

Internal Controls

Carefully designed positive and negative internal control assays are included in each reaction within the VeraCode ADME Core Panel to monitor sample processing and quality control (Figure 3). These controls aid in the identification of low DNA quality or quantity, reagent failures, operator failures, and run performance issues.

A panel of 13 high minor allele frequency SNPs are included as a positive control in each assay pool to create a sample barcode and enable detection of sample pipetting errors. Negative controls are included in each reaction to ensure proper pairing and position of assay subpools.

Integrated Software

VeraScan offers integrated system software with a convenient user interface that manages user authentication, enforces instrument maintenance, and produces detailed sample reports. Genotype data generated from a run is displayed in concise plots on the screen and is automatically translated into star allele calls in .CSV and .PDF reports. Reports can be configured to include specified genes and/or alleles within the ADME Core Panel for more focused analysis.

To ensure data integrity, the software only reports assay results when the controls perform as expected. Data from each assay pool is bioinformatically combined to create pharmacogenetic profiles for each sample. Sample identity is verified by the software using the 13 positive control SNPs present in each assay. Additionally, panel results are translated into a barcode that uniquely identifies each sample. This barcode is included in the analysis report for added traceability.

For added convenience, VeraReport, an off-line reporting tool that enables review of past runs and off-site analysis in other areas of the lab, is also included.

Conclusion

The VeraCode ADME Core Panel provides researchers with the most coverage of biologically relevant pharmacogenetic information. With a streamlined assay chemistry and precise, integrated internal controls, researchers can quickly and reliably assess pharmacogenetic profiles for their drug metabolism studies.

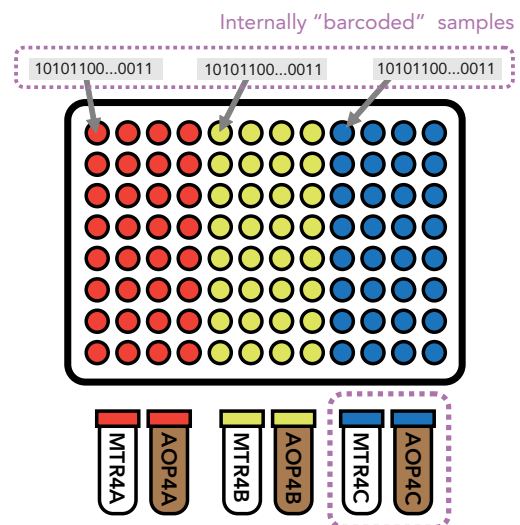
Table 2: ADME Core Panel Performance Specifications

| Parameter | Performance Specification | Illumina Validation (465 samples, 3 users, 3 systems) |
|-------------------------|---------------------------|---|
| Locus Success | ≥95% | ≥95% |
| Assay Time, 32 samples | | |
| DNA to data | ≤8 hr | 7 hr 38 min |
| Hands-on time | ≤2.5 hr | 1 hr 37 min |
| Sample Throughput | | |
| 1 user, 1 run, 1 plate | 32 | 32 |
| 1 user, 1 run, 2 plates | 64 | 64 |
| Average Call Rate | ≥98% | 99.5% |
| Concordance* | ≥99.5% | 99.8% |
| Reproducibility | ≥99.5% | 99.8% |

* Concordance with reference data from the Infinium® assay, Genome Analyzer, and Sanger sequencing.

In a study with 465 DNA samples, the VeraCode ADME Core Panel produced data with a high average call rate (99.49%), excellent reproducibility (99.77% on average), and high concordance (99.84% overall) with whole-genome genotyping and sequencing data for genotyping assays, and with quantitative PCR¹⁰ for CNV assays.

Figure 3: Fully Integrated Quality Control



Correct pairing of oligo pools is internally controlled

MTR = Subpool specific Targeting Mix
AOP = Subpool specific Assay Oligo Pool

Each VeraCode ADME Core Panel includes internal controls to monitor assay performance and detect potential error. Internally barcoded samples control for correct sample position and DNA quality and quantity while providing added traceability through a run. Negative controls monitor the correct pairing and position of the targeting mix and assay oligos within assay subpools.

