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Simple, reproducible & robust bioassays in cryopreserved ready-to-assay format

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One of the major bottlenecks in the development of biosimilars is the need for good bioassays to create potency, stability and neutralizing antibody (NAb) assays. Ideal bioassays need to reflect the clinical mechanism of action (MOA) of the biopharmaceutical drug and should be simple, precise, reproducible and robust. Here, we discuss the development and application of diverse PathHunter® cell-based assays that cover distinct cellular mechanisms either downstream of or at the level of receptor engagement by biosimilar molecules. Importantly many of these assays rely on expression of native receptors thereby reflecting the clinical MOA of the biopharmaceutical drug. These assays are highly specific, quantitative, scalable, robust and utilize a homogenous mix-and-read protocol, which facilitates rapid and reproducible detection of drug potency. The technology is also amenable to accurate and sensitive detection of neutralizing antibodies, even in high concentrations of human serum through a simple chemiluminescent output. The assays are developed in a convenient ready-to-use format that minimizes assay variability often occurring due to cell culture. The cell preparation, bioassay protocol and reagents have been optimized to provide superior bioassay performance with high reproducibility (<10% RSD).

Biography

Nadia Tagnaouti has completed her PhD in Neuroscience at the age of 27 in Hamburg University, Germany. She has joined DiscoveRx, an innovative Drug Discovery provider, in 2008 and focused her activities in building the European Business as well as extending the company's activities in Eastern Europe and the Middle East. While initial activities were mainly dealing with small molecules drug discovery, she has played an active role in broadening the usage of DiscoveRx Bioassays to Biologics and Biosimilars.

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