

**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

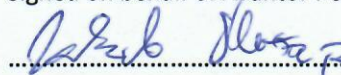
Catalogue Number/Numer katalogowy: 3800; 3856; 3870; 3873 ; 3855; 3554; 3555; 3556


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

## **Declaration of CE conformity**

Avantor Performance Materials B.V. reg. No. 38013066 who is an established manufacturer of Hematology- Reagents, Stains, Controls and Calibrators and products for Histopathology located at:

Teugseweg 20  
7418 AM Deventer  
the Netherlands

herewith declares the following:

The reagents (see attached list) are labeled with the J.T. Baker label and have the CE mark on the label where applicable. The devices comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the conformity assessment procedure according to Annex III.

The products are not part of List A and List B of Annex II of the IVD Directive 98/79/EC but are subject to self registration.

This declaration is valid for all the IVD medical devices described above and which are placed on the market by ourselves on or after the date hereof and which bear the CE marking.

Deventer, the Netherlands.

22 November 2011



Dr. J. Mittendorf  
QA & RA Manager

## J.T.Baker product list for CE marked products

Prod.no.	Product	Pack size
<b>Reagents for diluting and lysing</b>		
3961	Diluid™ 100 Plus	20 liter
3954	Diluid 590	20 liter
3969	Diluid 610	20 liter
3430.9010	Diluid Abacus	10 liter
3430.9020	Diluid Abacus	20 liter
3996	Diluid AC 900	20 liter
3996.9010PC	Diluid AC 900	10 liter
3476.9020PC	Diluid APR	20 liter
3957	Diluid Azide free	20 liter
3958	Diluid Azide free	10 liter
3963.9010	Diluid III Diff	10 liter
3963	Diluid III Diff	20 liter
3974	Diluid III Diff Seaccontainer	20 liter
3459.9020	Diluid Erma	20 liter
3483.9020PC	Diluid NR	20 liter
3439.9020PC	Diluid Mindray	20 liter
3832.9020	Diluid Sheath 3200-4000	20 liter
3976	Diluid ST 1600/2000	20 liter
3496.9020PC	Diluid M5	20 liter
3495.9010PC	Sheath D	10 liter
3826	Sheath Fluid 3000/3500	20 liter
3826.5000	Sheath Fluid 3000/3500	5 liter
3827.5000PC	LeucoLyse	5 liter
3998	CN-free Lyse Diff AC 900	5 liter
3744	CyMet™ 1000 CN free	5 liter
3773.5000PC	CyMet 4500 CN free	5 liter
3824	CyMet 3000	10 liter
3823.1000	CyMet 3200 CN free	1 liter
3825	CyMet 3500 CN free	5 liter
3839.5000PC	CyMet 3500	5 liter
3975	CyMet 530+ CN free	10 liter
3971	CyMet 590 CN free	5 liter
3970	CyMet 610 CN free	10 liter
3977	CyMet 610 CN free	5 liter
3918.5000	CyMet 9000 CN free	5 liter
3431.1000	CyMet Abacus CN free	1 liter
3444.1000PE	CyMet Abacus EO	1 liter
3445.1000PE	CyMet Abacus Baso	1 liter
3477.0500PE	CyMet APR CN free	500 ml
3478.1000PE	CyMet APR EO	1 liter
3479.1000PE	CyMet APR Baso II	1 liter
3755	CyMet Automated	5 liter
3757	CyMet Automated	500 ml
3780	CyMet Automated CN Free	1 liter
3460.0500	CyMet Erma	500 ml
3841.1000PE	CyMet H12 CN Free	1 liter
3842.1000	EO Reagent Autocounter	1 liter
3853.1000	CyMet H20	1 liter
3968	CyMet III Diff	1 liter
3964	CyMet III Diff	5 liter
3972.1000	CyMet III Diff CN free	1 liter
3972.5000	CyMet III Diff CN free	5 liter
3740.0500	CyMet KX CN Free	500 ml
3852.1000	CyMet Micro	1 liter
3852.0500	CyMet Micro	500 ml
3857.1000	CyMet Micro CN free	1 liter
3857.0500	CyMet Micro CN free	500 ml

3863.1000	CyMet Micro CN free	1L micros
3440.0500PE	CyMet Mindray CN Free	500 ml
3441.0500PE	CyMet Mindray	500 ml
3480.5000PC	CyMet SF Baso	5L
3481.5000PC	CyMet SF Diff 1	5L
3482.0500PE	CyMet SF Diff 2	500 ml
3775.1000	CyMet ST 1600/2000	1 liter
3759.1000	CyMet ST 1600/2000 CN free	1 liter
3759.5000	CyMet ST 1600/2000 CN free	5 liter
3788	CyMet STX/STL	1 liter
3919	CyMet STX/STL	5 liter
3484.1000PE	CyMet NR III	1 liter
3486.1000PE	CyMet NR III, CN Free	1 liter
3485.1000PE	CyMet NR V	1 liter
3497.0500PE	CyMet MH CN Free	500 ml
3489.1000PE	CyMet MBA	1 liter
3487.1000PE	CyMet MD(I)	1 liter
3488.0500PE	CyMet MD(II)	500 ml
3077	LyzerGlobin™	500 ml
3769	LyzerGlobin	6 x 15 ml
3771	LyzerGlobin PCE	6 x 15 ml
3770	LyzerGlobin II	10 x 10 ml
3850	LyzerGlobin CN free	6 x 15 ml
<b>Cleaners</b>		
3766.0500	DetectoTerge	500 ml
3763	DetectoTerge	5 liter
3766	DetectoTerge	1 liter
3900	ProClean™	5 liter
3768.1000	ProClean	1L micros
3867.1000PE	ProClean Extra	1L micros
3862.1000	ProClean Extra	1 liter
3862.5000	ProClean Extra	5 liter
3901	ProClean Plus	100 ml
3902.0100PE	ProClean CD	100 ml
3432.5000	ProClean Abacus	5 liter
3946	Blanking Solution Hgb	20 liter
3947	Blanking Solution 1600/2000	20 liter
3917	Hypochlorite 0.5%	1liter
3917.5000	Hypochlorite 0.5%	5 liter
3936.1000	Hypochlorite 5%	1liter
3442.5000PE	Rinse Mindray	5 liter
3915	Rinsing Solution Serono 9000	20 liter
3941.1000PE	HypoChlorite NR	1 liter
3941.5000PC	HypoChlorite NR	5 liter
3498.1000PE	ProClean MX5	1 liter
<b>Reagents for 5-part WBC diff. on STKS and MaxM.</b>		
3938	RBCLyse™	1 liter
3938G.1000PE	RBCLyse G	1 liter
3939	WBCStabilise™	500 ml
3492.0090	RetiCount MH	6 x 15 ml
3493.0500PE	RetiClear MHG	500 ml
3493.1000PE	RetiClear MHG	1 liter
3494.0200PE	RetiCount G	200 ml
3774	Reticount™	30 ml
3777	Reticount CD	15 x 3.5 ml

<b>Hematology Controls</b>		
3721/3722/3723	8 PMC Low/Normal/High	8 ml
3724/3725/3726	8 PMC Low/Normal/High	2.5 ml
3633/3634/3635	8 PMC Low/Normal/High ext	2.5 ml
3701/3702/3703	8 PMC Low/Normal/High	4.5 ml
3922/3923/3924	8 PMC L/N/H Swelab	4.5 ml
3746	8 PMC 1 x L <sub>1</sub> x N <sub>1</sub> x H	3 x 2.5 ml
3747	8 PMC 4 x Normal	4 x 2.5 ml
3748	8 PMC 4 x Normal	4 x 8 ml
3749	8 PMC 4 x Low	4 x 2.5 ml
3751	8 PMC 1x L, 4 x N, 1x H	6 x 2.5 ml
3734/3735/3736	3-Diff Control L/N/H	2.5 ml
3630/3631/3632	3-Diff Control L/N/H ext	2.5 ml
3820/3821/3822	3-Diff Control L/N/H	4.5 ml
3752	3-Diff Control 4 x Low	4 x 2.5 ml
3753	3-Diff Control 4 x Norm	4 x 2.5 ml
3754	3-Diff Control 4 x High	4 x 2.5 ml
3782/3783/3784	CA-Diff Control L/N/H	4.5 ml
3607/3608/3609	CA-Diff Control L/N/H	2.5 ml
3610/3611/3612	DIA Diff 5 Control L/N/H	4.5 ml
3731/3732/3733	XE-Diff Control L/N/H	4.5 ml
3693/3694/3695	SF-Diff Control L/N/H	4.5 ml
3613/3614/3615	BC Diff 5 Control L/N/H	4.5 ml

3684/3685/3686	ADV-Diff Control L/N/H	3.5 ml
3690/3691/3692	ADV Retic 1/2/3	4.0 ml
3828/3829/3830	CD-Diff Control	3.0 ml
3838	CD-Diff Control 2x L <sub>1</sub> N <sub>1</sub> H	6 x 3.0 ml
3687/3688	CD 4K Retic 1/2	3.0 ml
3892/3893/3894	AC-Diff Control	2.5 ml
3896/3897/3898	K-Diff Control	2.5 ml
3696/3697	WBC reduced Plt Control L/H	3.0 ml
3698/3699	WBC reduced RBC Control L/H	3.0 ml
<b>Laser controls for Coulter MaxM, GenS and STKS</b>		
3681/3682/3683	5D Control Low /N /H	5.0 ml
<b>Calibration Set for Cell Analysers.</b>		
3940	Cal Set 1	2 x 2.5 ml
3720	Platelet Control Ext. value	5 x 3 ml
<b>Phosphate Buffered Saline.</b>		
3059	PBS, diluting fluid for bloodgrouping	20 liter
3059.9010PC	PBS, diluting fluid for bloodgrouping	10 liter

Number	Product	Content
<b>Stains and Dyes</b>		
3554.1000PE	Papanicolaou Solution 2A	1 liter
3554.2500PE	Papanicolaou Solution 2A	2.5 liter
3554.9200PE	Papanicolaou Solution 2A	200 liter
3555.1000PE	Papanicolaou Solution 2B	1 liter
3555.2500PE	Papanicolaou Solution 2B	2.5 liter
3556.1000PE	Papanicolaou Solution 3B	1 liter
3556.2500PE	Papanicolaou Solution 3B	2.5 liter
3556.9200PE	Papanicolaou Solution 3B	200 liter
3800.1000PE	Eosine-Y Alcoholic	1 liter
3800.2500PE	Eosine-Y Alcoholic	2.5 liter
3801.1000PE	Eosin Y 0.5% Aqueous	1 liter
3801.2500PE	Eosin Y 0.5% Aqueous	2.5 liter
3871.1000	Eosine Solution 0.2% ready to use	1 liter
3871.2500	Eosine Solution 0.2% ready to use	2.5 liter
3856.0100	Giemsa	0.1 liter
3856.0500	Giemsa	0.5 liter
3856.1000	Giemsa	1 liter
3856.2500	Giemsa	2.5 liter
3870.1000	Hematoxyline er (Mayer)	1 liter
3870.2500	Hematoxyline er (Mayer)	2.5 liter
3873.1000	Hematoxyline (Harris, Gill II)	1 liter
3873.2500	Hematoxyline (Harris, Gill II)	2.5 liter
3879.1000	Leishman	1 liter
3855.0500	May Grünwald	0.5 liter
3855.1000	May Grünwald	1 liter
3855.2500	May Grünwald	2.5 liter

3864.1000	Papanicolaou 2A OG6	1 liter
3864.2500	Papanicolaou 2A OG6	2.5 liter
3865.1000	Papanicolaou 2B Orange II	1 liter
3865.2500	Papanicolaou 2B Orange II	2.5 liter
3866.1000	Papanicolaou 3B EA 50	1 liter
3866.2500	Papanicolaou 3B EA 50	2.5 liter
3876.1000	Shorr	1 liter
3878.1000	Wright	1 liter
<b>Clearing agent</b>		
3905.2500PE	UltraClear	2.5 liter
3905.5000PE	UltraClear	5 liter
3905.9010PE	UltraClear	10 liter
3905.9200	UltraClear	200 liter
<b>Mounting media</b>		
3921.0500	UltraKitt	500 ml
3921.0600	UltraKitt	6 x 100 ml
<b>Fixatives</b>		
3933.1000	10% v/v Buffered Formaldehyde	1 liter
3933.5000PC	10% v/v Buffered Formaldehyde	5 liter
3933.9010 (PE)	10% v/v Buffered Formaldehyde	10 liter (PE)
3933.9020 (PE)	10% v/v Buffered Formaldehyde	20 liter (PE)
3869.1200	Cervix Fixative	12 x 125 ml
3880.1000	Bouin's Fixative	1 liter
3058.9010	Immuno PBS 20x concentrated	10 liter

22 November 2011

## Giemsa

REF	Name	Packaging size
3856.1000	GIEMSA HEMATOLOGY/CYTOLOGY	1 l (glass bottle)
3856.2500	GIEMSA HEMATOLOGY/CYTOLOGY	2.5 l (glass bottle)

### Intended purpose

Giemsa 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. Giemsa solution should be used together with May-Grünwald solution, according to the May-Grünwald Giemsa methodology

### Principle

Giemsa and May-Grünwald 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.

## 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

### Procedures for histology samples

- Prepare the Giemsa working solution: Add 20 ml Giemsa solution to 80 ml deionized water. It is important to add the Giemsa to the water and not vice versa.
- Prepare the differentiation solution: Add 4 drops of Glacial Acetic Acid (96%) to 100 ml of deionized water. Measure the pH of the solution. It should be 3.0 – 3.2.
- Proceed according to the table below:

### DEPARAFFINATION OF TISSUE

Reagent sequence	Time**
UltraClear™/Xylene	3 x 1 min
Ethanol 100%	3 x 1 min
Ethanol 70%	1 min
Flush in tap or demi water	1 min

## STAINING OF TISSUE

Reagent sequence	Time**
Insert 3 times in deionized water	
Giemsa working solution (use only once)	30 min
Differentiation fluid (differentiation to purple)	dip just once
Ethanol 96% (differentiation to blue)	dip just once
Isopropanol (2-propanol)	dip just once
Isopropanol (2-propanol)	3 x 2 min
UltraClear™/Xylene (refresh each time)	3 x 2 min

## PERFORMANCE CHARACTERISTICS

**Nucleus:** blue / violet

**Cytoplasm:** blue

**Erythrocytes:** pink

**Eosinophilic granules:** orange

**Basophilic granules:** purple

## Composition

Component	Concentration
Methanol	< 60%
Glycerol	< 45%
Dye	< 1%

## Storage and shelf life



Store Giemsa solution in temperature 2-30°C.

The shelf life of Giemsa solution is 5 years from manufacturing date, if stored at the prescribed temperature range.


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

## Warnings and precautions

For in vitro diagnostic use.

For professional use only.

Giemsa solution meeting the criteria for classification in accordance with Regulation (EC) No 1272/2008.

	H226: 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
	P260: Do not breathe dust/fume/gas/mist/vapours/spray.
RESPONSE	P301+P310: IF SWALLOWED: Immediately call a POISON CENTRE/doctor.
	P308+P311: If exposed or concerned: Call a POISON CENTRE/doctor
	P370+P378: In case of fire: Use to extinguish.

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.

Staining solutions will lose their staining power when heavily used and the staining times should be longer or fresh solutions should be used.

The over-staining or under-staining which are only noted at the end of the procedure mean that a section must be re-stained, ensuring compliance with the periods of time indicated in the protocol. As a result of the subjective nature of the staining, the exact duration of each stage is impossible to predict. The optimum quality of the stain will be validated by passing through a control slide before starting the daily staining.

### 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.

## Hypochlorite solution 0.5%

REF	Name	Packaging size
3917	Hypochlorite solution 0.5%	1000ml

### Intended purpose

Hypochlorite solution 0.5% is a non – sterile reagent dedicated for intensive cleaning, rinsing and washing of hematology analyzers (capillaries, tubing, chambers).

### Principle

The use of reagents based on sodium hypochlorite is recommended by the manufactures of hematology analyzers to maintain equipment in proper working condition.

Hypochlorite solution 0.5% is cleaning agent “emergency cleaner”, used to remove residual specimen and the remaining reagents contained in the elements of the measuring system of hematology analyzers. It removes any residual cellular, proteinaceous deposits (serum albumins) and the remaining reagents that may appear during the operation of the analyzer.

### Specimens (collection and preparation)

Not applicable.

### Reagent preparation

This reagent is ready to use and can be applied straight from the bottle, no special reagent preparation is needed unless Operators manual for used instrument include it.

### Procedure (instruction for use)\*

Due to differences in the rules for implementing the procedures for cleaning in different types of analyzers, Hypochlorite solution 0.5% should be used according to instrument manufacturer`s instructions for use and should be connected as listed in the Operators manual for instrument.

Recommended models of instruments:

Hypochlorite 0.5% Emergency Cleaner	Model of instrument*
	Abbott Cell-Dyn 1800, 1700, 1600, 1300
	ABX Pentra80, 60, 60C, 60C+, 60MS, ABX Micros 60, ES60, 45
	Benesphera™ H32, Benesphera™ H32 VET
	Beckman Coulter AcT 5™, Beckman Coulter AcT Diff™, AcT Diff 2™, Beckman Coulter AcT 8™, AcT 10™
	Diatron Abacus, Diatron Abacus Junior VET
	Drew Excell 18 (BT2100)
	Erma PCE-210
	Hospitex Hemascreen 18
	HTI Micros CC18
	Medonic CA620-20, CA620-16, CA530-16
	Melet-Schloesing MS9, MS4, MS8, MS8 VET
	Mindray BC-3200, BC-3000 Plus, BC-2800, BC-2300, BC-2000
	Nihon Kohden Celltac™ F MEK-8222K, Celltac ES MEK-7300, Celltac E MEK-7222K, Celltac™ α MEK-8118K + QA-810V
	Seac H20 Genius, SEAC H12
	Sysmex K4500, Sysmex K1000, Sysmex KX21, KX21-N

## Composition (in water)

Component	Concentration
Sodium hypochlorite	< 0,6 %
Sodium hydroxide	< 0,5%
Fragrant	< 0.5 %

## Storage and shelf life



Store in temperature 2-30°C.

The shelf life of Hypochlorite solution 0.5% is 18 months from manufacturing date, if stored at the prescribed temperature range.

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


## Warnings and precautions

For in vitro diagnostic use  
For professional use only

Hypochlorite solution 0.5% meeting the criteria for classification in accordance with Regulation (EC) No 1272/2008.



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	H315: Causes skin irritation
	H319: Causes serious eye irritation
	H412: Harmful to aquatic life with long lasting effects.
PREVENTION	P264: Wash thoroughly after handling
	P280: Wear protective gloves/protective clothing/eye protection/face protection
	P273: Avoid release to the environment
RESPONSE	P332+P313: If skin irritation occurs: Get medical advice/attention
	P362+P364: Take off contaminated clothing and wash it before reuse
	P337+P313: If eye irritation persists: Get medical advice/attention

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 direct packaging damage.

Please refer to Operators manual for instrument for information about any additional limitation of use.

\*The information contained herein has not been approved by analyzers manufacturers, it is recommendation for use only. Always refer to the user manual provided with the equipment at issue.

### 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.



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.



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## 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.

## 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	<p>P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.</p> <p>P280: Wear protective gloves/protective clothing/eye protection/face protection</p>
RESPONSE	<p>P301+P310: IF SWALLOWED: Immediately call a POISON CENTRE/doctor.</p> <p>P303+P361+P353: IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].</p>

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.