# Instructions for Use

Sanquin Reagents B.V.
Plesmanlaan 125
1066 CX Amsterdam
The Netherlands

Phone: +31 20 4570707
reagents@sanquin.nl
www.sanquin.org/reagents

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| **Cellbind LISS** | REF **K7110** | IVD CE |
| **Cellbind LISS** | REF **K7130** | IVD CE |
| 100 version **01** Issued **29-FEB-2024** (en) | | *For professional use only* |

**Intended Purpose**

Cellbind LISS (Ref K7110, Ref K7130) is an in vitro diagnostic medical device intended to be used by laboratory professionals for dilution of red blood cells derived from EDTA blood samples to 0.5% suspensions, that can be tested 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 (Ref K7110) or
  3 tubes with 25 mL dilution medium (Ref K7130)
- Leaflet 100-version_01

Components of biological origin (w/v): per bottle/tube Bovine Serum Albumin (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).
- Optional: Validated blood group typing reagents.
- For manual use in Cellbind cards: Suitable centrifuge and incubator.
- For automated use: Validated automated analyser; optional: Stirrer balls (Ref K7390).

**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.
It is required to centrifuge blood collection tubes at 3,000 rcf (=3,000 xg) for 5 minutes (excluding acceleration and deceleration time) prior to testing, in order to separate red blood cells from plasma and prevent false positive or false negative reactions.
For further details see IFU Cellbind Screen (Ref K7000) or Cellbind Direct Type (Ref K7012).

**Test Principle**

Cellbind LISS is used to prepare 0.5% red cell suspensions of EDTA blood samples 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 LISS 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:

- for Ref K7110: 1 month after opening, whereof 8.5 hours per day kept at 18-25°C and stored at 2-8°C during the night;
- for Ref K7110: two weeks on board of automated analyser (without cap) at 18-25°C;
- for Ref K7130: 10 days on board of automated analyser (without cap) at 18-25°C.

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**Precautions and Warnings**

For in vitro diagnostic use only. Keep only in original packaging. Strict adherence to the Instructions for Use is required to obtain reliable results. Cellbind LISS should be stored at 2-8°C; do not freeze. Cellbind LISS (unopened or opened) should not be used beyond the expiration date, which is printed on the label of the bottle/tube. Product should be stored upright. Do not mix the content of different bottles/tubes and/or batches. Leaking or damaged bottles/tubes should not be used. Chloramphenicol (0.025%) and neomycin (0.015%) are used as preservatives. Although the sources have been tested for infectious diseases and found negative, the reagent cannot be assumed to be free from infectious agents. Turbidity may indicate microbial contamination. If contamination is evident, discard. Waste disposal, after completion of the test, should be performed according to your laboratory regulations. In case the UDI on the bottle/tube 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**

Preparation of 0.5% red cell suspensions:
11 µL packed patient or donor red cells + 2 mL Cellbind LISS (Ref K7110 or Ref K7130).

To prevent settling of the 0.5% diluted reagent red cells, they must be gently resuspended before each use.
Stability of 0.5% dilutions of red cells in Cellbind LISS can be guaranteed for 8.5 hours at 2-8°C, whereof maximum 5 hours at 18-25°C.

For further details see IFU Cellbind Screen (Ref K7000) or Cellbind Direct Type (Ref K7012).

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

**Limitations**

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

**Analytical Performance**

| Performance Characteristic | Specification |
|---|---|
| **Carry-over** | Carry-over is defined as the introduction of material into a reaction or mixture to which it does not belong. Carry-over of sample or reagent by the two pipetting tips of the Magister C24 blood group serology analyser is assessed and no carry-over is detected. As red blood cells were diluted in Cellbind LISS, carry-over of Cellbind LISS has been tested and the results obtained in this study also apply for Cellbind LISS.<br>In case of alternative automated analyser, validation by the user, according to the manufacturer's instructions, to exclude carry-over is mandatory.<br>Carry-over for manual testing has not been determined. During manual use disposable pipet tips are used for each pipetting step. Therefore, carry-over does not occur. |

For other performance characteristics, see IFU Cellbind Screen (Ref K7000) or Cellbind Direct Type (Ref K7012).

**Clinical Performance**

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

**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 v1.0.