# Instructions for use



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PeliControl	<b>REF</b> K1379	IVD CE0344
PeliControl CcEe-K	<b>REF</b> K1399	IVD C€0344
088_v03 01/2017 (en)		For professional use only

## **General information**

The PeliControl whole blood samples can be used as patient samples for internal quality control procedures for checking ABO/Rh-D, as well as reverse blood typing and antibody screening.

PeliControl consists of 2 blood samples, each containing packed cells and control serum.

Sample 1: blood group A2B rhesus D positive with control serum.

Sample 2: blood group O rhesus D negative with control serum containing anti-A,B and anti-D.

In addition, a separate control is available for checking rhesus phenotype and K blood grouping. PeliControl CcEe-K ( $\overline{\text{REF}}$  K1399): blood group C+;c+;E+;e+; K+.

### Precautions

For in vitro diagnostic use only. PeliControl should be stored at 2–8°C; do not freeze. Leaking or damaged tubes should not be used. Blood samples (unopened or opened) should not be used beyond the expiration date, which is printed on the label of the tube. Chloramphenicol 0.02%, neomycin sulfate 0.008% and gentamicin 0.004% are used as preservatives. Although all blood products are tested for infectious diseases and found negative, the blood samples cannot be assumed to be free from infectious agents. Care must be taken in the use and disposal of each container and its contents. If contamination or excessive haemolysis is evident, discard. Wastedisposal should be performed according to your laboratory regulations.

## **Test procedures**

PeliControl can be used in manual and automated techniques and should be handled as a patient sample in the corresponding technique. Perform the ABO, rhesus phenotype and K blood grouping, reverse blood typing and antibody screening (indirect antiglobulin test) according to the standard procedures of your laboratory. This product has been validated on the following blood grouping test systems using column techniques:

WA Diana (Diamed) AutoVue (Ortho) Magister (Menarini / Sanguin)

Users are advised to confirm suitability of PeliControl before using other techniques.

## Interpretation

Enclosed you will find a '7-days datasheet' with the minimal required results and possibilities to fill in your own results. In the first empty column you can note the date and a signature.

- A, B, A,B, D1 and D2 are respectively anti-A, anti-B, anti-A,B and 2 anti-D blood grouping reagents.
- CTRL means Control Reagents for typing reagents.
- A1, A2 and B cells are respectively A1, A2 and B Reagent Red Cells.
- SCR. CELL 1, 2 or 3 means Screening panel with 2 or 3 cell suspensions.
- C, c, E, e and K are respectively anti-C, anti-c, anti-E, anti-e and anti-K blood grouping reagents.
- R.T. means Room Temperature (18–25°C) / immediate spin.
- 37°C: after incubation at 37°C.
- AHG: results after adding Anti Human Globulin reagent using tube techniques.
- CCC: reactions after adding Coombs Control Cells to the negative reactions in tube techniques.

### Limitations

In case one of the screening cells is D negative, there will be no visible reaction with serum 2. However with Coombs Control Cells there must be a reaction. In some commercially available screening panels all three cells could be rhesus D positive. This in contrast with the results in the in '7-days datasheet'.

### References

- 1. Race R.R. and Sanger R.; Blood Groups in Man, 6th ed. Oxford Blackwell Scientific Publishers 1975.
- 2. Issitt P.D.; Applied Blood Group Serology, 3rd ed. Montgomery Scientific Publications, Miami, Florida, USA, 1985.
- 3. Daniels G.; Human Blood Groups. Blackwell Science Ltd. 1995.
- 4. Reid M.E. and Lomas-Francis C.; The Blood Group Antigen Facts Book.Facts Book Series, 1997.
- 5. Mollison P.L. et al.; Blood Transfusion In Clinical Medicine, 9th ed. Blackwell, Oxford, 1993.

Sanquin products are guaranteed to perform as described in the original manufacturer's instructions for use. Strict adherence to the procedures, test layouts and recommended reagents and equipment is essential. Sanquin declines all responsibility arising from any deviation thereof.