May Grunwald – Giemsa - Wright

IVD CE

Ready for Use Stains for Hematic Cellular Elements

Instructions for use (IFU)

Product	Code	Format
May Grunwald	REF G54350150	n° 1 tank x 2500 mL
Giemsa	REF G54350250	n° 1 tank x 2500 mL
Wright	REF G54350450	n° 1 tank x 2500 mL

RECOMMENDED USE

Products used for the staining and identification of blood cell elements, for either manual use or on automatic systems. Qualitative test, used for the staining and identification of blood, histological and cytological cellular elements, which allow the diagnostic analysis of target structures such as whole blood and bone marrow smears.

PRINCIPLE OF THE METHOD

The typical colour of cell nuclei (prevalently purple) is due to the interaction between eosin G and a blue B-DNA compound. The two stains form a compound. The intensity of the colour depends on the blue B content and the ratio between blue B and eosin G. The resulting colour can be influenced by several factors, such as: the pH of the solutions and buffer, the buffer substances, the staining and fixing times.

Composition

	Conc.	U.M.	
May Grunwald			
Eosin Methylene Blue	-	-	*1 Warning: DANGER
Methanol	≥ 50	%	
Giemsa			
Eosina Blu di Metilene			*2 Warning: DANGER
Metanolo	≥ 25 - ≤ 50	%	
Wright			
Eosin Methylene Blue			*3 Warning: DANGER
Methanol	≥ 50	%	
Ethylen Glycol	≥ 1 - ≤ 10	%	

Warning: DANGER

***1- May Grunwald**

H225 - Highly flammable liquid and vapor.
H301+H311+H331 - Toxic if swallowed, in contact with skin or if inhaled.
H370 - Causes damage to organs.
P210 - Keep away from heat sources, hot surfaces, sparks, open flames or other sources of ignition. Not smoking.
P233 - Keep container tightly closed.
P280 - Wear protective gloves/ protective clothing/eye protection/face protection/ hearing protection/…
P301+P310 - IF SWALLOWED: immediately call a POISON CONTROL CENTER/ doctor.
P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P304+P340+P311 – IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor.

***2 - Giemsa:**

H225 - Highly flammable liquid and vapor.
H301+H311+H331 - Toxic if swallowed, in contact with skin or if inhaled.
H370 - Causes damage to organs.
H317 – May cause an allergic skin reaction
P210 - Keep away from heat sources, hot surfaces, sparks, open flames or other sources of ignition. Not smoking.
P280 - Wear protective gloves/ protective clothing/eye protection/face protection/ hearing protection/…
P301+P310 - IF SWALLOWED: immediately call a POISON CONTROL CENTER/ doctor.
P303+P361+P353 - IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
P304+P340+P311 – IF INHALED: Remove person to fresh air and keep comfortable for breathing. Call a POISON CENTER/ doctor.

***3 - Wright:** *Contains Methanol (CAS 67-56-1)*

H225 - Highly flammable liquid and vapour.
H301+H311+H331 - Toxic if swallowed, in contact with skin or if inhaled.
H370 - Causes damage to organs.
P210 - Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P261 - Avoid breathing dust / fume / gas /mist / vapours /spray.
P264 - Wash hands thoroughly after handling.
P280 - Wear protective gloves, protective clothing, eye protection, face protection.
P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER or doctor.
P308+P311 - IF exposed or concerned: Call a POISON CENTER or doctor.

Storage and Stability

Storage Temperature 15-25 °C

If stored closed at 15-25 °C, avoiding direct light, the intact reagents are stable until the expiration date, printed on the label. Slight variations in composition among batches will not affect test results.

Disposal instructions

Used solutions and expired solutions must be disposed of as hazardous waste in accordance with Community provisions on waste or with existing national or regional provisions.

Classification of dangerous substances

The classification, labelling and packaging of products comply with EC regulation 1272/2008 and subsequent amendments and additions. According to this regulation, the reagent is classified as DANGEROUS and must be used with caution. Observe the classification of hazardous substances on the label and follow the instructions in the Safety Data Sheet. The safety data sheet is available on the website or on request.

Reporting of serious incidents

Please inform the manufacturer (through its distributor) and the competent authority of the member state of the European Union in which the user and / or patient is established, of the cases of serious accident occurring in relation to the device. For other jurisdictions, reporting of serious incidents must be made in accordance with the regulatory requirements of the home member state. By reporting serious incidents, you help provide more information about the safety of the in vitro diagnostic medical device.

SAMPLE COLLECTION

Type of Sample

Native whole blood and bone marrow smears, clinical cytological material (urine sediment, sputum, smears from needle aspiration, rinses, imprints).

Sample preparation

Sampling should only be carried out by specialized personnel. All samples must be treated according to the current technique carefully observing the manufacturer's indications about the application and the instructions for use. All samples must be clearly marked so that they can be easily identified.

Precautions

Biological samples must be handled and disposed of as potentially infected samples.

Instructions for use

Use on automatic systems

The method of using these dyes on automatic systems is described in the respective instruction manuals.

Materials required but not supplied

Microscope; Slide covers; Staining plates (rack); Embedding oil Phosphate buffer
G54350600 - Buffer Solution (pH 7.2) 1 x 10 L
G54350350 - Sysclean - 1 x 2500

Preparation and dilution of staining solutions (manual method)

Kit 1 x 2 500 mL - REF G54350150 - "**May Grunwald**"
Dilute 6.0 ml of staining solution in 30 ml of distilled water, mix carefully, then add 4.0 ml of Phosphate Buffer Solution (*). Mix and let stand for about 10 minutes before use. Filter if necessary.

Kit 1 x 2 500 mL - REF G54350250 "**Giemsa**"
Dilute 2,0 mL of staining solution with 38 mL of Phosphate buffer solution (*). Mix and let stand for about 10 minutes before use. Filter if necessary.

Kit 1 x 2 500 mL - REF G54350450 "**Wright**"
Dilute 6,0 mL of staining solution in 30 mL of distilled water, mix, then add 4,0 mL of Phosphate buffer solution (*). Mix and let stand for about 10 minutes before use. Filter if necessary.

Note: The quantities described for each preparation refer to the staining on a rack. In the event of making a cuvette staining, the quantities must be proportionally modified for each individual stain.
Dye precipitates can form in diluted staining solutions and can be eliminated by filtering.
(*) Phosphate buffer: The use of this buffer, according to Weise's method, prevents the formation of incorrect staining (Buffer Solution (pH 7.2) - Ref G54350600)

Stability after dilution

The stability of the stains, once diluted and stored at a temperature of +15°C and + 25°C, is 7 days.

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Instructions for use (IFU)

Manual use

Slide preparation:
- Swipe a drop of sample on a storage slide.
- Allow the slide to dry at room temperature.
- Fix the slide with the addition of a 95% solution of Methanol* for 3-5 minutes. ("**Sysclean**" - Code G54350350)

Procedure for staining "May Grunwald - Giemsa":
1) Cover the smear with 1.0 mL of diluted May Grunwald solution
2) Incubate 3 minutes at room temperature
3) Add 1.0 mL of Buffer Solution (*) (pH 7.2) then mix
4) Incubate 5 minutes at room temperature
5) Eliminate the dye by inversion without rinsing
6) Cover the slide with 1.0 mL of diluted Giemsa solution
7) Incubate for 15-20 minutes at room temperature
8) Rinse the slide with buffer solution
9) Dry the slide at room temperature or at a controlled temperature (50 ° C) or in the air at room temperature for one night
10) The slide, after addition of immersion oil, is ready for reading on a microscope

Procedura per colorazione di "**Wright**":
1) Cover the smear with 1.0 mL of Wright's diluted solution
2) Incubate 1 minute at room temperature
3) Add 1.0 mL Buffer Solution (*) (pH 7.2) then mix
4) Rinse the slide with Buffer Solution
5) Dry the slide at room temperature over night or at a controlled temperature (50 ° C) until complete drying.
6) The slide, after addition of immersion oil, is ready for reading on a microscope

Results obtained with phosphate buffer according to Weise's method (pH 7.2):

Cell type	May Grunwald	Giemsa	Wright
Nuclei	Violet	Red/ Violet	Blu /Violet
Lymphocytes	Cytoplasm Blue	Cytoplasm Blue	Cytoplasm Blue
Monocytes	Cytoplasm Blue / Grey	Cytoplasm Blue / Grey	Cytoplasm Blue / Grey
Neutrophyl granulocytes	Light Violet Granules	Violet Granules	Light Violet Granules
Eosinophyl granulocytes	Red / brown granules	Red / brown granules	Red / brown granules
Basophyl granulocytes	Granules Dark Purple / Black	Granules Dark Purple	Granules Dark Purple / Black
Thrombocytes	Violet	Violet	Violet
Erythrocytes	Reddish / Grey	Reddish / Brownish	Reddish / Brownish

PRECAUTIONS and WARNINGS

1. The kit should only be used by qualified and adequately trained technical personnel.
2. Diagnoses should only be carried out by authorized and qualified personnel.
3. It is recommended to handle the reagent according to the rules of good laboratory practice and make use of the appropriate personal protective equipment.
4. Comply with national directives on occupational safety and quality assurance.
5. Use microscopes that comply with current standards.
6. Laboratory standards for infection protection must be used.

Symbols used in IFU and Packaging	
IVD In vitro diagnostic medical device vitro	Manufacturer
REF Catalogue Number	Instruction for use
LOT Lot Number	Temperature limitation
Expiration date	

Bibliografia

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REVISION	DATE	CHANGE
Rev.D	01/2025	Update of the "Instructions for use" chapter.

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