INF109/3 – Instructions for Use - Internal Proficiency Exercise (IPEx)

NHS Blood and Transplant

Copy No:

Effective date: 29/04/2024

Product code: PN083
NHSBT Reagents,14 Estuary Banks, Liverpool, L24 8RB.
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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. The samples can also be used for a serological crossmatch by testing each plasma/serum sample against the red cells provided.

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 kit contains donated human plasma or serum and red blood cells from non-remunerated blood donors. The kit usually consists of 3 serum and 3 matching cell 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±0.2% suspension to be used directly from the vial, are leucodepleted, washed and suspended in Modified Alsevers solution.
Plasma/serum samples are sterile filtered and contain sodium azide as preservative.

The expected results for ABO and Rh typing, antibody screening and identification are emailed to a designated person.
To make this a true 'learning experience' exercises are accompanied by questions with answers and relevant references.

Preparation
Mix before use**.**

Storage and shelf life after first opening
Store at 2-8ºC.
Do not freeze.
Do not use beyond the notified expiry date.

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.
If a precipitate, gel or particles are present the samples should be centrifuged before use.
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.

Examination procedure
It is intended that the usual tests and protocols of the participating laboratory will be used to examine this material. The product has been verified as reacting as intended by routine tube, BioRad ID, Grifols DG 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 of the serological tests and appropriate answers, including appropriate references are supplied to designated individuals to initiate discussion with their departmental staff. Results are not required to be returned.
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If you have any comments about this exercise or suggestions for future exercises, please contact Reagent Customer Services on 0151 268 7157.