

Instructions for use - Internal Proficiency Exercise ('IPEX')

Reagents for use as part of
internal laboratory QC
for *in vitro* diagnostic use only
Product code: PN083
NHSBT Reagents,
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Intended use

These samples are to be used as part of internal laboratory quality assessment of grouping, antibody screening, antibody identification as appropriate. Occasionally a post transfusion investigation may be used in the exercise.

These samples can also be used for a serological crossmatch by testing each plasma/serum sample against the red cells of the other individual(s).

The phenotype and specificity of the cells and plasma/serum will vary in accordance with the intended purpose of the exercise and therefore is dependent upon the requirements of the design team.

Principles of the examination method

Plasma/serum samples are incubated with red cells to determine the presence of agglutinins by direct or indirect methods.

Components

This reagent contains donated human plasma or serum and red blood cells from non-remunerated blood donors. The kit usually consists of a maximum of 3 cell samples and 3 plasma/serum samples. For exercises involving transfusion reactions pre and post samples from the patient and up to 3 donor samples are provided.

The red cells, supplied as $2.8 \pm 0.2\%$ suspension to be used directly from the vial, are leucodepleted, washed and suspended in Modified Alsevers solution (AP), which has been specially formulated to preserve red cell integrity and antigenicity, containing trisodium citrate 8g/L, D-glucose 20.0g/L, citric acid monohydrate 0.5g/L, sodium chloride 4.2g/L, inosine 0.938g/L ATP 0.4g/L, chloramphenicol 0.34g/L and neomycin sulphate 0.1g/L

Plasma/serum samples are sterile filtered and contain sodium azide as preservative. If the plasma/serum samples require dilution, this will be with a pre-determined volume of 3% bovine serum albumin in saline.

Reagent Preparation

Mix before use.

Storage and shelf life after first opening

Store at 2-8°C.

Do not freeze.

Do not use beyond the notified expiry date.

Serum samples may be stored frozen at -20°C or below, once thawed, these samples should be used with 24 hours.

Do not use if serum/plasma is turbid, or if a precipitate, gel or particles are present.

Warnings and precautions

For professional use only.

Cells must not be pooled.

The recommended conditions of storage and use must be rigidly applied to prevent accelerated loss of reactivity.

The donations used in this product have been tested at source and found negative for the mandatory microbiological tests required by the Guidelines for UK BTS at the time of donation. No known test methods can offer assurances that products derived from human blood will not transmit infectious diseases. Appropriate care should be taken in the use and disposal of this product.

Chloramphenicol is classed as a carcinogen, neomycin sulphate as an irritant.

Examination procedure

It is intended that the usual tests and protocols of the participating laboratory will be used to examine this material. The reagent has been verified as reacting as intended by routine tube, BioRad/ID DiaMed and Ortho Biovue technologies.

Control procedure

Each batch of tests should be controlled with suitable positive and negative controls as required by the protocols of the laboratory using the exercise material.

Interpretation of results

The presence of agglutination indicates a positive result.

Case histories for samples are included to aid in interpretation of results and answering the questions.

The questions included (between 1 and 3) are aimed at assessing knowledge of serology theory and/or guidelines. Expected results to the serological tests and appropriate answers, including appropriate references are supplied to designated managers confidentially by email to initiate discussion with their departmental staff. Results are not required to be returned.

Literature references

The manufacture of these reagents complies with current version of the Guidelines for the Blood Transfusion Services in the UK.

If you have any comments about this exercise or suggestions for future exercises, please contact Reagent Customer Services on 0151 268 7157.



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