

## EU DECLARATION OF CONFORMITY

### */Deklaracja zgodności EU*

According to Regulation (EU) 2017/746 on in-vitro diagnostic medical devices/  
zgodnie z Rozporządzeniem (UE) 2017/746 w sprawie wyrobów medycznych do diagnostyki in-vitro

#### **Name and Address of Manufacturer/Nazwa i adres wytwórcy:**

Avantor Performance Materials Poland S.A;  
ul. Sowińskiego 11; 44-101 Gliwice; POLAND

We hereby declare that the below mentioned medical devices for in-vitro diagnostic procedures meet the provision of the Regulation (EU) IVDR 2017/746 for in-vitro diagnostic medical devices. This declaration is supported by the Quality System approval to ISO 13485.

This declaration of conformity is issued under the sole responsibility of Avantor Performance Materials Poland S.A. All supporting documentation is retained at the premises of the manufacturer.

*Niniejszym oświadczamy, że niżej wymienione wyroby medyczne do diagnostyki in-vitro spełniają wymagania rozporządzenia (UE) IVDR 2017/746 dla wyrobów medycznych do diagnostyki in -vitro. Niniejsza deklaracja jest poparta zatwierdzeniem systemu jakości zgodnie z normą ISO 13485.*

*Niniejsza deklaracja zgodności została wydana na wyłączną odpowiedzialność Avantor Performance Materials Poland S.A. Cała dokumentacja uzupełniająca jest przechowywana w siedzibie producenta.*

#### **In-vitro Medical Devices/ Wyroby medyczne do diagnostyki in-vitro: Stains & Dye**

Product Name/Nazwa Produktu: Eosin-Y Alcoholic; Giemsa; Hematoxylin er (Mayer)

Hematoxylin Modified (Harris, Gill II); May-Grünwald; Papanicolaou 2A; Papanicolaou 2B; Papanicolaou 3B

Basic UDI-DI code - 731205W027BF

Brand Name/Marka Produktu: J.T. Baker

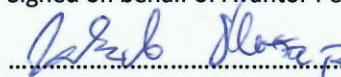
Catalogue Number/Numer katalogowy: 3800; 3856; 3870; 3873 ; 3855; 3554; 3555; 3556


Classification/Klasyfikacja: A

Conformity Assessment Route/Droga oceny zgodności: (EU) 2017/746 Annex II and III

Prepared by/Przygotowane przez: Magdalena Onufryjuk 25 MAY 2022

Signed on behalf of Avantor Performance Materials Poland S.A:

  
.....  
Plant Manager, Board President, Jakub Ślusarz

  
.....  
Board Vice President, Marek Nowaczyk



In Vitro Diagnostic Medical Device  
For professional use only

## May-Grünwald

REF	Name	Packaging size
3855.1000	MAY-GRUNWALD HEMATOLOGY/CYTOLOGY/HISTOLOGY	1 l (glass bottle)
3855.2500	MAY-GRUNWALD HEMATOLOGY/CYTOLOGY/HISTOLOGY	2.5 l (glass bottle)

### Intended purpose

May-Grünwald is Intended to be used in vitro for the examination of specimens derived from the human body. The reagent is designed for use in microscopic analysis. May-Grünwald solution should be used together with Giemsa solution, according to the May-Grünwald Giemsa methodology.

### Principle

May-Grünwald and Giemsa stains are used for tissue sections, cytology smears, blood smears and bone marrow. J.T.Baker® brand stains result in optimized color intensity for clear results in most testing procedures. The purple color of cell nuclei is due to molecular interaction between eosin Y and an azure B-DNA. May-Grünwald's eosin methylene blue and Giemsa's azure eosin methylene blue are intended to be used for staining of blood and bone marrow smears and cytological specimens, such as urine sediment or sputum. For staining of most histology specimens (mostly gastric sections), Giemsa is used. Sørensen buffer solution can be used for easy diluting.

### Specimens (collection and preparation)

As sample material can be used blood smears (dried by air) and bone marrow smears. Also cytology specimens such as urine sediment, sputum, FNAB, imprints, lavages.

### Reagent preparation

Depend on used method this reagent is ready to use and can be applied straight from the bottle or working solution should be prepared.



Avantor Performance Materials Poland S.A.  
ul. Sowińskiego 11, 44-101 Gliwice, Poland  
Tel: +48 32 2392 000

## Procedure (instruction for use)

### Procedures for bone marrow, cytology samples and blood smears

1. General method for bone marrow or cytology specimen or for whole blood smears:

– Prepare Sørensen buffer solution pH 7,

– Prepare the May-Grünwald working solution:

Dilute 250 ml May-Grünwald solution with 250 ml Sørensen buffer solution pH 7.

– Prepare the Giemsa working solution:

Dilute 50 ml Giemsa solution with 450 ml Sørensen buffer solution pH 7.

– Proceed according to the table below:

Reagent sequence	Time**
Undiluted May-Grünwald	3 min
May-Grünwald working solution	5 min
Sørensen buffer pH 7*	1 min
Giemsa working solution*	20 min (blood smears) 25 min (bone marrow, cytology)
Flush in tap or demi water	

2. Traditional method according to Pappenheim for whole blood smears.

– Prepare Sørensen buffer solution pH 7:

– Prepare the Giemsa working solution:

Dilute 25 ml Giemsa solution with 475 ml Sørensen buffer solution pH 7.

– Proceed according to the table below:

Reagent sequence	Time**
Undiluted May-Grünwald	3 min
Flush in demi water	1 min
Giemsa working solution*	20 min
Flush in tap or demi water	

3. Quick staining method for whole blood smears:

– Prepare Sørensen buffer solution pH 7:

– Prepare the Giemsa working solution:

Dilute Giemsa solution 1 to 6 up to 1 to 8 with Sørensen buffer solution pH 7.

– Proceed according to the table below:

Reagent sequence	Time**
Undiluted May-Grünwald	2-3 min
Sørensen buffer pH 7*	1 min
Giemsa working solution*	4-5 min
Flush in tap or demi water	

\*move slides gently

\*\*The times as listed in the tables are approximate and can be adjusted to suit personal preferences. Staining solutions will lose their staining power when heavily used so the staining times should be longer or fresh solutions should be used.

### PERFORMANCE CHARACTERISTICS

Type of blood cell	Characteristic
RBC	Pink/brown discs; clearer in the middle due to their concave structure
PLT	Purple colored granules; much smaller than RBC
NEUT	Transparent, pink/blue cytoplasm; 2-5 lobed bright purple nucleus
EO	Typical pink-orange granulated cytoplasm; generally 2-lobed purple nucleus
LYM	Transparent purple cytoplasm; one large, purple-pink nucleus
MONO	Largest of the leukocytes; transparent, pink/blue cytoplasm with horseshoe-shaped pink/purple nucleus
BASO	Granulo-rich cytoplasm exhibiting dark-blue stain overruling the dark-blue nucleus stain

### Composition

Component	Concentration
Methanol	< 100%
Dye	< 0,5%

### Storage and shelf life



Store MAY - GRUNWALD in temperature 2-30°C.

The shelf life of MAY - GRUNWALD is 5 years from manufacturing date, if stored at the prescribed temperature range.

Do not use reagent beyond the expiration date printed on label.




Avantor Performance Materials Poland S.A.  
ul. Sowińskiego 11, 44-101 Gliwice, Poland  
Tel: +48 32 2392 000

## Warnings and precautions

For in vitro diagnostic use.  
For professional use only.

MAY - GRUNWALD meeting the criteria for classification in accordance with Regulation (EC) No 1272/2008.

	H225: Highly flammable liquid and vapour
	H301+H311+H331: Toxic if swallowed, in contact with skin or if inhaled.
	H370: Causes damage to organs
PREVENTION	P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
	P280: Wear protective gloves/protective clothing/eye protection/face protection
RESPONSE	P301+P310: IF SWALLOWED: Immediately call a POISON CENTRE/doctor.
	P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].

For further information please refer to Master Safety Data Sheet.

## Limitations of use

Do not use reagents with visible physical or chemical changes (color, turbidity) or in case of packaging damage.

## Disposal information

Dispose of contents/container to an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristic at time of disposal.