[0016] Some aspect of the invention also aims to provide compatibility tests which are easy to produce. The latter reduces production costs.

Summary ~~of the invention~~

[0017] In one aspect, there is provided an assaying kit for testing pre-transfusion blood group matching between two blood samples, said kit comprising at least two assemblies corresponding to a first and a second blood sample, each assembly comprising at least two test units, each test unit comprising:

- a reagent containing an antibody able to bind to an antigen present on erythrocytes, and
- a membrane permeable to free erythrocytes and impermeable to hemagglutinated erythrocytes, wherein the antibody contained in the first test unit for both the first assembly and the second assembly is corresponding to a first blood group and the antibody contained in the second test units for both the first assembly and the second assembly is corresponding to a second blood group, and each assembly comprises means for receiving a blood sample and distributing said blood sample between the test units of each assembly and said kit comprising a device comprising a rotating support, for supporting the first assembly and the second assembly, said rotating support being suitable for generating in use a flow of the blood sample through the membrane by centrifugation.

~~The present invention is related to~~In one example, there is provided a method for assaying (detecting the presence) an analyte present (artificially or naturally) in a biological sample, said analyte being a first member of a binding pair, said binding pair consisting of an antigen present on erythrocytes and an antibody binding to said antigen present on erythrocytes, said method comprising the step of :

- treating the biological sample with a reagent containing the second member of the binding pair to generate hemagglutination in a test unit,
- separating by filtration through a membrane permeable to free erythrocytes and impermeable to hemagglutination, the hemagglutination, if any has formed, from the free erythrocytes, and
- detecting said free erythrocytes and/or said hemagglutination and correlating the presence of the analyte in the sample through the detection of free erythrocytes downstream of the membrane and/or hemagglutination upstream of the membrane.

[0018] ~~Advantageously~~In one example, the upper and lower limits of the pores sizes of the membrane can be combined to yield optimal porosity ranges, depending on the

erythrocyte size in the biological sample (i.e. mainly depending on the species from which the erythrocyte originates). The lowest porosity limit for the membrane is the diameter of the involved free cell from a *species*; the diameter of a human RBC is 6 to 8 µm. Included in the porosity range is two times the diameter of the involved free cell. ~~Preferably~~In a specific example, the membrane has a porosity comprised between 6 µm and 25 µm.

[0019] ~~Advantageously~~In one example, the membrane is free of an analyte-binding material.

[0020] ~~Preferably~~In one example, the membrane or a layer thereof is selected from the group consisting of woven tissue, non woven tissue, track-etched membrane and a porous film or a combination thereof. ~~More preferably~~In one specific example, the membrane or a layer thereof comprises (or essentially consist of) polyamide.

[0021] ~~Advantageously~~In one example, the filtration is promoted by centrifugation, capillarity, vacuum downstream of the membrane, overpressure upstream of the membrane or a combination thereof. In one example~~Preferably~~, in case of vacuum or overpressure, the difference of pressure should be adapted to avoid hemolysis.

[0022] ~~Advantageously~~In one example, the analyte to be assayed is a blood group antigen present on erythrocytes or an antibody binding to a blood group antigen.

[0023]~~Preferably~~In one example, the free erythrocytes or the hemagglutination is detected by optical means, such as preferably IR absorption measurements. Alternatively or in combination of optical detection, the detection can be done or checked by visual observation.

[0024]~~Advantageously~~In one example, the detection of the erythrocytes or the hemagglutination is compared with an assay without the second member of the binding pair (blanco).

[0025]~~Preferably~~In one example, the biological sample comprises whole blood.

[0026]~~Advantageously~~In one example, at least two analyte are assayed simultaneously in two separate test units, a first analyte corresponding to A blood group antigen or antibody binding to the said antigen and the second analyte is corresponding to B blood group antigen or antibody binding to the said antigen.

[0027]~~Preferably~~In one example, a third test unit is used for assaying an analyte corresponding to Rh blood group antigen or antibody binding to the said antigen.

[0028]~~A second aspect of the invention is related to~~In present disclosure also provides a method for verifying (transfusional) compatibility matching wherein the blood group antigens or antibodies of two biological samples are tested essentially simultaneously by the method ~~of the invention~~as disclosed herein, the two biological samples corresponding to a first individual and a second individual and wherein the results are compared for compatibility matching.

[0029]~~Advantageously~~In one example, the first individual is corresponding to a donor, and the second individual is corresponding to a recipient. ~~More preferably~~In another example the compatibility matching verification is performed at the point of care (recipient's room) just before administration of a transfusion.

[0030]~~Preferably~~In one example, the results are further compared to predetermined data stored in a database.

[0031]~~A third aspect of the invention is related to~~In one example there is provided a kit suitable for use in the process according to the ~~second aspect of the invention~~the present disclosure for (transfusional) compatibility matching between two samples , said kit comprising at least two test units for the first sample and two test units for the second sample, each unit comprising:

- a reagent containing an antigen present on erythrocytes or an antibody able to bind to an antigen present on erythrocytes, and
- a membrane permeable to free erythrocytes and impermeable to hemagglutination,

wherein the antigen or antibody contained in the first test units for both the first sample and second sample is corresponding to a first blood group (A) and the antigen or antibody

contained in the second test units for both the first sample and second sample is corresponding to a second blood group (B).

[0032] ~~Preferably~~In one example, the kit ~~of the invention~~ further comprises filtering promotion (centrifugation) means for generating a flow of the biological sample through the membrane.

[0033] ~~Advantageously~~In one example, the test units comprises a first cavity for receiving the reagent and the biological sample and a second cavity for receiving the filtrate, the first and second cavity being separated by the membrane.

[0034] ~~Advantageously~~In one example, the kit further comprise optical means for detecting free erythrocytes in the second cavity and/or for detecting hemagglutination on the membrane. ~~More preferably~~In one example, optical detection is performed on both the membrane and the second cavity for improving reliability of the test.

[0035] ~~Advantageously~~In one example, the test units corresponding to each sample are assembled in assemblies, one assembly corresponding to a donor blood sample, and one assembly for the recipient blood sample.

[0036] ~~Preferably~~In one example, each assembly is produced in one part, for example by polymer injection molding.

[0037] ~~Another aspect of the invention, is related to~~Also provided here is a procedure for reducing the probability of ABO compatibility mistakes wherein the method for assaying an analyte in a biological sample, said analyte consisting of an antigen present on erythrocytes or an antibody binding to an antigen present on erythrocytes is used as POCT. ~~Preferably~~In one example in said procedure telecommunication means are used to compare the results of the method for assaying with a database of a central laboratory, permitting an additional verification of the compatibility match.

Brief Description of the Drawings

[0038] Fig. 1 represents an example of a test unit used according to one preferred embodiment of the invention before testing.

[0039] Fig. 2 represents an example of a test unit used according to one preferred embodiment of the invention after testing, with free erythrocyte passing through the membrane.

[0040] Fig. 3 represents an example of a test unit used according to one preferred embodiment of the invention after testing, with agglutinated erythrocyte on the membrane.

[0041] Fig. 4 represents an example device used in an embodiment of the invention.

CLAIMS

1. An assaying kit for testing pre-transfusion blood group matching between two blood samples , said kit comprising at least two assemblies (101,201) corresponding to a first and a second blood sample, each assembly comprising at least two test units (1), each test unit (1) comprising:

- a reagent containing an antibody able to bind to an antigen present on erythrocytes, and

- a membrane (2,102,202) permeable to free erythrocytes (6) and impermeable to hemagglutinated erythrocytes,

wherein the antibody contained in the first test unit for both the first assembly (101) and the second assembly (201) is corresponding to a first blood group and the antibody contained in the second test units for both the first assembly (101) and the second assembly (201) is corresponding to a second blood group, and each assembly comprises means for receiving a blood sample and distributing said blood sample between the test units of each assembly and said kit comprising a device comprising a rotating support (300), for supporting the first assembly (101) and the second assembly(201), said rotating support (300) being suitable for generating in use a flow of the blood sample through the membrane (2) by centrifugation.

2. The assaying kit according to claim 1 wherein the antibody contained in the first test unit of each assembly is corresponding to blood group A and the antibody contained in the second test unit of each assembly is corresponding to blood group B.

3. The assaying kit according to claim 1 or 2 wherein each of the at least two assemblies of the kit further comprises a third test unit (110r, 210r) without antibody, used as a control unit.

4. The assaying kit according to any of the previous claims wherein each of the at least two assemblies of the kit further comprises an additional test unit (110r, 210r) containing an antibody corresponding to the Rhesus (Rh) blood group.

5. The assaying kit according to any of the previous claims wherein each test unit (1) comprises a first cavity (9, 109a, 109b, 209a,209b) for receiving the reagent and the biological sample (3) and a second cavity (10,110a,110b, 210a,210b) for receiving the filtrate (6 or 8) , the first and second cavity being separated by the membrane (2, 102,202).

~~6. The assaying kit according to any of the previous claims wherein each assemblies comprises means for receiving a blood sample and distributing said blood sample between the test units of each assembly.~~

~~7.~~6. The assaying kit according to any of the previous claims~~claim 6~~, wherein the means for receiving the blood sample of the assembly (101) corresponding to the first blood sample further comprises means (120) for taking a blood sample from a blood bag, said means being not adapted to receive a sample directly sampled from an individual.

~~8.~~7. The assaying kit according claim ~~6~~7 wherein the means for receiving the blood sample of the assembly (101) corresponding to the first blood sample further comprises an hollow needle (120) able to pierce a plastic tube of a blood bag to take a blood sample and said hollow needle (120) being unable to directly take a blood sample from an individual.

~~9.~~8. The assaying kit according to any of the previous claims~~claim 6 to 8~~, wherein the means for receiving the blood sample of the assembly (201) corresponding to the second blood sample further comprises means (220) for receiving a blood sample from a syringe, said means being not adapted to take a sample directly from a blood bag or a blood bag tubing.

~~10.~~9. The assaying kit according claim ~~8~~9 wherein the means for receiving the blood sample of the assembly (101) corresponding to the second blood sample further comprises a female luer or a septum able to receive a blood sample from a syringe.

~~11.~~10. The assaying kit according to ~~claim 1~~any of the previous claims wherein the device further comprises optical sensor(s) for detecting the presence either of hemaglutinated erythrocytes (7) on the membranes, or of erythrocytes (6) downstream (10) of the membranes.

~~12.~~11. The assaying kit according to claim 10~~11~~ wherein each assembly comprises an optical marker (335,334) for checking the presence of both assemblies, and for aligning the optical sensors with the assemblies.

~~13.~~12. The assaying kit according to any of the previous claims ~~1~~ wherein the device further comprises communication means for comparing the results of the compatibility test with predetermined compatibility data stored in a database.