Instructions for use

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PeliControl	REF K1379	IVD CE 0344
PeliControl CcEe-K	REF K1399	IVD CE 0344
088_v05 05/2022 (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, antibody screening and crossmatch.
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 (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. In-use stability: open tubes can be kept for 3 hours per day over 10 days at 18-25°C, otherwise stored at 2-8°C with original cap. 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. Waste-disposal 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, antibody screening (indirect antiglobulin test) and crossmatch according to the standard procedures of your laboratory. This product has been validated on the following blood grouping test systems using column techniques:
Sanquin Reagents B.V. Cellbind system (all tests mentioned above);
Biorad Laboratories, Inc. ID-system (all tests mentioned above except crossmatch);
Ortho Clinical Diagnostics BioVue system (all tests mentioned above except crossmatch).
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.
- Major: major crossmatch with incubation at 37°C, using red cells from PeliControl sample 1 and serum from PeliControl sample 2.
- Minor: minor crossmatch with incubation at 37°C, using red cells from PeliControl sample 2 and serum from PeliControl sample 1.

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
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