

nP.v3 Validation

The Tempus nP pharmacogenomics assay is a germline DNA test that clinically reports 13 genes with known roles in the pharmacokinetics and pharmacodynamics of, and immune response to, certain FDA approved medications. The assay includes genotyping for single nucleotide variants (SNVs), insertion-deletion variants (indels), and copy number variations (CNVs) in *CYP2D6*. The test is validated for use with genomic DNA isolated from saliva or buccal swabs. The Tempus nP assay uses MassARRAY (a MALDI-TOF system) for SNV and indel genotyping, and capillary electrophoresis for *CYP2D6* copy number change and *SLC6A4* promoter genotyping. The results from the MassARRAY and capillary electrophoresis workflows are married for bioinformatic analysis. Results of this genetic test can be used by clinicians to help inform treatment decisions (i.e., medication selection, medication dose).

TABLE 1: PERFORMANCE SPECIFICATIONS

Variant Class	Limit of Detection at 5ng/ul (at LOI*) DNA input (%)	Sensitivity (%)	Specificity (%)
Single Nucleotide Variants (SNVs)	>99	>99	>99
Insertions and Deletions	>99	>99	>99
<i>CYP2D6</i> Copy Number Variants	>99	>99	>99

* Limit of Input