CLAIMS

1. An *in vitro* method for genotyping one or more single–nucleotide polymorphisms (SNPs) in a nucleic acid sample, said method comprising:

a) amplifying one or more regions of the nucleic acid containing the SNP(s) to be genotyped, the amplification products comprising a label capable of directly or indirectly generating a detectable signal, and

b) analysing the amplification products obtained in step (a) using a lateral–flow assay device comprising a reaction zone comprising one or more nucleotide probes, preferably at least two nucleotide probes, immobilized on distinct sites, each probe having a sequence complementary to an allelic variant of a SNP to be genotyped,

the detection of a signal at the probe immobilization site indicating that the nucleic acid comprises the allelic variant specific of the probe,

and wherein the lateral flow assay device comprises a porous matrix comprising a nitrocellulose membrane.

2. The method according to claim 1, wherein the amplification is carried out by asymmetric PCR, preferably by LATE–PCR.

3. The method according to claim 1 or 2, wherein the simultaneous amplification of several regions of the nucleic acid is carried out by multiplex PCR.

4. The method according to any one of the preceding claims, wherein the amplification products are 5′–labelled, preferably by the use of 5′–labelled primers during the amplification.

5. The method according to any one of the preceding claims, wherein the amplification products are labelled with a coloured, luminescent, fluorescent, phosphorescent

or radioactive compound, with an enzyme or the first member of a ligand/anti–ligand pair, preferably with a biotin.

6. The method according to any one of the preceding claims, wherein the lateral–flow assay device comprises

a porous matrix comprising

(i) a migration buffer application zone,

(ii) an amplification product application zone positioned downstream of the migration buffer application zone, and

(iii) the reaction zone positioned downstream of the amplification product application zone, and

(iv) optionally, a reagent migration monitoring zone downstream of the reaction zone, and/or

(v) optionally, a labelling zone comprising a substrate or binding partner specific for the amplification product label capable of directly or indirectly generating a detectable signal, positioned downstream of the migration buffer application zone and upstream of the amplification product application zone, and/or

(vi) optionally, an absorbent pad positioned downstream of the reaction zone or the monitoring zone when the latter is present,

the various zones of the porous matrix being in fluid communication with the adjacent zone(s) and the absorbent pad being in fluid communication with the porous matrix.

7. The method according to any one of the preceding claims, wherein the amplification products are analysed directly using the lateral–flow assay device with no preliminary purification or denaturation step.

8. The method according to any one of the preceding claims, wherein the analysis comprises

i) loading the amplification products obtained in step (a) onto the lateral–flow assay device

ii) applying a migration buffer on said device,

iii) incubating the device until the signals generated directly or indirectly by the amplification product label are detected in the reaction zone and/or a signal is detected in the migration monitoring zone, when the latter is present, and

iv) reading and interpreting the results.

9. The method according to any one of the preceding claims, wherein the matrix is further made of polyester, glass fibre, cellulose fibre, polyether sulphone (PES) and/or cellulose ester.

10. The method according to any one of the preceding claims, wherein the nitrocellulose membrane comprises the reaction zone of the matrix.

11. The method according to claim 10, wherein the nitrocellulose membrane further comprises the amplification product application zone and/or the monitoring zone of the matrix, preferably the amplification product application zone and the monitoring zone of the matrix.

12. The method according to any one of the preceding claims, wherein the migration buffer application zone of the matrix and/or the absorbent pad are made of cellulose fibre.

13. The method according to any one of the preceding claims, wherein the labelling zone of the matrix is made of glass fibre.

14. The method according to any one of the preceding claims, wherein the migration buffer comprises a buffer system for maintaining a neutral pH, one or more surfactants and/or one or more denaturing agents that destabilize hydrogen bonds.

15. The method according to any one of the preceding claims, wherein the nucleic acid to be genotyped and contained in the sample is genomic DNA, preferably human genomic DNA.

16. The method according to any one of the preceding claims, wherein the nucleic acid sample is a total blood, serum or plasma sample.

17. The method according to claim 16, wherein the step of amplifying one or more regions of the nucleic acid containing the SNP(s) to be genotyped is carried out on the total blood, serum or plasma sample, with no preliminary step of partial or total purification of the nucleic acid.

18. The method according to any one of the preceding claims, wherein the amplification product label is biotin, and the migration buffer or the labelling zone comprises an anti–biotin antibody coupled to a detectable label, preferably coupled to a gold particle.

19. A kit comprising a lateral–flow assay device as defined in any one of claims 6 and 9 to 13, and at least one primer pair for amplifying a genomic region containing one or more SNPs, and optionally a migration buffer, the amplification reagents, preferably dNTPs, a polymerase and/or a buffer, and/or an instruction leaflet explaining the use of said kit.

20. The kit according to claim 19, comprising one or more primer pairs for amplifying one or more genomic regions containing one or more SNPs associated with blood group antigen systems, preferably the Duffy, MNS and/or Kidd systems.

21. The kit according to claim 19 or 20, comprising one or more primers selected from the group consisting of SEQ ID NO: 1 to 8.

22. Use of the kit according to any one of claims 19 to 21, for genotyping one or more SNPs according to the method of any one of claims 1 to 18.