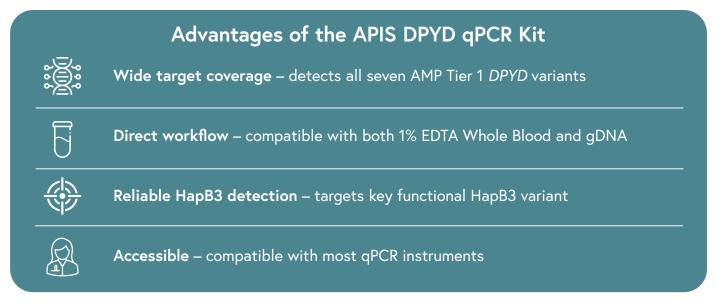




The APIS DPYD qPCR Kit is designed for fast and efficient detection of all seven Tier 1 *DPYD* alleles recommended for testing by AMP PGx Working Group¹. Each reaction identifies both wildtype (WT) and variant alleles, directly from blood or extracted genomic DNA (gDNA). The kit's rapid turnaround time, cost-effectiveness, and easy integration into existing qPCR workflows, makes it a perfect solution for both centralised and decentralised laboratories.

APIS



Analytical Sensitivity

The analytical sensitivity of the kit was evaluated by testing homozygous (wildtype) and heterozygous samples and defined as the minimum amount of DNA necessary to correctly genotype 95% of the samples. The APIS DPYD qPCR Kit can detect seven key *DPYD* variants in as little as 0.11ng gDNA.

Table 1: DPYD variants and analytical sensitivity of the APIS DPYD qPCR Kit

| Variant (NM_000110.4) | rsID | Sensitivity (ng per reaction) |
|-----------------------|-------------|-------------------------------|
| c. 1905+1G>A | rs3918290 | 0.11 |
| c.1679T>G | rs55886062 | 0.04 |
| c.1129-5923C>G | rs75017182 | 0.11 |
| c.557A>G | rs115232898 | 0.04 |
| c. 2846A>T | rs67376798 | 0.04 |
| c.868A>G | rs146356975 | 0.04 |
| c.2279C>T | rs112766203 | 0.04 |

1 AMP DPYD Genotyping Recommendations

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APIS DPYD qPCR Kit shows excellent concordance with alternative genotyping methods

gDNA extracted from 29 specimens with known *DPYD* variant status (characterised via NGS, microarrays or qPCR) and one synthetic DNA sample were assessed with the APIS DPYD qPCR Kit.

| Variant (NM_000110.4) | N° Homozygous WT specimens | N° Heterozygous specimens | N° Homozygous Variant specimens | N° of correctly genotyped specimens |
|--------------------------|-------------------------------|------------------------------|------------------------------------|--|
| c.1905+1G>A | 24 | 4 | 2 | 30/30 |
| c.1679T>G | 27 | 2 | 1 | 30/30 |
| c.1129-5923C>G | 23 | 5 | 2 | 30/30 |
| c.557A>G | 24 | 5 | 1 | 30/30 |
| c.2846A>T | 24 | 5 | 1 | 30/30 |
| c.868A>G | 26 | 3 | 1 | 30/30 |
| c.2279C>T | 24 | 5 | 1 | 30/30 |

Table 2: Concordance of the APIS DPYD qPCR Kit with other methods

APIS DPYD qPCR Kit Specifications

The kit has undergone testing as part of APIS unique RUO assay development pipeline, including both *in silico* and wet laboratory testing. As a result, researchers can depend on the kit for consistent and high-quality detection of *DPYD* variants. A positive and negative control (PC and NTC), which monitor assay set up and assay performance, are also supplied with the kit.

| Format | 11 Tubes: 7 PP mixes (Primer-Probes), 2 Enzyme mixes, 1 Positive Control, 1 Negative Control qPCR | | |
|----------------------|---|--|--|
| PCR Method | | | |
| Turnaround Time | lands-on Time <1 hours per PCR plate | | |
| Hands-on Time | | | |
| Intended Sample Type | | | |
| Instrument | | | |
| Shelf Life | | | |

APIS DPYD qPCR Kit Ordering Information

| Assay Name | Test Type | Kit Size | Catalogue Number | Price |
|--------------------|-----------|--------------------------|------------------|------------------------|
| APIS DPYD qPCR Kit | RUO | 24 samples plus controls | 03501 | Available upon request |

All scientific and analytical information in this brochure comes from the APIS DPYD qPCR Kit Handbook ART0180.

The APIS DPYD qPCR Kit is intended for Research Use Only (RUO). Not for use in diagnostic procedures.

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