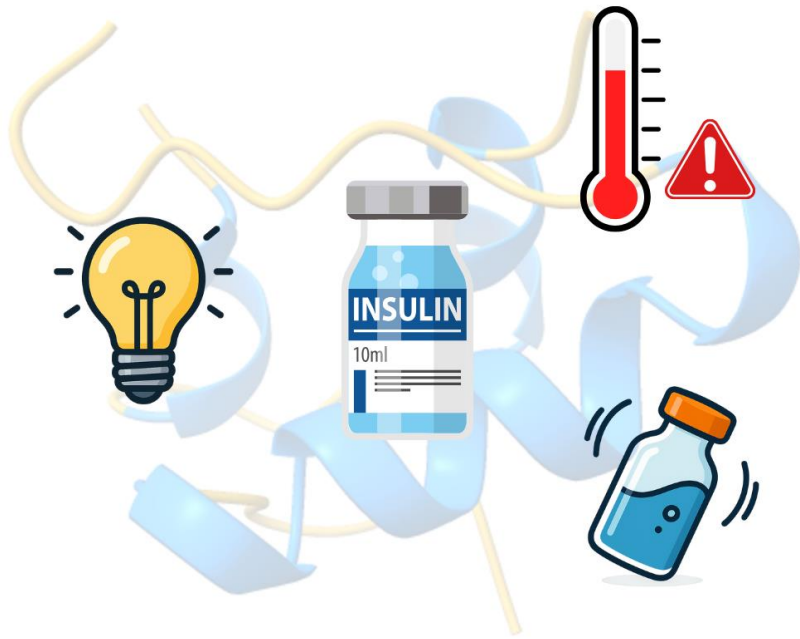
It seems to work
best "fresh" from
the pharmacy.

- Recommended storage and usage conditions $\neq$ daily life
- Treatment uncertainty
- Affects glycaemic control, insulin waste, and healthcare costs



State-of-the-Art Research

Current biological and analytical methods cannot simply determine insulin efficacy.



- High-performance liquid chromatography (HPLC) is the standard stability indicating method
- Rabbit blood sugar tests and in cell Western (ICW) assays determine insulin bioidentity, but are not used under stress conditions

The INSPIRE LAB Approach

We combine biological evidence with advanced bioanalytical techniques and clinical outcomes.

Develop Reference
Method(s)

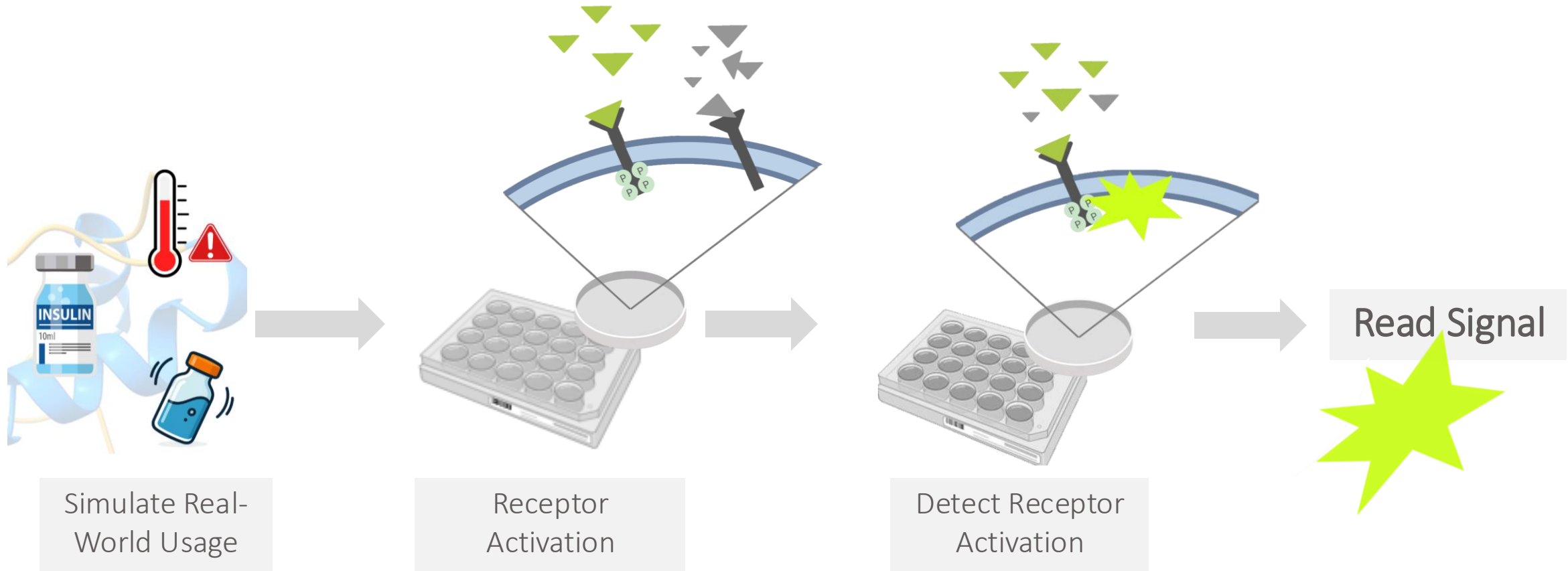
Real-World Factor
Simulation & Sample
Collection

In vivo Functional &
Clinical Studies

Advanced Analytical
Techniques

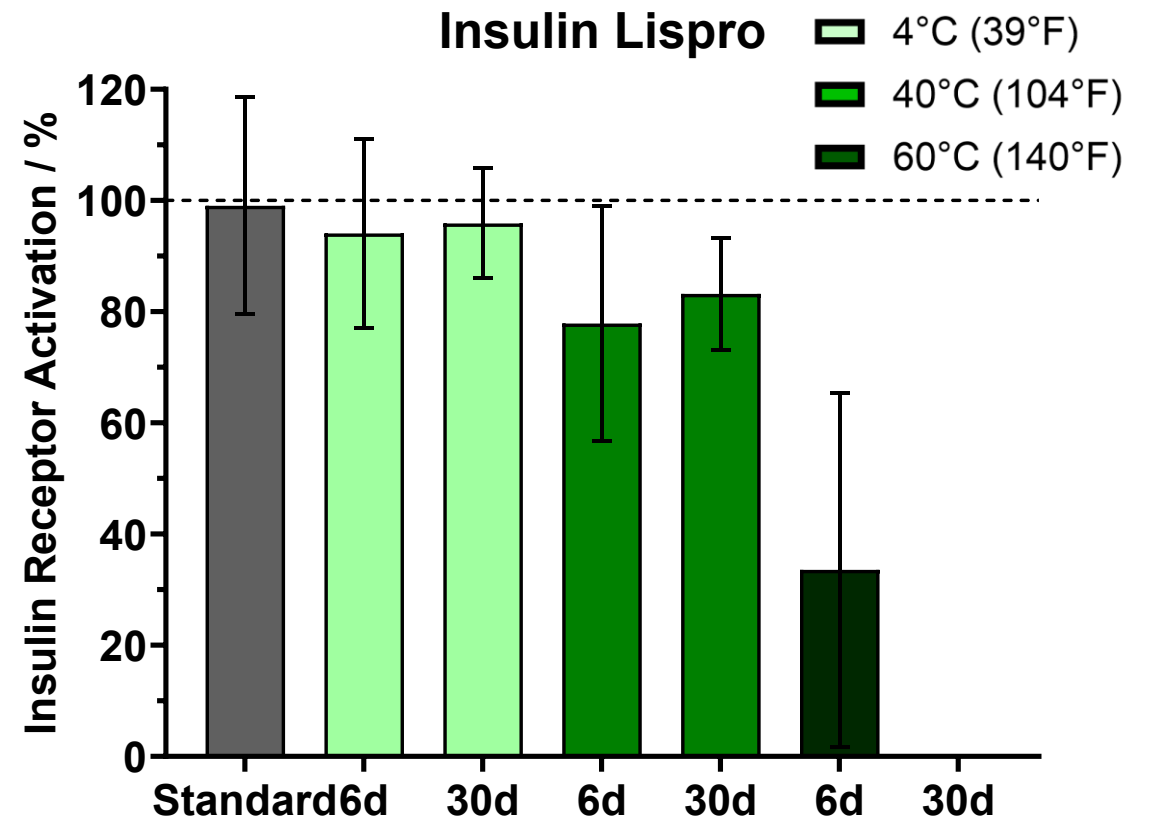
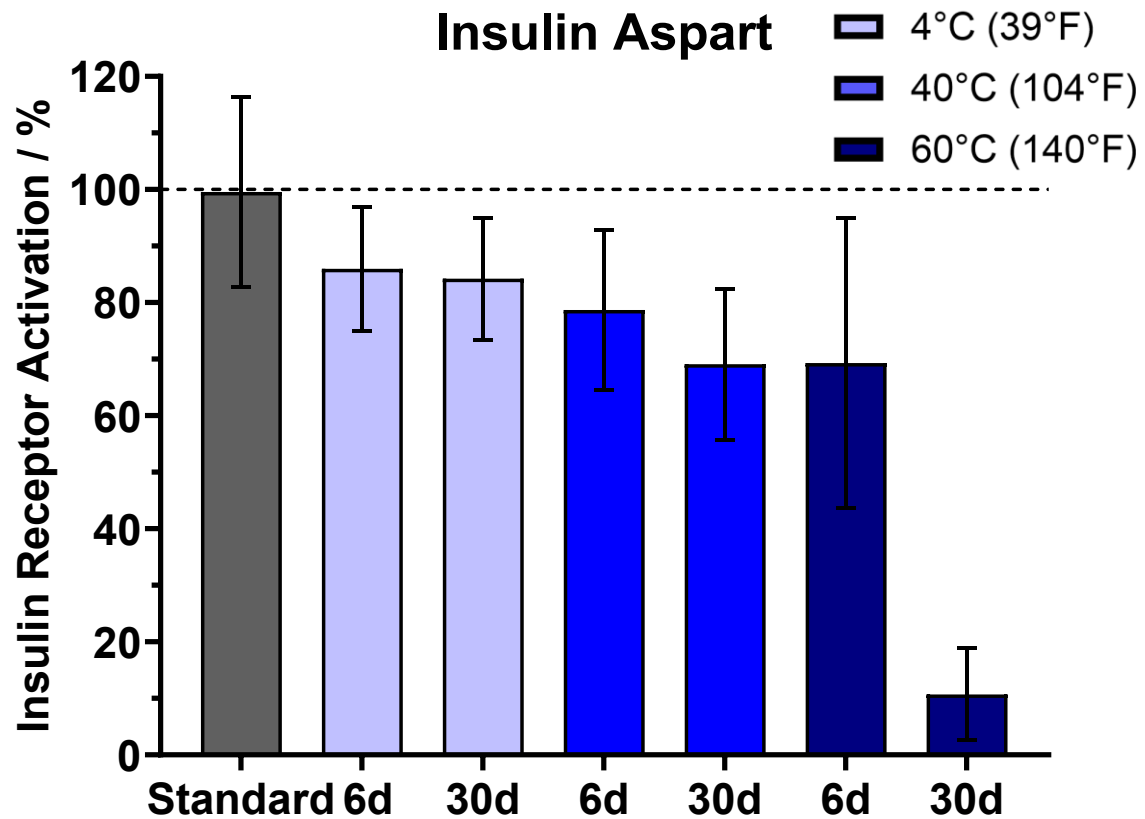
In Cell Western (ICW) Assay

Quantifying insulin biological activity in vitro by insulin receptor activation.



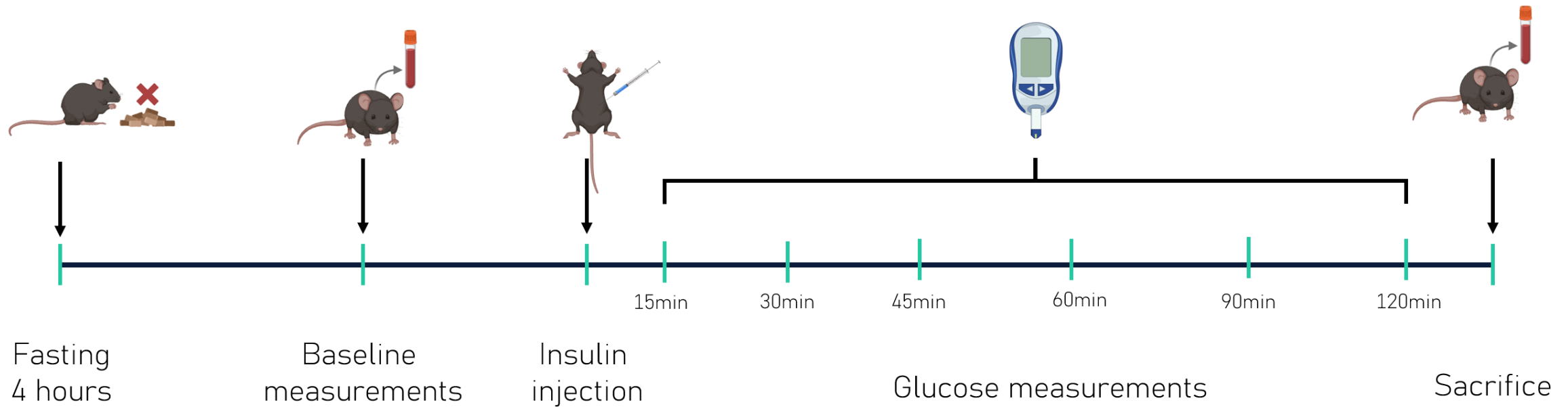
In Cell Western (ICW) Assay

Both short-acting insulins degrade outside recommended conditions, with different patterns.



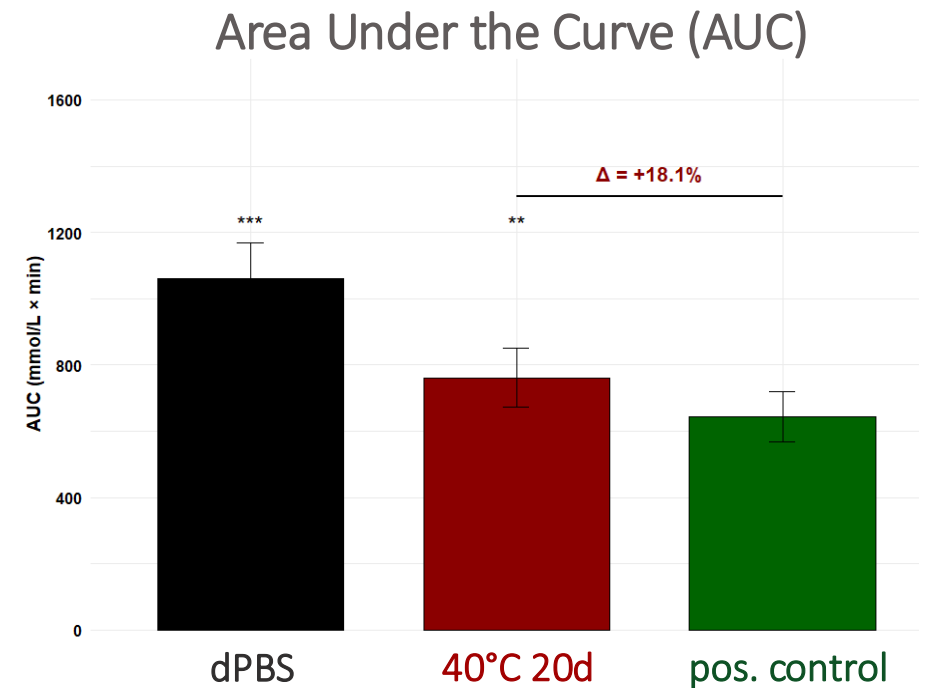
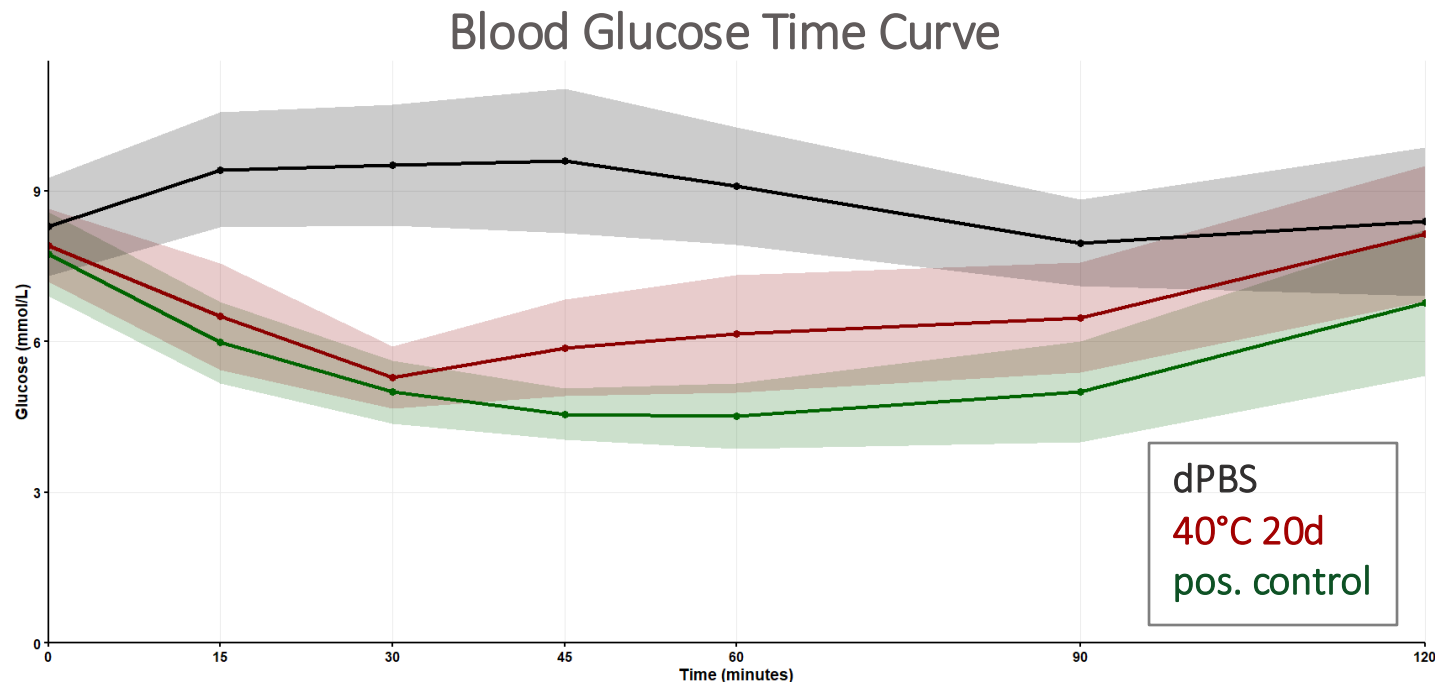
Insulin Tolerance Test (ITT) in a Non-Diabetic Mouse Model

Determining insulin's biological activity in vivo by tracking blood glucose levels (BGL).



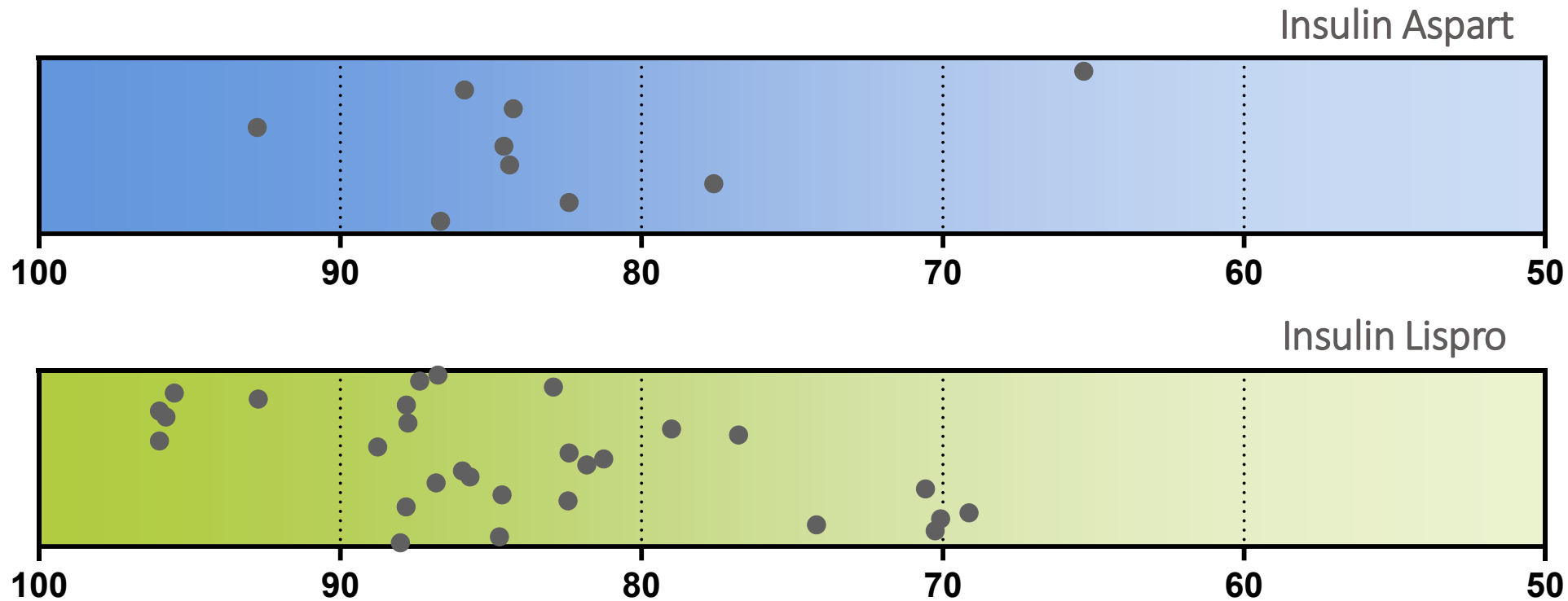
ITT of Insulin Aspart

Stressed insulin cannot lower BGL to the same extent as the positive control.



A Sneak Peak

Preliminary insulin activity data from anonymously donated real-world insulin samples.



Advancing insulin research together.

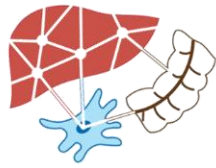
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