

# Instructions for Use



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## Cellbind DILUENT

REF K7180

IVD CE

108 version 01 Issued 13-MAR-2025 (en)

*For professional use only*

### Intended Purpose

Cellbind DILUENT (Ref K7180) is an in vitro diagnostic medical device intended to be used by laboratory professionals for dilution of 3% reagent red cells to 0.5% suspensions that can be used for testing in Cellbind microcolumn cards manually or in an automated analyser.

### General Information

See IFU Cellbind Screen (Ref K7000) or Cellbind Direct Type (Ref K7012).

### Package Contents

- 1 bottle with 100 mL dilution medium
- Leaflet 108-version\_01

Components of biological origin (w/v): Bovine Serum Albumin (0.03%), Citric Acid (0.015%), Dextran (4.0%), Dextrose (D-(+)-glucose) (2.0%), Inosine (0.0016%), Neomycin Trisulfate Salt Hydrate (0.015%).

### Materials Required (not provided)

- Standard laboratory materials and equipment (e.g. round bottom glass tubes, pipette tips)
- Cellbind Screen (Ref K7000) or Cellbind Direct Type (Ref K7012)
- For manual use in Cellbind cards: Suitable centrifuge and incubator
- For automated use: Validated automated analyser; optional: Stirrer balls (Ref K7390)
- Reagent red cells:
  - Screening panel 123 (Ref K1148)
  - Makropanel 16 (Ref K1385)
  - Equivalent or other validated 3% reagent red cells (to be used as 0.5% suspension in Cellbind Diluent (Ref K7180))

### Specimen Collection and Handling

Standard blood collection methods (EDTA plasma tubes) should be used. The use of samples with or without another anticoagulant should be validated by the user.

Samples can be stored at 18-25°C for 4 days, at 2-8°C for 7 days, and at -30°C to -18°C for two months, including 2 freeze/thaw cycles.

It is required to centrifuge blood collection tubes at 3000 rcf (=3000 xg) for 5 minutes (excluding acceleration and deceleration time) prior to testing, in order to prevent false positive or false negative reactions.

### Test Principle

The device is a medium for dilution of 3% reagent red cells to 0.5% suspensions for use in Cellbind Screen (Ref K7000) or Cellbind Direct Type (Ref K7012).

### Calibrators and Controls

To ensure reagent quality, testing of the reagent as part of the laboratory quality control program using appropriate controls, is mandatory.

### Storage and Shelf-Life

Cellbind DILUENT should be stored directly upon arrival, and after use, at 2-8 °C in the original packaging (preferably shielded from light). Product should be stored upright. When stored under the recommended conditions, a shelf-life of 24 months is guaranteed. For in-use can be guaranteed: 1 month after opening, whereof 8.5 hours per day kept at 18-25°C and stored at 2-8°C during the night. Stability of 0.5% red cell suspensions in Cellbind DILUENT is guaranteed for 8.5 hours at 18-25°C.

### Precautions and Warnings

For in vitro diagnostic use only. Strict adherence to the Instructions for Use is required to obtain reliable results. Keep only in original packaging. Cellbind DILUENT should be stored at 2-8°C; do not freeze. Cellbind DILUENT (unopened or opened) should not be used

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beyond the expiration date, which is printed on the label of the bottle. Product should be stored upright. Do not mix the content of different bottles and/or batches. Leaking or damaged bottles should not be used. Although the sources have been tested for infectious diseases and found negative, the reagent cannot be assumed to be free from infectious agents. Waste disposal, after completion of the test, should be performed according to your laboratory regulations. Turbidity may indicate microbial contamination. If contamination is evident, discard. In case the UDI on the bottle label(s) is/are not legible, please make use of the UDI that is also available on the lot specific CoA, available through the website.

## Assay Procedure

Allow all reagents to reach room temperature (18-25 °C).

Resuspend the 3% reagent red cell suspensions before use.

Preparation of 0.5% reagent red cell suspensions:

200 µL 3% reagent red cells suspension + 1 mL Cellbind DILUENT.

Stability of 0.5% red cell suspensions in Cellbind DILUENT is guaranteed for 8.5 hours at 18-25°C.

Resuspend the 0.5% reagent red cell suspension before use. To prevent settling of the 0.5% diluted reagent red cells, these must be gently resuspended before each use.

User should perform a validation according to specifications in the IFU of the Cellbind card (Cellbind Screen (Ref K7000) or Cellbind Direct Type (Ref K7012)) if alternative (automated) equipment with Cellbind cards will be used.

User should perform a validation if other reagent red cells than listed in section Materials Required (not provided) will be used.

## Limitations

Limitations depending on the specific tests using Cellbind DILUENT with Cellbind Screen (Ref K7000) or Cellbind Direct Type (Ref K7012), see respective IFU.

## Analytical Performance

Analytical performance depends on the specific tests using Cellbind DILUENT with 3% reagent red cells in Cellbind Screen (Ref K7000) or Cellbind Direct Type (Ref K7012), see respective IFU or demonstrate analytical performance of validated 3% reagent red cells.

## Clinical Performance

Clinical performance depends on the specific tests using Cellbind DILUENT with 3% reagent red cells in Cellbind Screen (Ref K7000) or Cellbind Direct Type (Ref K7012), see respective IFU or demonstrate clinical performance of validated 3% reagent red cells.

## Notice

Any serious incident that has occurred in relation to this product should be reported to the manufacturer and the competent authority of the EU Member State in which the user and/or the patient is established.

## References

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## Disclaimer

Products from Sanquin Reagents B.V. 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 Reagents B.V. declines all responsibility arising from any deviation thereof.

## Changes to Previous Version

This is the first version under the IVDR 2017/746, using template v1.