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Validation of a Multiplex ADME SNP Assay for clinical trial studies. The Illumina® VeraCode® ADME Core Panel – an alternative to DMET

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Abstract

Assays for novel genetic biomarkers must be validated for use in late stage Clinical Trials. For example, the Illumina® VeraCode® ADME Core Panel Kit on the BeadXpress® System is one of the available pharmacogenetic platforms used to genotype human genomic DNA for variations in genes coding for proteins relevant to ADME. This method interrogates 184 biomarkers in 34 ADME-related genes which cover >95% of the genetic content considered by the PharmaADME Working Group to be important for pharmacogenetic drug studies including single nucleotide polymorphisms (SNPs), SNPs in close proximity, insertions/deletions (indels), homologous regions, and copy number variants.

In this study, the ADME Core Panel Kit was validated as a category IV (identity) test per International Council on Harmonization (ICH) Q2(R1) and current United States Pharmacopeia (cUSP) <1225> standards. The observed Call concordance and Call Rate performance was consistent with that expected of a mature ADME genotyping platform. The test system had additional performance characteristics that clearly distinguish it from its competitors and BioReliance is offering this validated assay to support clinical phase 1-4 trials in regulated environment. In particular, the Kit excels in the difference in acceptable mass of input genomic DNA relative to commercial competitor assays: DMET Plus Microarray and the iPLEX ADME PGx panel. A broad dynamic range is useful in cases where limited amounts of genomic DNA are available, for example, in the case of extraction from buccal swabs or FTA Cards.

Biography

Kolman leads the BioReliance Genomics business and supports biotech and pharmaceutical clients who require the custom validated information-rich test technologies such as massively parallel sequencing and genotyping. These services are available in regulated laboratories to clients in both the biologics manufacturing and clinical trial and diagnostics industries. Dr. Kolman received his PhD from Yale University and continued with a Post-doc at the Salk Institute, eventually rising to Staff Scientist. His career has been motivated by the study of difficult biological questions using new molecular approaches and a desire to “get closer to the patient”.