

CANCER SCIENCE AND THERAPY**BIOMARKERS & CLINICAL RESEARCH**

October 18-20, 2017

Baltimore, USA

Recommendations and use for multiplex biomarker assays to support drug development**Paul W Rhyne**

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Multiplex ligand binding biomarker assays (LBAs) are commonly used to support many stages of drug development. The complexity of multiplex assays creates many unique challenges in comparison to single-plexed assays leading to various adjustments for validation and potentially during sample analysis to accommodate all of the analytes being measured. This often requires a compromise in decision making with respect to choosing final assay conditions and acceptance criteria of some key assay parameters, depending on the intended use of the assay. The critical parameters that are impacted due to the added challenges associated with multiplexing include the minimum required dilution (MRD), quality control samples that span the range of all analytes being measured, quantitative ranges which can be compromised for certain targets, achieving parallelism for all analytes of interest, cross-talk across assays, freeze-thaw stability across analytes, among many others. This session will describe the challenges encountered with multiplex LBAs and provide recommendations on how to address them.

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