

Developing a Single Activity Assay Against 6 Biological Matrices for IND-Enabling Studies



Large Molecule Drug Discovery & Development Services:

Novel biotherapeutics are difficult to break through in today's market. Regulatory agencies are often specific and strict with what is required for a successful filing. At Prolytix, we offer unparalleled scientific expertise to tailor robust bioanalytical assays to support your products lifetime: from IND through commercialization.

> The Challenge:

Plan, develop, validate, and employ a novel assay that could measure a client's drug product within plasma and several different tissue matrices with only minor adjustments.

> Background:

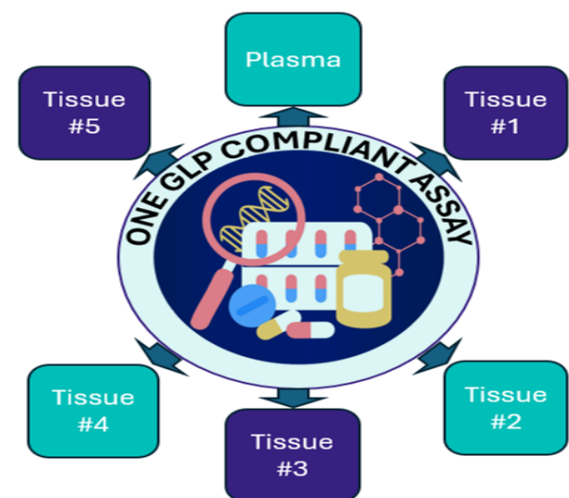
In support of a new filing, our client needed a unique assay that could detect their drug product in plasma and 5 different biological tissues. Each of these assays needed to be validated with a sensitivity ~5x lower than the concentration of interest. The client needed the basis of an assay they could provide to regulatory agencies for their filing to move their therapeutic to the next phase.

> Client Challenge:

In a limited amount of time, Prolytix was asked to immediately develop and validate an assay that could measure the concentration of the client's drug product in plasma for an animal study. Following that, modify the assay with minimal adjustments from tissue to tissue. The client required a robust assay that could also be developed, validated, and employed for additional challenge studies prior to their upcoming regulatory meeting.

> PROLYTIX Solution:

Whereas the clients's drug product was not compatible with traditional ELISAs, Our scientific experts here at Prolytix adeptly modified a commercial activity assay for evaluation of the drug product in plasma. Using similar scientific concepts, the development team transformed that assay to a *de novo* activity assay that can indirectly measure the target drug product in 5 different biological tissues. Prolytix created a robust assay with lower sensitivity that surpassed the clients needs and expectations. With this assay in hand, our client is confident it will exceed the requirements needed for their discussions with regulatory authorities. Prolytix is excited to help them through their next bioanalytical challenge.



Looking for the right partner for biotherapeutic development and release?

> GO WITH THE PRO

PROLYTIX
Biotherapeutic Experts
from Discovery to Release