

# Hematology Cell Counter Reagents



**MEDIA IVD**  
diagnostics worldwide



## Introduction

MeDia IVD chemicals know-how and over 20 years of experiences are the foundation of the products for hematology. MeDia IVD understands not just cell lysing and chemicals interference of compounds in aqueous solutions and their long term behavior in the presence of other chemicals.

MeDia IVD has become one of the most significant suppliers of hematology products and laboratory chemicals.

## Production

The hematological reagents are produced using state-of-the-art production techniques in modern, certified manufacturing facilities, to assure a minimum of impurities. Production is centralized at the MeDia IVD production unit in the town of Melegnano ( Milan ) , Italy.

The high quality water manufactured by MeDia IVD guarantees the quality of the solution produced.

The products are bottled under controlled conditions to prevent contamination and degradation, thus assuring maximum stability.

## Quality control

Every batch of a hematological reagent is use-tested and released in accordance with ISO-9001 regulations. A highly educated staff of hematology specialists, working in a well-equipped R&D and QC laboratory, guarantees lot-to-lot consistency and provides technical customer support.

## ISO 9001

MeDia IVD ongoing pursuit of total quality has resulted in an ISO-9001 certified quality system

for MeDia IVD Europe. The ISO-9001 certification includes design, development, production and supply of the products.

## CE mark, European IVD directive, 98/79/EC




From 2000 in vitro diagnostic devices ( IVD ) , sold in the European market, have to be in compliance with the IVD directive 98/79/EC and have to show the CE mark when the registration is completed.

For MeDia IVD this means that almost all hematology and histopathology products have to be CE marked.

MeDia IVD has now completed most technical dossiers of the hematology products and has registered these products at the competent authorities of the countries that require such registration.

This means, no difference in quality and all products are produced in the same way as before, QC tested and packed as before and guaranteed as before.

The difference :CE marking requires some additional information on the label. Therefore the label of the IVD's has changed. Symbols instead of text are used to express some data

<b>REF</b>	Production number
<b>IVD</b>	For in vitro diagnostic use
<b>LOT</b>	Lot number
	Expiry date
	Store and use temperature
	Manufactured by
<b>CE</b>	CE registered product

The lot numbering system for hematology reagents ( except hematology controls ) has the following system traceability purposes and shows the manufacturing date :

- yy : year of production
- dd : day of production
- mm : month of production

Further the product description will be printed in 2 languages.  
 Products that are not CE marked are no IVD's according to the definition of the directive.

- E.g. the decyanide kit is not CE marked. It is :
  - not for medical purposes
  - not designed to provide information about a pathological or physiological state to monitor therapeutic measures or about a congenital abnormality.
  - not specific for human samples.

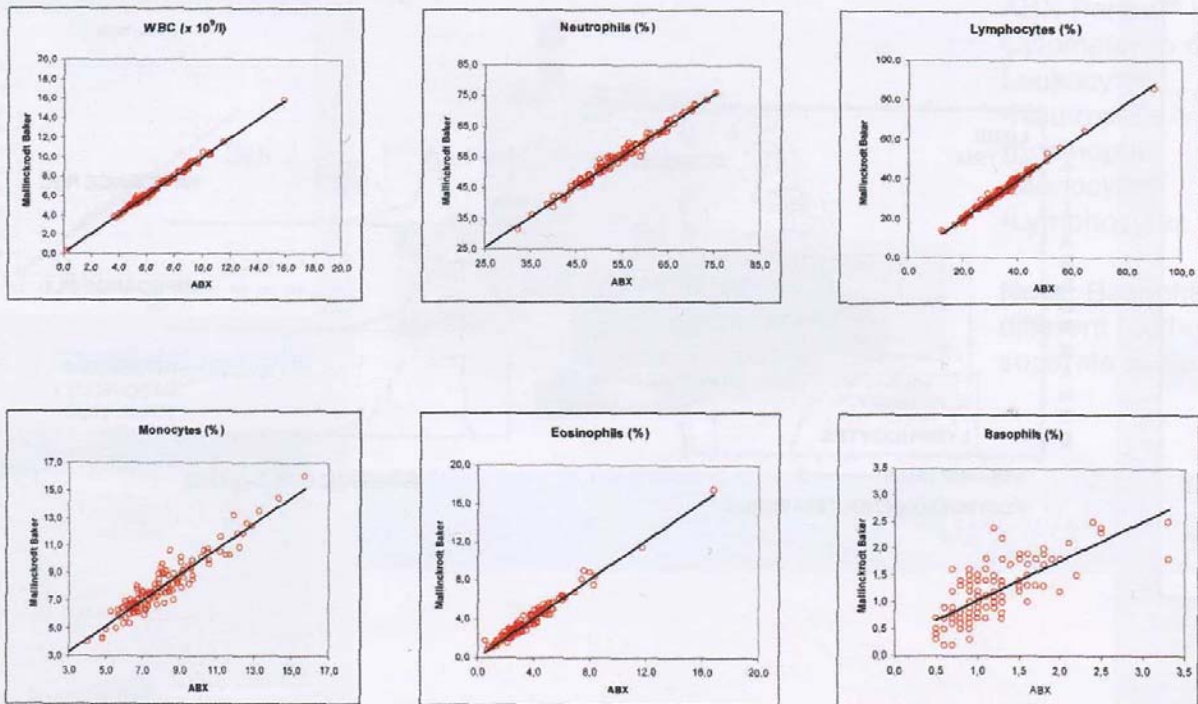
Documentation  
 All documentation is available free of charge.  
 This approach has proven to help you to be successful and guarantees a long term fruitful relation.  
 Our web site inform you in detail about our product program, advised protocols and troubleshooting information.



Table: Overview of analytical results

Parameter	ORIGINALS Overall MEAN 130 samples	MEDIA IVD Overall MEAN 130 samples	TEST/REF Comparison	Correlation
WBC	6,5	6,5	99,9	0,9963
NE%	33,2	33,8	99,0	0,9925
LY%	53,9	53,4	101,7	0,9925
MO%	8,0	8,0	100,9	0,9465
EO%	3,7	3,6	97,0	0,9819
BA%	1,2	1,2	100,5	0,7393
RBC	4,75	4,78	100,6	0,9909
HGB	8,2	8,5	104,6	0,9935
MCV	89,4	93,8	104,9	0,9834
PLT	222,0	228,0	103,0	0,9858
MPV	8,6	8,5	98,5	0,9703

# Correlation graphs



## Kits with exceptional performance

MeDia IVD diagnostic kits are used in over 1,000 laboratories in 10 countries around the world on a variety of automated clinical analysers. All products and services are ISO 9001 accredited which signifies MeDia IVD's commitment to maintaining high quality standards.

MeDia IVD s.r.l. declare that all quality system management procedure are applied to design, production and marketing of in vitro diagnostic devices.

MeDia IVD s.r.l. products, are in accordance to DL 8 september 2000 n. 332 implementation of EC 98/79 directive for in vitro diagnostic devices.

Technical file concerning the product, is kept in reserved archives stored at MeDia IVD s.r.l. head office.

Technical data are at disposal of authorized authority for any consultation .

Certificate of analysis and material safety data sheet are at disposal of customers.

# HEMATOLOGY - CELL COUNTER REAGENTS

For automated or semiautomated instruments. Three of five part diff, differential or laser measurement mode.

REF	DESCRIPTION	SIZE	ANALYZER	FUNCTION
3001013	ISOTONIC AVL	20 LT	AVL 808/816/818	Diluent
3001014	LYSE 816/818	1 LT	AVL 808/816/818	HgB Lising
4592,1	ENZYDET	5 LT	AVL 808/816/818	Enzimatic Detergent
3001015	HEMAPUR	1 LT	AVL 808/816/818	Detergent
4590,3	ISOTONIC CT DIFF	20 LT	Mindray BC-3000P	Diluent
4593,9	LYSE CT DIFF	1 LT	Mindray BC-3000P	HgB Lising
4590,9	LYSE CT DIFF	5 LT	Mindray BC-3000P	HgB Lising
4592,1	ENZYDET	5 LT	Mindray BC-3000P	Enzimatic Detergent
3690,3	ISOTONIC CD	20 LT	CELL DYN 1.6 - 3.5	Diluent
3663,9	LYSE CD 1,6	1 LT	CELL DYN 1.6 - 3.5	HgB Lising
3663,9/5	LYSE CD 1,6	5 LT	CELL DYN 1.6 - 3.5	HgB Lising
3690,3	ISOTONIC CD	20 LT	CELL DYN 1.6 - 3.5	Diluent
3690,6	SHEAT CD 30/35	20 LT	CELL DYN 1.6 - 3.5	Hidrodynamic Fluid
3690,9	RINSE CD 16/35	20 LT	CELL DYN 1.6 - 3.5	Washing solution
3691,2	LYSE CD 3,0	5 LT	CELL DYN 1.6 - 3.5	HgB Lising
	LYSE CD 3,5	5 LT	CELL DYN 1.6 - 3.5	HgB Lising
3001020	ISOTONIC CD 32	20 LT	CELL DYN 3200	Diluent
3001022	LYSE WBC 32	5 LT	CELL DYN 3200	HgB Lising
3001023	LYSE HGB 32	5 LT	CELL DYN 3200	HgB Lising
3001024	ENZYDET C	250 ML	CELL DYN 3200	Enzimatic Detergent
4531.2	VISCOSED	8X15 ML	COULTER SEMIAUTO	Wetting agent
4590.3	ISOTONIC CT DIFF	20 LT	COULTER AUTOMATED	Diluent
4593.9	LYSE CT DIFF	1 LT	COULTER AUTOMATED	HgB Lising
4590.9	LYSE CT DIFF	5 LT	COULTER AUTOMATED	HgB Lising
4592.1	ENZYDET	5 LT	COULTER AUTOMATED	Enzimatic Detergent
3001012	LEUCO PACK	2x1LT+ 0,5	COULTER AUTOMATED	Leucocyte reagent pack
4590,3	ISOTONIC CT DIFF	20 LT	MEDONIC CA 480-620	Diluent
300116	LYSE 480 DIFF	5 LT	MEDONIC CA 480-620	HgB Lising
4592,1	ENZYDET	5 LT	MEDONIC CA 480-620	Enzimatic Detergent
4590,3	ISOTONIC CT DIFF	20 LT	SWELAB	Diluent
6630,3	RINSE SWE	5 LT	SWELAB	Washing solution
6630,9	LYSE SWE	5 LT	SWELAB	HgB Lising
3001005	ISOTONIC H DIFF	20 LT	HYCEL 510,520,680,720 DATACELL8, 10, 16, 20	Diluent
3001006	LYSE H plus DIFF	5 LT	HYCEL 510,520,680,720 DATACELL8, 10, 16, 20	HgB Lising
3001008	RINSE H	20 LT	HYCEL 510,520,680,720 DATACELL8, 10, 16, 20	Washing solution
191,33403	ENZYDET	5 LT	HYCEL 510,520,680,720 DATACELL8, 10, 16, 20	Enzimatic Detergent
3001005	ISOTONIC H DIFF	20 LT	HYCEL 510,520,680,720 DATACELL8, 10, 16, 20	Diluent
191,33403	ENZYDET	5 LT	HYCEL 510,520,680,720 DATACELL8, 10, 16, 20	Enzimatic Detergent
3001002	ISOTONIC LMG	20 LT	ROCHE/ABX 8/10 PAR.	Diluent
3001003	LYSE LMG DIFF	1 LT	ROCHE/ABX 8/10 PAR.	HgB Lising
3001004	CLAIR	1 LT	ROCHE/ABX 8/10 PAR.	Alkaline detergent
4592,1	ENZIDET	5 LT	ROCHE/ABX 8/10 PAR.	Enzimatic Detergent

# HEMATOLOGY - CELL COUNTER REAGENTS

For automated or semiautomated instruments. Three of five part diff, differential or laser measurement mode.

REF	DESCRIPTION	SIZE	ANALYZER	FUNCTION
6930,3	ISOTONIC SYS DIL	20 LT	TOA SYSMEX	Diluent ALL SERIES
6930,9	DETERGENT T	5 LT	TOA SYSMEX	Enzimatic Detergent
6931,5	LYSE S	5 LT	TOA SYSMEX	HgB Lising ALL SERIES
6934,8	CLEAN T	1 LT	TOA SYSMEX	Alkaline detergent
6936,6	QUICKLYSE T	1 LT	TOA SYSMEX C,SERIES	HgB Lising C SERIES
6960,9	LYSE C	5 LT	TOA SYSMEX - K/ NE	HgB Lising K-NE
6961,5	LYSE 3WP	5 LT	TOA SYSMEX - K/ NE	HgB Lising K-NE
3001009/5	LYSE WHB	5 lt	TOA SYSMEX - KX 21	HgB Lising KX 21
3001009/5	LYSE WHB	0,5 lt	TOA SYSMEX - KX 21	HgB Lising KX 21
3001030	LYSE ABX CN	500 mL	ABX PENTRA 60-80	ABX alphalyse 0,4Lt. ABX Lysebio CN free 0,4 Lt.
3001031	LYSE ABX EO	1 Lt.	ABX PENTRA 60-80	Eosinophilis lyse
3001032	LYSE ABX BASO	1 Lt.	ABX PENTRA 60-80	Basophilis lyse
6930.3	ISOTONIC SYS DIL	20 Lt.	TOA SYSMEZ SF 3000	CELL PACK
6931.5	LYSE S	5 Lt.	TOA SYSMEZ SF 3000	HGB lyse
3001005	LYSE SF BASO	5 Lt.	TOA SYSMEZ SF 3000	Basophilis lyse
3001007	LYSE SF DIFF 1	5 Lt.	TOA SYSMEZ SF 3000	
3001029	LYSE SF DIFF 2	500 mL.	TOA SYSMEZ SF 3000	
	ISOTONC NK DIL	20 Lt.	NIHON KOHDEN	DILUENT
	LYSE NK 3+	1 Lt.	NIHON KOHDEN	
	LYSE NK 5	1 Lt.	NIHON KOHDEN	



REG. N. 3525  
UNI EN ISO 9001 : 2000

## ***MEDIA IVD***

Head office

MeDia IVD srl , via Costiera 31D, 31E 47100 Forlì FC , Italy

Tel.0039 0543 782786, Fax 0039 0543 782787

Production unit

Via Giovanni XXIII , 24 20090 Milan MI, Italy

email : [info@mediagnostics.com](mailto:info@mediagnostics.com)