EUROIMMUN Medizinische Labordiagnostika AG

Secondary reagents immunoblot (IgG)
Instructions for use

For in vitro diagnostic use IVD

ORDER NO.	PRODUCT	FORMAT
ZD 1129-0101-1 G	Secondary reagents immunoblot (IgG)	01 X 01

CE

Intended use

The reagents are intended for the processing of immunoblots of EUROIMMUN Medizinische Labordiagnostika AG (EUROLINE, EUROLINE-WB, Westernblot) that are used for the detection of human antibodies of immunoglobulin class G. They must only be used according to the respective instructions for use of the test kits and by healthcare professionals.

Package contents

Component	Format	Symbol
1. Enzyme conjugate Alkaline phosphatase-labelled antibody against human IgG (< 0.2 %), 10x concentrate Preservative: sodium azide < 0.1 % (w/w)	5 x 3 ml	CONJUGATE 10x
2. Sample buffer Contains protein {<5%) in buffer solution, ready for use preservative: sodium azide < 0.1 %	5 x 100 ml	SAMPLE BUFFER
3. Wash buffer Buffer solution, 10x concentrate	5 x 50 ml	WASH BUFFER 10x
4. Substrate solution Nitroblue tetrazolium chloride/5-bromo-4-chloro-3-indolyl phosphate (NBT/BCIP) (<1 mM), ready for use	5 x 30 ml	SUBSTRATE

Additional materials and equipment required (not included in the Secondary Reagents Immunoblot (IgG) kit)

The Secondary Reagents Immunoblot may only be used in conjunction with immunoblots from EUROIMMUN Medizinische Labordiagnostika AG (EUROLINE, EUROLINE-WB, Westernblot).

All further materials and equipment required to perform the test are listed in the instructions for use of the test system used.

Storage and stability

The reagents have to be stored at +2 °C to +8 °C; do not freeze. Unopened, the reagents are stable until the indicated expiry date. The reagents may not be used after the expiry date.

In-use stability

After initial opening, the reagents are stable for 12 months, provided that the indicated expiry date is not exceeded. After initial opening, the reagents must continue to be stored at +2 °C to +8 °C and protected from contamination.

Updates with respect to the previous version are marked in grey.

Warnings and precautions

- The product must only be used by healthcare professionals in suitable laboratory rooms.
- Do not use the reagents if the packaging is damaged.
- Before using the product, read the instructions for use carefully. Only use the valid version, which can be downloaded from the customer portal (https://products.euroimmun.de).
- The EUROIMMUN products must not be mixed with or replaced by products from other manufacturers.
- Observe Good Laboratory Practice (GLP) and safety guidelines. Some of the reagents contain preservatives.
- Information on classification according to CLP 1272/2008 is included in the safety data sheet. This is available on the EUROIMMUN website.

H/P code	H/P phrase
H317	May cause an allergic skin reaction.
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P280	Wear protective gloves/protective clothing/eye protection/face protection.
P333+P313	If skin irritation or rash occurs: Get medical advice/attention.
P362+P364	Take off contaminated clothing and wash it before reuse.

Preparation and stability of the reagents

Notes

- The reagents must be brought to room temperature (+18 °C to +25 °C) before use.
- Some secondary reagents are named differently in the different test systems (e.g. sample buffer or blocking buffer or wash buffer or universal buffer).

Enzyme conjugate

The enzyme conjugate is supplied as a 10x concentrate. **The concentrated enzyme conjugate must be diluted with the buffer specified for use with the test system to be incubated.**

For the preparation of the working-strength enzyme conjugate the amount required should be removed from the bottle using a clean pipette tip and diluted 1: 10 with sample buffer, wash buffer or universal buffer before use (see instructions for use of the test system to be incubated). For one test strip, add 0.15 ml enzyme conjugate to 1.35 ml buffer. The working-strength enzyme conjugate should be used within the same working day. For optimal activity of the enzyme, a working temperature of +18 °C to +25 °C should be maintained.

Sample buffer I Blocking buffer

Ready for use

Wash buffer/universal buffer

The wash buffer/universal buffer is supplied as a 10x concentrate. For the preparation of the working-strength wash buffer/universal buffer the amount required should be removed from the bottle using a clean pipette tip and diluted 1: 10 with deionised or distilled water. For example, for one test strip, add 1 ml concentrate to 9 ml deionised or distilled water. The working-strength wash buffer/universal buffer should be used within the same working day.

Substrate solution

Ready for use. Close bottle immediately after use, as the contents are sensitive to light.

Waste disposal

All products must be disposed of in accordance with local disposal regulations.

Limitations of the procedure

- The specifications in the instructions for use of the test system used, e.g. pipetting volumes, incubation times, temperatures and preparation steps must be observed to avoid incorrect results.
- With regard to the preparation of the reagents, the information in these instructions for use must be observed (see "Preparation and stability of the reagents").
- The immunoblots DL 1130-X G and DL 1620-1 0 of EUROIMMUN Medizinische Labordiagnostika AG cannot be processed with the immunoblot (IgG) secondary reagents.

Liability

The product must only be used in accordance with the intended use. EUROIMMUN accepts no liability for any other use (e.g. non-compliance with the instructions for use and improper use) or for resulting damages.

Technical Support

In case of technical problems you can obtain assistance via the EUROIMMUN website (https://www.euroimmun.de/en/contact/). Instructions for use, test kit information and certificates are available at the customer portal (https://products.euroimmun.de). You can also order them via telephone: +49 451 2032 0.

Additional information

- Further information on the product can be found in the European Database on Medical Devices **(EUDAMED).**
- Regulatory information for customers in the European Union: Please observe the obligation to report any serious incidents occurring in connection with the product to the competent authorities and to **EUROIMMUN.**

Meaning of the symbols

The following symbols are used on the packaging and in the instructions for use.

Symbol	Meaning	Symbol	Meaning
CONJUGATE 10x	Conjugate, 10x concentrate	-/	Protect from sunlight
SAMPLE BUFFER	Sample buffer	t	Storage temperature
WASH BUFFER 10x	Wash buffer, 10x concentrate		Unopened usable until (YYYY-MM-DD)
SUBSTRATE	Substrate solution	CE	CE marking
IVD	In vitro diagnostic medical device		Manufacturing date (YYYY-MM-DD)
LOT	Lot number		Manufacturer
REF	Order number		Observe instructions for use
W	Contains biological material of animal origin	UDI	Unique Device Identifier