

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

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Globally, almost 600 million people are living with diabetes. Around 100 million of them require the biologic insulin for their diabetes management. Insulin is sensitive to its environment and exposure to heat, cold, extensive shaking, or light can reduce its efficacy, i.e., its ability to lower blood glucose levels (BGL). People living with diabetes (PwD) use insulin multiple times per day to keep their BGL within a specified range. If insulin efficacy is impaired by physical stress, it is unable to lower BGL to the extent required by PwD, resulting in undertreatment, psychological stress, and ultimately short- and long-term complications, including serious adverse events such as severe hypoglycaemia requiring hospitalization.

Within the INSPIRE LAB we have developed an in vitro (in cell Western = ICW) assay which allows us to determine the biological activity (= efficacy) of stressed insulins. Insulin tolerance tests (ITT) in non-diabetic mouse models verified our in vitro results. Storing insulin aspart in-use for 20d at 40°C (104°F) lead to a reduction of biological activity: – 20% in vivo and –30% in vitro. Anonymously donated real-world insulin samples underline our findings, none of the pens, reservoirs, or vials collected still had full efficacy compared to positive control. Overall, our research underscores the importance of real-world handling and storage conditions in maintaining biologic quality and, ultimately, therapeutic efficacy.