PRODUCT(S)

Product name	Packaging size	Id-n°	REF
ID-Diluent 2	2 x 100 ml	05761	009260
	1 x 500 ml		009280
˝ID-Diluent 2˝ Rack for IH-Analyzers	10 racks with 60 x 700 µl		009290

INTENDED USE

The ˝ID-Diluent 2˝ is a Low Ionic Strength Solution (LISS) intended for the preparation of human Red Blood Cells (RBCs) suspensions for immunohematology testing.

˝ID-Diluent 2˝ can be used manually or with instruments intended for the ID-System.

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

PRINCIPLE OF THE TEST

Refer to the related instructions for use of the ID-Cards requiring ˝ID-Diluent 2˝.

REAGENT COMPOSITION

˝ID-Diluent 2˝ is a modified LISS solution in 100 ml and 500 ml bottles or racks of 60 x 700 µl for the IH-Analyzers. Ready-to-use. Preservatives: Trimethoprim and sulfamethoxazole.

MATERIAL PROVIDED

- ID-Diluent 2

MATERIAL REQUIRED BUT NOT PROVIDED

For manual method
Refer to the related instructions for use of the ID-Cards requiring ˝ID-Diluent 2˝.

For automated method
- IH-1000, REF 001000
- IH-500, REF 001500
- Swing TwinSampler II, REF 009899
- Saxo ID-Reader II, REF 009951
- Banjo ID-Reader, REF 009945

For automated methods, please refer to the corresponding user manuals.

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Location: Moldova
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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 6 months.
- On-board stability: ″ID-Diluent 2″ Rack for IH-Analyzers can be kept on-board in the IH-500 for a maximum of 30 days and in the IH-1000 for a maximum of 7 days.

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.
- Erroneous and abnormal results may be caused by bacterial or other contamination of materials.
- 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.
- 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** 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

Refer to the related instructions for use of the ID-Cards requiring ″ID-Diluent 2″.

TEST PROCEDURE FOR MANUAL METHOD

Refer to the related instructions for use of the ID-Cards requiring ″ID-Diluent 2″.

For automated systems, please refer to the corresponding user manuals.

CONTROL PROCEDURE

Refer to the related instructions for use of the ID-Cards requiring ″ID-Diluent 2″.

VISUAL READING AND INTERPRETATION OF THE RESULTS

Refer to the related instructions for use of the ID-Cards requiring ″ID-Diluent 2″.

PERFORMANCE

Refer to the related instructions for use of the ID-Cards requiring ˝ID-Diluent 2˝.

LIMITATIONS

Refer to the related instructions for use of the ID-Cards requiring ˝ID-Diluent 2˝.

BIBLIOGRAPHY

Refer to the related instructions for use of the ID-Cards requiring ˝ID-Diluent 2˝.

GLOSSARY OF SYMBOLS

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

REF	Catalogue number
LOT	Batch code
SN	Serial number
IVD	*In vitro* diagnostic medical device
	Consult instructions for use
	Caution
	Use-by date = Expiry date (YYYY-MM-DD)
	Temperature limit
	Manufacturer
EC REP	Authorized representative in the European Community
	This side up
CE	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.