



PRODUCT(S)

Product name	Packaging size	Id-n°	REF
ID-CellStab	1 x 500 ml	05740	005650
	2 x 100 ml		005660

INTENDED USE

The "ID-CellStab" is a suspension medium formulated in a glycine buffered saline solution intended for the stabilisation of human Red Blood Cells (RBCs) at 0.8% concentration for antibody screening and identification procedures.

This pre-analytical step is carried out manually and intended for the ID-System.

For *in vitro* diagnostic use, by trained laboratory personnel.

PRINCIPLE OF THE TEST

The test combines the principles of agglutination and gel filtration. Non agglutinated red cells are collected at the bottom of the wells while the agglutinates are dispersed throughout the length of the gel, depending upon their size. Their position in the gel determines the intensity of the reaction [1].

REAGENT COMPOSITION

"ID-CellStab" is a ready-to-use glycine buffered saline solution containing Bovine Serum Albumin (BSA); trimethoprim and sulfamethoxazole (preservatives).

MATERIAL PROVIDED

- ID-CellStab

MATERIAL REQUIRED BUT NOT PROVIDED

- Clean glass tubes
- Pipettes
- Centrifuge

STORAGE AND HANDLING

- Store at 2–8 °C
- Do not store near any heat, air conditioning sources or ventilation outlets
- Store in an upright position
- Shelf life: see expiry date on the label
- In use stability: Once opened and if handled in accordance with Good Laboratory Practice (GLP) principles and stored as described in these instructions for use, each bottle may be used for a maximum of 9 months.

WARNINGS AND PRECAUTIONS

- Adherence to the instructions for use is necessary to ensure proper performance of this product.
- Do not use expired reagents. Do not freeze or expose reagents to excessive heat.
- Bacterial or other contamination may interfere with the red blood cell stability.
- These devices should be handled only by qualified personnel trained in laboratory procedures and familiar with the potential hazards. Wear appropriate protective clothing, gloves and eye/face protection and handle appropriately in accordance with Good Laboratory Practices.
- The bovine albumin used to produce these reagents is from BSE-free sources. Reagents of biological origin and human specimens must be regarded as potentially infectious and appropriate safety precautions are recommended.
- Dispose of all specimens and materials used to perform the test as they could contain an infectious agent. Laboratory, chemical, or biohazardous wastes must be handled and discarded in accordance with all local, regional and national regulations.
- For a patient/user/third party in the European Union and in countries with identical regulatory regime requirements (Regulation 2017/746/EU on *In vitro* Diagnostic Medical Devices); if during the use of this device or as a result of this use, a serious incident occurs, please report it to Bio-Rad Laboratories and/or its authorised representative and to your national Competent Authority.
- Consult [downloads.bio-rad.com](https://www.bio-rad.com/downloads.bio-rad.com) to download the latest version of these instructions for use.
- For technical support, visit the **contact us** section at www.bio-rad.com website. Then select a location and select "Clinical Diagnostics".

SAMPLES

- Blood samples should be collected into EDTA, CPD or citrate anticoagulant. Blood samples drawn into tubes without anticoagulant may also be used. Blood samples, stored at 2–8 °C, can be used for up to 5 days.
- RBCs units can be used until expiry date of the unit.
- Prior to testing, blood samples or samples collected from RBCs units must be centrifuged according to local Laboratory Practices, e.g., 10 minutes at 1500 g, to obtain a distinct separation between RBCs (packed cells) and plasma/serum.

TEST PROCEDURE

Allow all reagents and samples to reach room temperature (18–25 °C) prior to use.

Red Blood Cells suspension preparation

1. Wash RBCs 3 times:
 - a. Add 4 volumes of "ID-CellStab" to 1 volume of packed RBCs.
 - b. Centrifuge at 2000 g for 2 min and discard the supernatant.
2. Discard the supernatant completely after the last wash.
3. Prepare a 1% RBC suspension in "ID-CellStab" as follows:
 - a. Dispense 5 ml of "ID-CellStab" into a clean glass tube.
 - b. Add 50 µl of the washed packed cells.
4. Store at 2–8 °C.

The RBC suspension is stable for up to 4 weeks when stored at 2–8 °C.

CONTROL PROCEDURE

Known positive and negative samples should be included in accordance with local guidelines.

PERFORMANCE

Each manufactured lot of "ID-CellStab" is compliant with the internal specifications of DiaMed GmbH.

LIMITATIONS

ID-CellStab has not been validated with samples from patients, neither with haemolysed, lipemic, icteric samples.

BIBLIOGRAPHY

1. Lapierre, Y., Rigal, D., Adam, J. et al.: The gel test; A new way to detect red cell antigen-antibody reactions. Transfusion 1990; 30: 109-113.

GLOSSARY OF SYMBOLS

The following symbols **may** be used for labelling purpose.

	Catalogue number
	Batch code
	<i>In vitro</i> diagnostic medical device
	Consult instructions for use
	Caution
	Use-by date = Expiry date (YYYY-MM-DD)
	Temperature limit
	Manufacturer
	Authorized representative in the European Community
	This side up
	Conformity with European Regulation (EU) 2017/746

These products are guaranteed to perform as described on the label and in the instruction sheet. The manufacturer declines all responsibility arising out of the use or sale of these products in any way or for any purpose other than those described therein.