CLAIMS

1. A method of assessing or evaluating a subject's likelihood of developing an adverse reaction in response to an administration of a therapeutic agent, or a method of assessing or evaluating a therapeutic agent's efficacy on a subject, the method comprising determining in a single real-time polymerase chain reaction run the presence of a variant in a set of genes consisting of CYP2D6, CYP2C9, CYP2C19 and SLCO1B1 in a sample obtained from the subject, wherein the presence of a variant on any one of the genes in the set of genes is indicative of a risk of an adverse reaction and/or change in efficacy to the therapeutic agent.

2. The method according to claim 1, wherein the presence of the variant is determined by providing a plurality of primer pairs and probes for amplifying a nucleic acid in the sample, wherein each primer pair amplifies a region of the nucleic acid associated with the genes or its variant, and detecting the presence or absence of a polymerase chain reaction product is indicative of the variant.

3. The method according to claims 1 or 2, wherein the variant of the gene is any variant selected from the group consisting of rs1065852, rs5030655, rs3892097, rs35742686, rs16947, rs28371725, rs1135840, rs769258, rs5030865, rs5030656, rs59421388, rs267608319, exon 9 conversion (*36), deletion (*5), rs1799853, rs1057910, rs4244285, rs4986893, rs12248560 and rs4149056.

4. The method according to any one of claims 2 or 3, wherein the plurality of primer pairs and probes is any one selected from the list in Tables 3 and 4.

5. The method according to any one of claims 2 to 4, wherein the plurality of primer pairs comprises at least one primer pair for amplifying a conserved area of the gene.

6. The method according to any one of the preceding claims, wherein the method further comprises the step of determining the presence of the copy number variation comprising an RNaseP as a housekeeping gene.

7. The method according to claim 6, wherein the step of determining the presence of the copy number variation further comprising providing a control having a human genomic DNA to determine the subject's CYP2D6 gene copy number variations.

8. The method according to any one of claims 2 to 7, wherein the probes for targeting non-variant genes are tagged with a FAM fluorophore at the 5' end, and the probes for targeting variant genes are tagged with HEX or Cy5 fluorophore at the 5' end.

9. The method according to claim 6, wherein the probes for targeting the copy number variation of CYP2D6 are tagged with a FAM fluorophore at the 5', and the probes for targeting the housekeeping gene are tagged with a VIC fluorophore at the 5' end.

10. The method according to claim 9, wherein the probes have a 3' modification of either a BHQ1 quencher, an IBFQ quencher, or an IBRQ quencher.

11. The method according to any one of claims 8 to 10, wherein the ratio between primer pairs and FAM, HEX, Cy5 probes are asymmetric.

12. The method according to any one of the preceding claims, wherein the therapeutic agent is any one selected from the list in Table 2.

13. The method according to any one of the preceding claims, wherein the single real-time polymerase chain reaction run comprises 50 cycles of denaturation and annealing/extension, said denaturation is carried out at about 95°C for about 15 seconds and said annealing/extension is carried out at about 60°C for about 60 seconds.

14. A kit comprising a plurality of means for assessing or evaluating a subject's likelihood of developing an adverse reaction in response to an administration of a therapeutic agent, or for assessing or evaluating a therapeutic agent's efficacy on a subject by determining in a single real-time polymerase chain reaction run the presence of a variant in a set of genes consisting of CYP2D6, CYP2C9, CYP2C19 and SLCO1B1 in a sample obtained from the subject, wherein the presence of a variant on any one of the genes in the set of genes is indicative of a risk of an adverse reaction and/or change in efficacy to the therapeutic agent, wherein the plurality of means are selected from the group consisting of primer pairs and probes set out in Tables 3 and 4.