Treaty Series No. 75 (1978)

Revised Text

of the Protocol to the European Agreement on the Exchanges of Blood-Grouping Reagents

(with Annex)

adopted by the Committee of Ministers of the Council of Europe on 1 October 1977

Presented to Parliament
by the Secretary of State for Foreign and Commonwealth Affairs
by Command of Her Majesty
August 1978

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REVISED TEXT OF THE PROTOCOL TO THE EUROPEAN AGREEMENT ON THE EXCHANGES OF BLOOD-GROUPING REAGENTS AND ANNEX TO THE SAID PROTOCOL

Certificate of the Secretary General of the Council of Europe

Whereas it is stated in the fourth paragraph of Article 4 of the European Agreement of 14 May 1962 on the Exchanges of Blood-grouping Reagents[1] that the Protocol[2] and its Annex may be amended or supplemented by the Governments of the Contracting Parties to the said Agreement;

Whereas, at the 254th meeting of the Ministers' Deputies held in Strasbourg from 9 to 18 February 1976, the representatives to the Committee of Ministers of the Council of Europe of the Governments of Belgium, Cyprus, Denmark, France, Ireland, Italy, Luxembourg, Malta, the Netherlands, Norway, Sweden, Switzerland, Turkey and the United Kingdom, Contracting Parties to the said Agreement, approved the proposal by the European Public Health Committee to replace the units of measurement haematology by the International System of Units (SI) in the Protocol to the European Agreement on the Exchanges of Blood-grouping Reagents;

Whereas at the same meeting, the representatives of the above-mentioned Governments further agreed that the Governments of the Contracting Parties to the Agreement, which are not represented on the Committee of Ministers, should be invited to make known their agreement to the amendments made to the said Protocol;

Whereas, at the 265th meeting of the Ministers' Deputies held in Strasbourg from 14 to 21 February 1977, the representatives of the above-mentioned Governments took note of the revision of the text of the Protocol to the European Agreement on the Exchanges of Blood-grouping Reagents;

Whereas by letters of the Secretary General dated 31 August 1977, the Governments of the Principality of Liechtenstein and of Spain, Contracting Parties to the Agreement, but not represented on the Committee of Ministers, were invited to make known their agreement to the amendments made to the said Protocol before 1 October 1977;

Whereas by letters of 5 September 1977 and 29 November 1977 respectively, the Governments of the Principality of Liechtenstein and of Spain made known their agreement to the said amendments,

The Secretary General hereby certifies as follows :

The following text constitutes the Protocol to the European Agreement on the Exchanges of Blood-grouping Reagents.

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(1) Treaty Series No. 28 (1965), Cmnd. 2596.

(2) Treaty Series No. 111 (1968), Cmnd. 3823 (text as revised in January 1968).

PROTOCOL
TO THE EUROPEAN AGREEMENT ON THE EXCHANGES OF BLOOD-GROUPING REAGENTS
GENERAL PROVISIONS

1. *Specificity*

A blood-grouping[3] reagent must react with all blood samples tested which contain the antigen homologous to the antibody or other substance mentioned on the label.

When a reagent is used according to the technique recommended by the producer there must be no evidence of any of the following factors or phenomena:

(*a*) haemolytic properties;

(*b*) antibodies or other substances besides those mentioned on the label;

(*c*) bacterial products liable to cause false positive or false negative reactions;

(*d*) pseudo-agglutination through the formation of rouleaux;

(*e*) prozone phenomena.

2. *Potency*

Titre is measured by making successive two-fold dilutions of the reagent under study in an appropriate medium. To each dilution is added an equal volume of a suspension of red corpuscles. The titre is the reciprocal of the figure representing the highest serum dilution in which a reaction occurs, the dilution being calculated without the inclusion of the volume of the corpuscular suspension in the total volume.

In the case of anti-A, anti-B and other reagents intended for use on slides, avidity is expressed by means of the time required for agglutination on a slide.

3. *International Standards and International Units*

International Standards have been established by the World Health Organisation for anti-A and anti-B and incomplete anti-D blood-grouping reagents and are in process of being established for blood-grouping reagents of other specificities. An International Standard Preparation contains, by

(3) At the time of approving the present version of the Protocol and its annexes, it was understood by the representatives of the Contracting Parties that when in the English text of the Agreement the expression " blood incompatibilities " was mentioned, " blood grouping incompatibilities " was implied.

It was also agreed that the expression " blood-grouping " with a hyphen in the English text of the Agreement and of the Protocol should read as " blood grouping " without a hyphen.

definition, a certain number of International Units per mg or ml and this definition is independent of the titres observed against particular red corpuscle preparations(4).

4. *Stability and expiry date*

Each reagent, when kept under the conditions of storage recommended by the manufacturer, should retain the requisite properties for at least one year.

The expiry date of a reagent in the liquid form as given on the label shall be not more than one year from the date of the last satisfactory potency test. The expiry date can be extended for further periods of one year by repetition of potency tests.

The expiry date of reagents in the dried form as given on the label, shall be in accordance with evidence obtained from experiments on stability and shall be approved by the national control authorities.

5. *Preservation*

Blood-grouping reagents may be preserved in the liquid or dried state. Dried reagents shall be kept in an atmosphere of an inert gas or in vacuo, in the glass container in which they were dried and which shall be closed so as to exclude moisture. A dried reagent must not lose more than 0·5 per cent of its weight when tested by further drying over phosphorus pentoxide at a pressure not exceeding 0·02 mm of mercury for 24 hours.

Reagents shall be prepared with aseptic precautions and shall be free from bacterial contamination. In order to prevent bacterial growth the competent national authority may decide that an antiseptic and/or antibiotic

(4) The potency of blood-grouping reagents of most specificities is expressed as the agglutination titre observed in a dilution series, against a suspension of red-cells. The titre indicates the dilution of reagent in the last mixture of the series which shows agglutination microscopically visible.

The potency of blood-grouping reagents for which International Standard Preparations exist (at present anti-A and anti-B and incomplete anti-D) can be expressed in International Units* on the basis of the titration of the unknown reagent in comparison with the International Standard, or a national sub-standard.

The International Standard Preparations of blood-grouping sera are dispensed in ampoules containing dried human serum. When reconstituted to the volume of 1 ml, the anti-A and anti-B sera contain by definition 256 International Units per ml. They can be obtained free of charge, from the International Laboratory for Biological Standards of WHO, Statens Seruminstitut, Copenhagen.

The following table shows an example of a comparative titration of the International Standard anti-A Serum (S) and an " unknown " anti-A reagent (U) against A_1 red corpuscles and A_2B red corpuscles.

	Serum S	Reagent U	Serum S	Reagent U
A_1 corpuscles	1 : 512	1 : 128	256	64
A_2B corpuscles	1 : 32	1 : 16	256	128
	titres (observed)	titres (observed)	Units (by definition)	Units (by comparison)

* See Bull. Wld. Hlth. Org. 1954, 10, 937, 941—1950, 3, 301.

shall be added to the reagent (or to any solvent issued with dried reagents), provided that, in the presence of the added substance, the reagent still fulfils the requirements for specificity and potency.

Blood-grouping sera of human origin must contain at least 2·5 mg of protein nitrogen per ml of liquid or reconstituted serum.

Reagents whether in the liquid state or after reconstitution should be transparent and should not contain any sediment, gel or visible particles.

6. *Coloration*

Blood-grouping reagents for international exchanges should preferably not be artificially coloured at least until an international agreement is reached on a uniform system. Any added colouring matter must not interfere with the specific reaction.

7. *Dispensing and volume*

Blood-grouping reagents shall be dispensed in such a way and in such volumes that the reagent in one container is sufficient for the performance of tests with positive and negative control corpuscles in addition to the performance of tests with the unknown corpuscles. The volume in one container shall be such that the contents can if necessary be used for the performance of the appropriate tests for potency described in this Protocol.

8. *Records and samples*

Written records shall be kept by the producing laboratory of all steps in the production and control of blood-grouping reagents. Adequate samples of all reagents issued shall be retained by the laboratory until it can be reasonably assumed that the batch is no longer in use.

9. *Classification of reagents*

Reagents used for blood-grouping may contain substances of human, animal, vegetable (or mineral) origin, of which some constitute the active principle and others are adjuvants for enhancing the activity or maintaining the stability of the reagent.

For technical reasons these reagents have been divided into three categories according to the origin of their active principle. This does not mean that reagents of human origin contain exclusively substances of human origin or that animal or vegetable reagents cannot contain substances of human origin.

10. *Labels, leaflets and certificates*

A label printed in English and French, in black on white paper, shall be affixed to each final container and shall contain the following information:

1. Name and address of producer
2. Name of the reagent as it appears in the heading of the relevant specification
3. Name and amount of antiseptic and/or antibiotic, if present, or indication of absence

4. The volume or, where the reagent is dried, the volume and composition of the fluid needed for reconstitution
5. Expiry date
6. Batch number.

Moreover, this label or the label of the carton enclosing several final containers, or the leaflet accompanying the containers, shall contain the following information:

1. Full name and address of producer
2. Name of the reagent as it appears in the heading of the relevant specification
3. The volume, or, where the reagent is dried, the volume and composition of the fluid needed for reconstitution
4. Date of last potency test
5. Expiry date (if any)
6. Batch number
7. Adequate description of the method of use recommended by the producer
8. Conditions of storage of unopened ampoules and precautions to be taken after opening
9. Exact composition, including antiseptic and/or antibiotic if any
10. Statement whether the product contains or does not contain material of human origin.

Each consignment shall be accompanied by a certificate as provided in Article 4 of the Agreement and the Annex to the present Protocol. Examples of labels and leaflets are attached to the present Protocol.

SPECIFIC PROVISIONS

A. BLOOD-GROUPING SERA OF HUMAN ORIGIN

(a) *Sera of human origin for ABO grouping*

(i) *Anti-A blood-grouping serum (human)*

Anti-A serum is derived from the blood of selected group B persons, who may or may not have been immunised by group A red corpuscles or group A specific substance. Anti-A serum agglutinates human red corpuscles containing A antigen, i.e. those of blood groups A and AB, including sub-groups A_1, A_2, A_1B and A_2B, and does not agglutinate human red corpuscles which do not contain A antigen, i.e. those of blood groups O and B.

Potency

Titration

An anti-A serum shall be titrated separately against suspensions of A_1, A_2, and A_2B corpuscles, in parallel with the reconstituted but undiluted International Standard Preparation of anti-A blood-grouping serum or an equivalent reference preparation. The potency of the serum shall in each case be not less than 64 International Units per ml.

Determination of avidity

When anti-A serum is mixed on a slide with an equal volume of a suspension of A_1, A_2 and A_2B cells with a volume fraction of 0·05 to 0·1, agglutination of each suspension should first appear in not more than twice the time taken when the same test is performed with the reconstituted but undiluted International Standard Preparation of anti-A blood-grouping serum or with a reference standard of equivalent avidity.

(ii) *Anti-B blood-grouping serum (human)*

Anti-B serum is derived from the blood of selected group A persons, who may or may not have been immunised by group B red corpuscles or group B specific substance. Anti-B serum agglutinates human red corpuscles containing B antigen, i.e. those of blood groups B and AB, and does not agglutinate human red corpuscles which do not contain B antigen, i.e. those of blood Groups O and A.

Potency

Titration

An anti-B serum shall be titrated against a suspension of group B corpuscles in parallel with the reconstituted but undiluted International Standard Preparation of anti-B blood-grouping serum or an equivalent reference preparation. The potency of the serum shall be not less than 64 International Units per ml.

Determination of avidity

When anti-B serum is mixed on a slide with an equal volume of a suspension of B cells with a volume fraction of 0·05 to 0·1, agglutination should first appear in not more than twice the time taken when the same test is performed with the reconstituted but undiluted International Standard Preparation of anti-B blood-grouping serum or with reference standard of equivalent avidity.

(iii) *Anti-A + Anti-B (group O) blood-grouping serum (human)*

Anti-A + anti-B (group O) serum is derived from the blood of selected group O persons who may or may not have been immunised by Group A and group B red corpuscles or group A and group B specific substances. Anti-A + anti-B (group O) serum agglutinates human red corpuscles containing A or B agglutinogens or both, *i.e.* those of group A including sub-groups A_1 and A_2, group B and group AB including sub-groups

A_1B and A_2B, and does not agglutinate human red corpuscles which do not contain A or B agglutinogens, *i.e.* those of group O. It agglutinates human red corpuscles containing the A_x (A_y or A_0) antigen (which are not, in general, agglutinated by anti-A serum derived from group B donors).

Potency

Titration

An anti-A + anti-B (group O) serum shall be titrated separately against suspensions of A_1, and A_2 corpuscles in parallel with the reconstituted but undiluted International Standard Preparation of anti-A blood-grouping serum or an equivalent standard preparation. It shall also be titrated against a suspension of group B corpuscles in parallel with the reconstituted but undiluted International Standard Preparation of anti-B blood-grouping serum or an equivalent standard preparation.

The potency of the serum shall in every case be not less than 64 International Units per ml.

Anti-A + anti-B (group O) blood-grouping serum used undiluted shall also give readily detectable agglutination of group A_x (A_y or A_0) corpuscles.

Determination of avidity

When anti-A + anti-B (group O) serum is mixed on a slide with equal volumes of suspensions of A_1 and A_2 cells with a volume fraction of 0·05 to 0·1 agglutination shall first appear in not more than twice the time taken when the same tests are performed with the reconstituted but undiluted International Standard Preparation of anti-A blood-grouping serum or with a reference standard of equivalent avidity. When anti-A + Anti-B (group O) serum is mixed on a slide with an equal volume of a suspension of B cells with a volume fraction of 0·05 to 0·1, agglutination shall first appear in not more than twice the time taken when the same test is performed with the reconstituted but undiluted International Standard Preparation of anti-B blood-grouping serum or a reference preparation of equivalent avidity. When anti-A + anti-B (group O) serum is mixed on a slide with an equal volume of a suspension of A_x (A_y or A_0) cells with a volume fraction of 0·05 to 0·1, agglutination shall first appear in not more than 5 minutes at a temperature between 18 and 25°C.

(b) *Sera of human origin for Rh grouping*

Anti-Rh blood grouping sera, whatever their specificity, may be of either of two varieties differing in the conditions under which agglutination of homologous corpuscles is obtained. Certain sera commonly known as "complete" agglutinate corpuscles suspended in saline. With others, commonly known as "incomplete", agglutination can only be obtained in the presence of certain colloids such as bovine albumin or by means of other special techniques. The sera should be used under the conditions specified by the laboratory preparing them.

Some " incomplete " sera will also agglutinate homologous red corpuscles suspended in their own serum or plasma on slides.

The following requirements of potency for Rh grouping sera may need to be revised when International Standard Preparations become available.

(i) *Anti-D (anti-Rh_0) blood-grouping serum (human)*

Anti-D serum is derived from the blood of one or more persons immunised by the D antigen of the Rh system. It reacts with human red corpuscles containing the D antigen, but not with human red corpuscles which do not contain the D antigen.

Potency

Titration

" Complete " anti-D sera shall have a titre not less than 32 against CcDee cells in a solution containing 9 gram sodium chloride per litre.

An " incomplete " anti-D serum shall be titrated against CcDee corpuscles in parallel with the reconstituted but undiluted International Standard Preparation of Incomplete Anti-D (anti-Rh_0) or an equivalent reference preparation. It shall have a potency of not less than 32 International Units. Besides reacting with all red corpuscles containing the D antigen, the serum should, as far as possible, react with corpuscles containing the D^u antigen.

Determination of avidity

Anti-D sera intended for use in the slide test of Diamond and Abelson should, when mixed on a slide with an equal volume of a 40% to 50% suspension of CcDee corpuscles at approximately 40°C, show visible agglutination within 30 seconds, and agglutination should be complete within 120 seconds.

(ii) *Anti-C (anti-Rh') blood-grouping serum (human)*

Anti-C serum is derived from the blood of one or more persons immunised by the C agglutinogen of the Rh system. It agglutinates suspensions of human red corpuscles containing the C antigen, but not with human red corpuscles, which do not contain the C antigen. In this connection the C antigen is regarded as including the C^w antigen.

Most diagnostic anti-C sera contain " complete " anti-C together with " incomplete " anti-D. These sera are therefore specific for the C antigen only when the cells under test are suspended in a solution containing 9 gram sodium chloride per litre.

Potency

Titration

Anti-C sera (" complete " or " incomplete ") should have a titre not less than 8 against Ccddee corpuscles.

Determination of avidity

Anti-C sera intended for use in the slide test of Diamond and Abelson (and which must not contain any form of anti-D) should, when mixed on a slide with an equal volume of a suspension of Ccddee cells with a volume fraction of 0·4 to 0·5, at approximately 40°C, show visible agglutination within 30 seconds, and agglutination should be complete within 120 seconds.

(iii) *Anti-E (anti-rh") blood-grouping serum (human)*

Anti-E serum is derived from the blood of one or more persons immunised by the E antigen of the Rh system. It reacts with human red corpuscles containing the E antigen.

Potency

Titration

Anti-E sera (" complete " or " incomplete ") should have a titre not less than 8 against ccddEe corpuscles.

Determination of avidity

Anti-E sera intended for use in the slide test of Diamond and Abelson (and which must contain any form of anti-D) should, when mixed on a slide with an equal volume of a suspension of ccddEe cells with a volume fraction of 0·4 to 0·5, at approximately 40°C, show visible agglutination within 30 seconds, and agglutination should be complete within 120 seconds.

(iv) *Anti-D + C (anti-Rh_orh') blood-grouping serum (human)*

Anti-D + E (anti-Rh_orh") blood-grouping serum (human)

Sera of specificity anti-D + C and of specificity anti-D + E may be obtained directly from the blood of immunised individuals or may be prepared by mixing anti-D with anti-C or anti-E serum. In a given serum both antibodies must be simultaneously active under the conditions of reaction specified by the producer. Each serum must react with all types of red corpuscles which would react with either of the component antibodies, and must fail to react with red corpuscles which contain neither the C nor D antigen in the case of anti-D + C and neither D nor E antigen in the case of anti-D + E. The titres should not be less than those specified for the component antibodies, but in the case of anti-D + C (which is a frequent combination in the serum of immunised persons) it is desirable that the anti-C titre should not be less than 32 and in the case of anti-D + E it is desirable that the anti-E titre should not be less than 8. Where a serum is intended for use in the slide test of Diamond and Abelson, the times of agglutination for all reacting types of red corpuscles should not be less than those specified for the component antibodies.

B. REAGENTS OF NON-HUMAN ORIGIN

(a) *Sera of animal origin*

(i) *Anti-A blood-grouping serum (animal)*

Anti-A serum is derived from the blood of animals which may or may not have been immunised by group A red corpuscles or group A specific substances. Anti-A serum agglutinates human red corpuscles containing A antigen, i.e. those of blood groups A and AB, including sub-groups A_1, A_2, A_1B and A_2B, and does not agglutinate human red corpuscles which do not contain A antigen, i.e. those of blood groups O and B.

Potency

Titration

An anti-A serum shall be titrated separately against suspensions of A_1, A_2, and A_2B red corpuscles, in parallel with the reconstituted but undiluted International Standard Preparation of anti-A blood-grouping serum or an equivalent reference preparation.[5] The potency of the serum shall in each case be not less than 64 International Units per ml.

Determination of avidity

When anti-A serum is mixed on a slide with an equal volume of a suspension of A_1, A_2 and A_2B cells with a volume fraction of 0·05 to 0·1, agglutination of each suspension shall in each case first appear in not more than twice the time taken when the same test is performed with the reconstituted but undiluted International Standard Preparation of anti-A blood-grouping serum or with a reference standard of equivalent avidity[5].

(ii) *Anti-B blood-grouping serum (animal)*

Anti-B serum is derived from the blood of animals which may or may not have been immunised by group B red corpuscles or Group B specific substances. Anti-B serum agglutinates human red corpuscles containing B antigen, i.e. those of blood groups B and AB, and does not agglutinate human red corpuscles which do not contain B antigen, i.e. those of blood groups O and A.

Potency

Titration

An anti-B serum shall be titrated against a suspension of group B corpuscles in parallel with the reconstituted but undiluted International Standard Preparation of anti-B blood-grouping serum or an equivalent reference preparation[5]. The potency of the serum shall be not less than 64 International Units per ml.

Determination of avidity

When anti-B serum is mixed on a slide with an equal volume of a suspension of B cells with a volume fraction of 0·05 to 0·1, agglutination shall first appear in not more than twice the time taken when the same

[5] The International Standard Preparation is of human origin; an equivalent reference preparation, if used, may be of human or non-human origin.

test is performed with the reconstituted but undiluted International Standard Preparation of anti-B blood-grouping serum or with a reference standard of equivalent avidity.

(iii) *Anti-human-globulin serum (animal)*[6]

Anti-human globulin serum for use in blood group serology must contain agglutinating antibodies against I_gG globulin and agglutinating antibodies against complement factors. It is derived from the blood of animals immunised by the injection of human serum protein. It must agglutinate all human red corpuscles coated with human I_gG and/or complement factors. Under the conditions specified by the manufacturers it does not agglutinate uncoated human red corpuscles, to whatever group they may belong.

Specificity

The specificity of an anti-human globulin serum for use in blood group serology must be tested with human red corpuscles coated with a variety of antibodies i.e. red corpuscles sensitised with human incomplete antibodies anti-D, anti-K and anti-Fya, red corpuscles sensitised with complement-binding incomplete antibodies anti-Le^a in the presence of fresh human serum, and red corpuscles sensitised with so-called " incomplete cold antibodies " and with tanned red corpuscles sensitised with human I_gG and, finally, with 10 different samples of non-coated human red corpuscles with and without A and B antigens.

Potency

Titration

An anti-human globulin serum, as supplied, or at the dilution recommended on the label, shall strongly agglutinate human red corpuscles coated with a human incomplete anti-D serum, having a titre of 4 (or less) against D-positive corpuscles, when the titration is performed by the albumin replacement method. At the same dilution it shall agglutinate K-positive human red corpuscles sensitised with selected weak anti-K antibodies and Fy^a positive red corpuscles sensitised with selected weak anti-Fy^a antibodies.

It shall also, at the same or a different dilution, as specified on the label, agglutinate human red corpuscles sensitised with weak complement-binding incomplete anti-Le^a antibodies in the presence of fresh serum.

For clinical use it is desirable that the coating of all the types of incomplete antibodies above shall be detectable with a single dilution of the anti-human globulin serum.

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(6) Coombs, R. R. A.; Mourant, A. E. and Race, R. R. (1945), *Lancet*, iii 5.
Coombs, R. R. A., Mourant, A. E. and Race, R. R. (1945), *Brit. J. exp. Path*, 26, 255.

(b) *Blood-grouping reagents of vegetable origin*

(i) *Anti-A blood-grouping reagent (vegetable)*

Anti-A reagent is prepared by extraction from the seeds or other parts of a suitable plant, followed, if necessary, by purification. Anti-A reagent agglutinates human red corpuscles containing A antigens, *i.e.* those of blood groups A and AB, including sub-groups A_1, A_2, A_1B and A_2B, and does not agglutinate human red corpuscles which do not contain A antigens, *i.e.* those of blood groups O and B.

Potency

Titration

An anti-A reagent shall be titrated separately against suspensions of A_1, A_2 and A_2B corpuscles, in parallel with the reconstituted but undiluted International Standard Preparation of anti-A blood-grouping serum or an equivalent reference preparation(5).

The potency of the reagent shall in each case be not less than 64 International Units per ml.

Determination of avidity

When anti-A reagent is mixed on a slide with an equal volume of a suspension of A_1, A_2 and A_2B cells with a volume fraction of 0·05 to 0·01, agglutination of each suspension shall first appear in not more than twice the time taken when the same test is performed with the reconstituted but undiluted International Standard Preparation of anti-A blood-grouping serum or with a reference standard of equivalent avidity.

(ii) *Anti-B blood-grouping reagent (vegetable)*

Anti-B reagent is prepared by extraction from the appropriate part of a suitable plant, followed, if necessary, by purification. Anti-B reagent agglutinates human red corpuscles containing B antigen, *i.e.* those of blood groups B and AB, and does not agglutinate human red corpuscles which do not contain B antigen, *i.e.* those of blood groups O and A.

Potency

Titration

An anti-B reagent shall be titrated against a suspension of group B corpuscles in parallel with the reconstituted but undiluted International Standard Preparation of anti-B blood-grouping serum or an equivalent reference preparation(5). The potency of the reagent shall not be less than 64 International Units per ml.

Determination of avidity

When anti-B reagent is mixed on a slide with an equal volume of a suspension of B cells with a volume fraction of 0·05 to 0·1, agglutination shall first appear in not more than twice the time taken when the same test is performed with the reconstituted but undiluted International Standard Preparation of anti-B blood-grouping serum or with a reference standard of equivalent avidity.

EXEMPLES D'ETIQUETTE

EXAMPLES OF LABEL

CONSEIL DE L'EUROPE
COUNCIL OF EUROPE

Accord européen relatif à l'échange des réactifs pour la détermination des groupes sanguins

European Agreement on the exchange of blood-grouping reagents

(*a*) *sérum liquide* 1. Laboratoire X, Amsterdam 2. Sérum anti-A (humain) 3. N_3Na 0,1% 4. 5 ml 5. 7 septembre 1965 6. N° 1 2 3 4	(*a*) *fluid serum* 1. ... Laboratory, Amsterdam 2. Anti-A serum (human) 3. Sodium Azide 0·1% 4. 5 ml 5. 7th September, 1965 6. N° 1 2 3 4
(*b*) *sérum desséché* 1. Laboratoire X, Amsterdam 2. Sérum anti-B (animal) 3. Mersalate 0,1% 4. Reconstituer avec 5 ml d'eau distillée 5. 31 décembre 1968 6. N° 4321	(*b*) *dried serum* 1. ... Laboratory, Amsterdam 2. Anti-B serum (animal) 3. Mersalate 0·1% 4. To be reconstituted with 5 ml of distilled water 5. 31st December, 1968 6. N° 4321

CONSEIL DE L'EUROPE
COUNCIL OF EUROPE

Accord européen relatif à l'échange des réactifs pour la détermination des groupes sanguins
European Agreement on the exchange of blood-grouping reagents

1. Laboratoire central de transfusion sanguine, 1 Main Street, Metropolis, Westland.
2. Sérum anti-E (anti-rh") (humain).
3. 10 ml.
4. Date du dernier contrôle d'activité: 30 mai 1961
5. Date de péremption: 30 mai 1962.
6. N° 5432.
7. Les globules rouges à examiner doivent être lavés une ou plusieurs fois avec une solution saline de 9 g/l. Une suspension de globules rouges d'une fraction de volume d'environ 0,03 est préparée ensuite en mélangeant un volume ou une goutte de culot globulaire avec 30 volumes ou gouttes de solution saline isotonique. Avec un peu d'habitude, la concentration d'une suspension peut être évaluée de façon satisfaisante à l'oeil nu.

   Une petite goutte de sérum est déposée dans un tube à hémolyse (6 mm × 30 mm) à l'aide d'une pipette Pasteur. On ajoute ensuite une petite goutte de suspension de globules rouges. (Avec un peu d'habitude, on peut réaliser une économie considérable en distribuant le sérum et la suspension globulaire à

1. Central Blood Transfusion Laboratory, 1 Main Street, Metropolis, Westland.
2. Anti-E (anti-rh") serum (human).
3. 10 ml.
4. Date du dernier co test: 30th May 1961.
5. Expiry Date, 30th May 1962.
6. No. 5432.
7. The red blood cells to be tested are washed one or more times with a NaCl solution of 9 g/l. An erythrocyte suspension with a volume fraction of approximately 0·03 is prepared by mixing one volume or drop of packed red cells with 30 volumes or drops of isotonic NaCl-solution. With practice the strength of a suspension can be judged adequately by inspection.

   A small drop of serum is delivered into a precipitin tube (6 mm × 30 mm) from a Pasteur pipette, and a similar drop of red corpuscle suspension is added. (With practice considerable economy can be achieved by delivering the serum and cell suspension from pipettes marked at a volume of 10 μl).

l'aide de pipettes graduées à ul). Le contenu du tube est mélangé et mis à incuber deux heures à 37°C. Le conteu du tube est alors transporté et étalé avec précaution sur une lame de microscope. Si l'agglutination n'est pas clairement visible à l'oeil nu, la lame est examinée au microscope pour établir si l'agglutination s'est produite et déterminer son intensité.

8. Conserver à une température inférieure ou égale à-20°C. Si le produit n'est pas utilisé le jour même de l'ouverture, ajouter 0,1 ml d'une solution de N_3Na à concentration de 100 g/l.

9. — Sérum humain anti-E (" anti-rh "): 5 ml.
   — Albumine bovine à 300 g/l: 5 ml.

10. Ce réactif contient une substance d'origine humaine.

The contents of the tube are mixed and incubated at 37°C for two hours. The contents of the tube are then cautiously transferred to a microscope slide and gently spread upon it. Unless agglutination is unmistakable to the unaided eye the slide is examined for the presence and degree of agglutination under the microscope.

8. Store at −20°C or below. If to be used after day of opening, add 0·1 ml of a solution containing 100 gram sodium azide per litre.

9. Human anti-E ("anti-rh") serum: 5 ml; solution containing 300 gram bovine albumin per litre: 5 ml.

10. This product contains material of human origin.

ANNEX AU PROTOCOLE

ANNEX TO THE PROTOCOL

CONSEIL DE L'EUROPE
COUNCIL OF EUROPE

Accord européen relatif à l'échange
des réactifs pour la détermination des groupes sanguins
European Agreement on the exchange of blood-grouping reagents

Certificat

(article 4)

Certificate

A NE PAS DÉTACHER DE L'ENVOI
NOT TO BE SEPARATED FROM THE SHIPMENT

..... 19.....

(lieu) (date)
(place)

Nombre de colis
Number of packages
.....
.....

Le soussigné déclare que l'envoi spécifié en marge .....
The undersigned certifies that the shipment specified in the .....
.....
préparé sous la responsabilité de .....
margin prepared under the responsibility of .....

Désignation
Marked
.....
.....

.....
.....

organisme visé à l'article 6 de l'Accord, est conforme aux
one of the bodies referred to in Article 6 of the Agreement,

No. des lots
Batch No.
.....
.....
.....
.....

spécifications du Protocole à l'Accord et qu'il peut être
is in conformity with the specifications of the Protocol to the
délivré immédiatement au destinataire (nom et lieu) .....
Agreement and can be delivered immediately to the .....
.....
consignee (name and place) .....

(cachet) (signature) (titre)
(stamp) (signature) (title)

Done at Strasbourg, this 7th day of April 1978

GEORG KAHN-ACKERMANN
Secretary General

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