avantor™

To whom this may concern

Date: March 18, 2019 Letter of Authorization

Avantor Performance Materials Poland S.A., reg. No. 0000010108 who is an established manufacturer of Hematology- Reagents, Stains, Controls and Calibrators and products for Histology located at:

Sowińskiego 11
44-101 Gliwice
Poland

herewith confirms that:

I.M Global Biomarketing Group Moldova S.R.L
Republic of Moldova
MD-2001, Chisinau
Tighina str. 65, 607 office
Tel (373 22) 549 120, 549 121
Fax (373 22) 547 373

is authorized to act as our distributor for our hematology/histology reagents and controls (Products) in Moldova

.

We declare that we will supply the Products for the needs of tenders.
We declare that we will supply the Products for tenders with warranty as per the Avantor General Conditions of Sale.

Furthermore I.M Global Biomarketing Group is duly entitled to:

- Register, promote, offer, negotiate prices and sell our Products in Moldova;
- carry out the required product training of the medical and technical personnel who will use these products.

The product specialists of I.M Global Biomarketing Group have been duly trained and are qualified for providing all services in regards to consulting, sales, maintenance and training.

In all the above activities I.M Global Biomarketing Group is acting in its own name and on its own account.
This authorization letter is valid until about 1 year after date.

Avantor Performance Materials S.A.
Poland

H van den Berg,
Marketing Product Manager Diagnostics

Avantor Performance Materials Poland Spółka Akcyjna
Sowińskiego 11
44-101 Gliwice
Tel. 48 32 2392 000

Declaration of conformity

Avantor Performance Materials Poland S.A. who is an established manufacturer of reagents and products for diagnostic in vitro located at:

Sowińskiego 11 Street
44-101, Gliwice
Poland

Herewith declares the following:
Reagents mentioned in attached list are labeled with J.T.Baker label, comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the requirements of ISO 13485 Standard. This declaration is the basic for CE marking of the In Vitro Diagnostic Medical Devices.
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

Gliwice, Poland

January 25, 2019

Anna Szuba

Anna Szuba
Quality Director

AVANTOR
PERFORMANCE MATERIALS

J.T.Baker product list for CE marked products

Prod.no.	Product	Pack size
Reagents for diluting and lysing		
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
Cleaners		
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
Reagents for 5-part WBC diff. on STKS and MaxM.		
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 CN	200 ml
3774	Retecount™	30 ml
3777	Retecount CD	15 x 3.5 ml

AVANTOR
PERFORMANCE MATERIALS

Hematology Controls		
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_1 1 x N_1 1 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_1 4 x N_1 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_2N,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
Laser controls for Coulter MaxM, GenS and STKS		
3681/3682/3683	5D Control Low /N /H	5.0 ml
Calibration Set for Cell Analysers.		
3940	Cal Set 1	2 x 2,5 ml
3720	Platelet Control Ext. value	5 x 3 ml
Phosphate Buffered Saline.		
3059	PBS, diluting fluid for bloodgrouping	20 liter
3059.9010PC	PBS, diluting fluid for bloodgrouping	10 liter

Number	Product	Content
	Stains and Dyes	
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	2.5liter
3801.1000PE	Eosin Y 0.5% Aqueous	1 liter
3801.2500PE	Eosin Y 0.5% Aqueous	2.5liter
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
	Clearing agent	
3905.2500PE	UltraClear	2.5 liter
3905.5000PE	UltraClear	5 liter
3905.9010PE	UltraClear	10 liter
3905.9200	UltraClear	200 liter
	Mounting media	
3921.0500	UltraKitt	500 ml
3921.0600	UltraKitt	6 x 100 ml
	Fixatives	
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

S.R.L. "GBG-MLD" Nr. 4 IDNO 1003600117562 REPUBLICA MOLDOVA, MUN. CHIȘINĂU

AVANTOR™
PERFORMANCE MATERIALS

Diluid* Erma

Intended use
Diluid* Erma is a specially filtered, non-sterile blood diluting fluid for use in cell counting and sizing.
The reagent is designed for automated instrumentation, capable to monitor a three-part WBC differential, based on the aperture impedance principle and electronically adjusted to operate at an osmolality of 330 ± 20 mOsm/kg. Diluid* Erma should be used in combination with CyMet* ERMA III Diff and Lyzerglobin* PCE.

Summary and principle
The reagent is used to dilute whole blood prior to counting and sizing of RBC, PLT and WBC. Content of the reagent maintains stability of RBC, PLT and WBC during counting.

Content: Diluid* Erma is water based and contains:
NaCl, Na_2SO_4, procaïne HCl and preservatives in an inorganic buffer compound.

Warning and precautions
Harmful if swallowed. Avoid contact with eyes, skin and clothing.

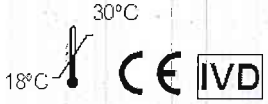
Storage and stability: Diluid* Erma is stable for three years at 18-30°C.

Indications of deterioration
There are no visible deteriorations; otherwise the reagent shouldn't give optimised performance. The reagent can be used through out shelf life, giving optimised performance. No guarantees to reagent performance are given after the expiry date.

Instructions for use
Diluid* Erma should be used undiluted according to instrument manufacturer's instructions for use and should be connected as listed in the Operators manual.
Reagent may be used with Hypochlorite 0.5% or Proclean* as a cleaning agent.
Furthermore reagent may be used with next lysing reagents: with CyMet* ERMA III Diff and Lyzerglobin* PCE.

Pack size
REF 3459.9020	Diluid* Erma	20 litres cubitainer

* Trademark of Avantor™ Performance Materials - Deventer – The Netherlands



Avantor™ Performance Materials
Teugseweg 20 – 7418 AM Deventer – The Netherlands
Tel: +31 (0)570 687500
The devices as mentioned in this sheet comply with the In Vitro Diagnostic Medical Device Directive 98/79/EG

VERSION: 2011-08-12

AVANTOR
PERFORMANCE MATERIALS

CyMet* Erma III Diff

Intended use
CyMet* Erma III Diff is a specially filtered, non-sterile blood lysing reagent fluid for use in cell counting and sizing.
The reagent is designed for automated instrumentation, capable to monitor a three-part WBC differential, based on the aperture impedance principle. CyMet* Erma III Diff is also used to analyse Hemoglobin by optical measurement. CyMet* Erma III Diff should be used in combination with Diluid* ERMA.

Summary and principle
The reagent is used prior to counting and sizing of WBC. The reagent stromatolysis RBC to release Hemoglobin prior to analyse it by optical measurement and modifies WBC for counting and sizing.

Content: CyMet* Erma III Diff is water based and contains:
Quaternary ammonium compounds and KCN (<0.1%).

Warning and precautions
Harmful if swallowed. Avoid contact with eyes, skin and clothing.

Storage and stability: CyMet* Erma III Diff is stable for two years at 18-30°C.

Indications of deterioration
There are no visible deteriorations; otherwise the reagent shouldn't give optimised performance. The reagent can be used through out shelf life, giving optimised performance. No guarantees to reagent performance are given after the expiry date.

Instructions for use
CyMet* Erma III Diff should be used undiluted according to instrument manufacturer's instructions for use and should be connected as listed in the Operators manual.
Reagent may be used with Proclean* And Hypochlorite 0.5% as a cleaning agent.
Furthermore reagent may be used with Diluid* ERMA.

Pack size
REF 3460.0500 CyMet* Erma III Diff 500 ml HDPE bottle

30°C
18°C

CE IVD

Avantor™ Performance Materials
Teugseweg 20 – 7418 AM Deventer – The Netherlands
Tel: +31 (0)570 687500
The devices as mentioned in this sheet comply with the In Vitro Diagnostic Medical Device Directive 98/79/EG

VERSION: 2011-08-12

AVANTOR
PERFORMANCE MATERIALS

ProClean*

Intended use
ProClean* is a specially filtered, non-sterile cleaning fluid for use in cleaning of cell counters.
The product is designed for semi-automated and automated instrumentation, capable to clean blood diluting parts of the instrument.

Summary and principle
The reagent is used to clean blood diluting parts prior to remove cell fragments from the instrument.

Content
ProClean* is water based and contains:
Proteolytic enzym, poly-oxy-ethylene-alkyl-alcohol, NaCl, Na_2SO_4 and preservatives in an inorganic buffer compound. ProClean Contains a purple inert dye.

Warning and precautions
Harmful if swallowed. Avoid contact with eyes, skin and clothing.

Storage and stability
ProClean* is stable for two years at 18-30°C.

Indications of deterioration
There are no visible deteriorations; otherwise the reagent shouldn't give optimised performance. The reagent can be used through out shelf life, giving optimised performance. No guarantees to reagent performance are given after the expiry date.

Instructions for use
ProClean* should be used undiluted according to instrument manufacturer's instructions for use and should be connected as listed in the Operators manual.
Reagent may be used with all kinds of Diluids* and CyMet's*.

Pack size
REF 3900	ProClean*	5 litres cubitainer

18°C 30°C CE IVD

Avantor™ Performance Materials
Teugseweg 20 – 7418 AM Deventer – The Netherlands
Tel: +31 (0)570 687500
The devices as mentioned in this sheet comply with the In Vitro Diagnostic Medical Device Directive 98/79/EG

VERSION: 2011-08-12

AVANTOR
PERFORMANCE MATERIALS

ProClean* Extra

Intended use
Proclean* Extra is a specially filtered, non-sterile cleaning fluid for use in cleaning of cell counters. Intended to be used in vitro for the examination of specimens derived from the human body.
The product is designed for semi-automated and automated instrumentation, capable to clean blood diluting parts of the instrument.

Summary and principle
The reagent is used to clean blood diluting parts prior to remove cell fragments from the instrument.

Content
Proclean* Extra is water based and contains:
Proteolytic enzym, poly-oxy-ethylene-alkyl-alcohol, NaCl, Na_2SO_4 and preservatives in an inorganic buffer compound. ProClean* Extra is colorless.

Warning and precautions
Harmful if swallowed. Avoid contact with eyes, skin and clothing.

Storage and stability
Proclean Extra* is stable for two years at 18-30°C.

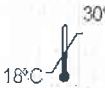
Indications of deterioration
There are no visible deteriorations; otherwise the reagent shouldn't give optimised performance. The reagent can be used through out shelf life, giving optimised performance. No guarantees to reagent performance are given after the expiry date.

Instructions for use
Proclean* Extra should be used undiluted according to instrument manufacturer's instructions for use and should be connected as listed in the Operators manual.
Reagent may be used with all kinds of Diluids* and CyMet's*.

Pack size

REF 3862.1000	ProClean* Extra	1 litre bottle
REF 3862.5000	ProClean* Extra	5 litres cubitainer

* Trademark of Avantor Performance Materials - Deventer – Netherlands



CE IVD

Avantor™ Performance Materials
Teugseweg 20 – 7418 AM Deventer – The Netherlands
Tel: +31 (0)570 687500
The devices as mentioned in this sheet comply with the In Vitro Diagnostic Medical Device Directive 98/79/EG

Version: 2013-03-25

Hypochlorite 0.5%

Intended use
Hypochlorite 0.5% is a specially filtered, non-sterile cleaning fluid for use in cleaning of cell counters.
The reagent is designed for semi-automated and automated instrumentation, capable to clean blood diluting parts of the instrument.

Summary and principle
The reagent is used to clean blood diluting parts prior to remove cell fragments from the instrument.

Content
Hypochlorite 0.5% is water based and contains:
Sodium hypochlorite (0.5% active chlorine) and poly-oxy-ethylene-alkyl-alcohol.

Warning and precautions
Harmful if swallowed. Avoid contact with eyes, skin and clothing.

Storage and stability
Hypochlorite 0.5 % is stable for one year at 18-30°C.

Indications of deterioration
There are no visible deteriorations; otherwise the reagent shouldn't give optimised performance. The reagent can be used through out shelf life, giving optimised performance. No guarantees to reagent performance are given after the expiry date.

Instructions for use
Hypochlorite 0.5% should be used undiluted according to instrument manufacturer's instructions for use and should be connected as listed in the Operators manual.
Reagent may be used with all kinds of Diluids* and CyMet's*.

Pack size
REF 3917.1000 Hypochlorite 0.5% 1 liter bottle
REF 3917.5000 Hypochlorite 0.5% 5 liter bottle

* Trademark of Avantor™ Performance Materials - Deventer – The Netherlands

18°C 30°C CE IVD

Avantor™ Performance Materials
Teugseweg 20 – 7418 AM Deventer – The Netherlands
Tel: +31 (0)570 687500
The devices as mentioned in this sheet comply with the In Vitro Diagnostic Medical Device Directive 98/79/EG

VERSION: 2011-08-12

Hematology controls

Intended use
Clinical hematology laboratories require material for quality control of automated, semi-automated and manual procedures that measure whole blood parameters. J.T.Baker Parameter or Retic Controls are hematology controls for these procedures. When handled like a patient sample and assayed on a properly calibrated and functioning instrument the control will provide values within the expected range indicated on the assay sheet.
Daily use of these controls provides quality control data to confirm the precision and accuracy of instrument operation.

Reagents
Parameter Controls contain stabilized human RBC's, platelet components and fixed RBC's and or simulated WBC's for partial differential analysis to simulate WBC's, in a plasma like fluid with preservatives.

Product no., pack size and open vial stability
See page 4.

Instructions for use
a. Remove the control from the refrigerator and allow vials to warm at room temperature (18 to 30°C) for 20 minutes before mixing.
b. Place the control on a mechanical mixer for 20 minutes or follow next steps to mix the control manually. Important: do not place the vial on a Vortex-mixer.
c. Hold the vial horizontally between the palms of the hands. Roll the vial back and forth for 30 seconds and gently invert the vial 10 times. Avoid vigorous shaking. Continue to mix in this manner until the cells are completely and uniformly suspended.
d. After mixing let the vial rest undisturbed about 15 seconds to allow small air bubbles to disperse. Gently invert the vial 10 times immediately before sampling. Analyze the control using the same technique used for a patient sample.
e. After sampling screw cap vials, carefully wipe the vial ring and cap with lint-free gauze and replace the cap immediately after cleaning.
f. Place vials back in the refrigerator within 30 minutes after measuring the controls. Store in upright position.

Storage and stability
Parameter Controls are to be stored upright at 2-8°C when not in use. Stored at this temperature, the Controls are guaranteed stable until the expiry date.

Procedures
Instrument procedure: make dilutions and assay according to manufacturer's instructions for patient samples. Refer to assay values and range for the system in use.
Manual procedure: reference methods can be applied to 8 parameter and 3-Diff Controls. Refer to a manual of clinical laboratory procedures.

Expected results
The mean assay values and standard deviation for each Parameter Control are derived from replicate analyses on whole blood calibrated instrumentation as well as by manual reference methods. The values obtained on Parameter Controls prior to its expiry date should be within the expected range. The expected ranges listed represent estimates of instrument or inter-laboratory variation for each parameter. Inter-laboratory variation is usually accounted for by instrument calibration, maintenance and operating technique or reagent brand. For this reason, the assay values given are guide-numbers useful for control but are not absolute assays for calibration.
Values and expected ranges for instruments not listed on the Assay Information sheet must be established by the user. It is recommended that at least 5 consecutive analyses will be performed on a properly calibrated instrument for each level to establish the assay mean and standard deviation.

Warning and precautions
Warning: Potential bio hazardous material.
Parameter Controls are intended solely for IN VITRO diagnostic use by trained, qualified personnel. Human blood components used in the Parameter Controls were found to be non-reactive for HBsAg and antibody to HIV when tested with licensed reagents. No known test methods can provide complete assurance that products derived from human blood will not transmit infectious diseases. Follow the same precautions as with patient samples when handling or disposing of vials. Do not inject or consume by mouth. Avoid direct mouth pipetting of samples.

Avantor Performance Materials B.V.
Teugseweg 18 – 7418 AM Deventer – The Netherlands
Tel: +31 (0)570 687500
Avantor.emea@avantormaterials.com
The devices as mentioned in this insert comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC.

8°C
2°C IVD CE

Contrôle hématologique de référence

D0000910
Version: 12.0

Usage indiqué
Les laboratoires d'hématologie clinique ont besoin de substances pour des contrôles de qualité de procédures automatiques, semi-automatiques et manuelles qui mesurent tous les paramètres du sang.
Les sangs de contrôle de J.T.Baker sont des contrôles hématologiques de référence pour ces procédures. S'il est manipulé comme un échantillon de patient et analysé sur un appareil de mesure correctement étalonné et bon état de fonctionnement, le sang de contrôle fournit des valeurs dans la fourchette prévue telle que spécifiée par la fiche de test. L'utilisation journalière de ces sangs apporte des données de contrôle qualité permettant de confirmer la précision et l'exactitude des mesures faites sur l'appareil.

Réactifs
Les sangs de contrôle contiennent des globules rouges humains stabilisés, des plaquettes, des globules rouges modifiés pour simuler les globules blancs, des globules blancs stabilisés combinés avec des cellules humaines modifiées de taille bien déterminée, dans un fluide plasmatique avec des conservateurs.

Références produits, conditionnements et stabilité des contrôles après ouverture.
Voir page 4.

Mode d'emploi
a. Retirer les contrôles du réfrigérateur et laisser les échantillons se réchauffer à température ambiante (18 à 30°C) pendant 20 minutes avant de les mélanger.
b. Placer les contrôles dans un mixeur automatique pendant 20 minutes ou suivre l'étape suivante pour mélanger le contrôle manuellement. Important NE PAS PLACER CES ECHANTILLONS DANS UN MIXEUR DE TYPE VORTEX.
c. Tenir l'échantillon horizontalement entre la paume des mains. Le mélanger en le retournant doucement 10 fois pendant 30 secondes. Eviter de secouer vigoureusement. Continuer à mélanger de cette manière jusqu'à ce que les cellules soient complètement et uniformément en solution.
d. Laisser ensuite l'échantillon se reposer pendant 15 secondes afin de permettre aux bulles d'air de se disperser. Avant d'échantillonner, mélanger doucement en retourner 10 fois l'échantillon. Analyser le contrôle avec la même technique utilisée pour les échantillons du patient.
e. Après avoir prélevé l'échantillon dans les flacons avec un bouchon à vis, essuyer avec précaution le tube et le bouchon avec une serviette en papier absorbant et remettre le bouchon immédiatement après nettoyage.
f. L'échantillon ne doit pas rester plus de 30 minutes à l'extérieur. Stocker l'échantillon au réfrigérateur en position verticale.

Conditions de conservation et stabilité
Les contrôles sanguins doivent être conservés en position verticale entre 2-8°C.Conservés à cette température, les sangs de contrôle sont stables jusqu'à leur date d'expiration.

Procédures
Procédure instrumentale: effectuer les dilutions et procéder selon les instructions des fabricants pour les échantillons de patients. Se référer aux valeurs et aux écarts de l'appareil utilisé.
Procédure manuelle: les méthodes de référence peuvent s'appliquer aux sangs de contrôle de 8 paramètrer et 3-diff. Se référer à un manuel de procédures de laboratoire clinique.

Résultats attendus
Les valeurs moyennes et les déviations standards indiquées sont fondées sur des analyses obtenues à partir de méthodes de référence utilisant des appareils calibrés ou à partir de méthodes de référence utilisant des procédures manuelles, sur tous les paramètres du sang. Les valeurs obtenues sur les sangs de contrôle de paramètres antérieurement à la date d'expiration du produit devraient être à l'intérieur de l'intervalle attendu. Les intervalles attendus listés représentent des estimations de variation entre laboratoires ou entre appareils pour chaque paramètre. La variation entre laboratoires est en général attribuée à la calibrage de l'instrument, la maintenance et la technique d'exploitation ou la marque des réactifs. Pour cette raison, les valeurs indiquées sont des valeurs repères nécessaires pour le contrôle et ne sont pas des données absolues pour la calibration. Les valeurs et les intervalles attendus pour les appareils qui ne sont pas listés sur la feuille d'information doivent être déterminés par l'utilisateur. Il est recommandé qu'au moins 5 analyses consécutives soient effectuées sur un appareillage correctement calibré pour chaque catégorie de sang afin d'établir la moyenne et l'écart type.

Danger et précautions d'emploi
Danger: substance biologique potentiellement dangereuse. Les sangs de contrôle sont uniquement prévus pour une utilisation en diagnostic in vitro par des personnes expérimentées et qualifiées. Les composants de sang humain de contrôle de paramètres ont subi un dépistage négatif concernant les anticorps anti - VIH - 1, - 2 et anti VHC et les antigènes HBS, mais doivent cependant être manipulés comme des produits potentiellement infectieux. Suivre les mêmes précautions qu'avec des prélèvements de sang humain lors de l'utilisation et du rejet des échantillons. Ne pas injecter ni ingérer. Éviter de pipetter les échantillons directement avec la bouche.

Certificate of Completion

This is to certify

Mr. Alexei Legun

Has successfully completed

The technical maintenance training course

On

Fully Automatic Blood Cell Counter

PCE-210

Particle(Blood Cell)Counter

PCE-170/PCE-170N

Hemoglobin meter

Hb-20N

March 24, 2005

Hiroshi Shimosaka
President
ERMA INC

SOCIETATEA CU RĂSPUNDERE LIMITATĂ
S.R.L.
"CBG-MLD"

KIMA

articoli per laboratorio analisi
disposable labware

www.kima.it

Messrs

"GBG-MLD" SRL
STR. TIGHINA 65
2001 CHISINAU
MOLDOVA

Piove di Sacco, 25/02/2019

DISTRIBUTOR AGREEMENT

To whom it may concern, we hereby declare that:

KIMA sas – Via Leonardo Da Vinci 22 – 35028 piove di Sacco - (PD) - ITALY

appoints "GBG-MLD" SRL – STR. TIGHINA 65. - 2001 CHISINAU –MOLDOVA

as authorized distributor of KIMA plastic labware products in the territory of MOLDOVA

GBG MLD has the right to import and distribute KIMA plastic labware products.

This Agreement is valid one (2) years from the present date.

The Distributor does not have any possibility to oblige the company KIMA sas with quantities or delivery time as well as prices without prior written authorization from KIMA sas.

KIMA sas keeps the right to modify the prices according to the market of the raw materials.

Renzo Chiarin
Managing Director

KIMA S.R.L.
Via Leonardo Da Vinci, 22
35028 PIOVE DI SACCO (PD)
Partita IVA 01466290283

CISQ is a member of

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

ICIM

CERTIFICATO n. / *CERTIFICATE No.* **4264/4/C**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

KIMA S.R.L.

UNITÀ OPERATIVE / *OPERATIVE UNITS*

Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - 35028 Piove di Sacco (PD)
Italia

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI EN ISO 9001:2015

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 29

Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili.

Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

Data emissione	Emissione corrente	Data di scadenza
First issue	*Current issue*	*Expiring date*
18/01/2007	18/01/2019	17/01/2022

ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI)
www.icim.it

S.R.L. "GBG-MLD" Nr.4 IDNO 1003600117582 SOCIETATEA CU RĂSPUNDERE LIMITATĂ REPUBLICA MOLDOVA

FEDERAZIONE CISQ

www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 004 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

0449CM_03_IT

CISQ is a member of

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

ICIM

CERTIFICATO n.
CERTIFICATE No. **4265/4/C**

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

KIMA S.R.L.

UNITÀ OPERATIVE / *OPERATIVE UNITS*

Via Leonardo Da Vinci, 22 - Zona Industriale Tognana - 35028 Piove di Sacco (PD)
Italia

È CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

UNI CEI EN ISO 13485:2016

Sistema di Gestione per la Qualità / *Quality Management System*

PER LE SEGUENTI ATTIVITÀ / *FOR THE FOLLOWING ACTIVITIES*

EA: 29

Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili.

Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles.

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato, si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.
For timely and updated information about any changes in the certification status referred to in this certificate, please contact the number +39 02 725341 or email address info@icim.it.

Data emissione	Emissione corrente	Data di scadenza
First issue	*Current issue*	*Expiring date*
18/01/2007	18/01/2019	17/01/2022

ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. "GBG-MLD" Nr.4 IDNO 1003600117582 REPUBLICA MOLDOVA MUN. CHIȘINĂU

FEDERAZIONE CISQ

www.cisq.com

CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 004 A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

0660CIM_02_IT

VACUTEST kima

www.vacutestkima.it

DICHIARAZIONE DI CONFORMITÁ CE
EC DECLARATION OF CONFORMITY

conforme all'Allegato III della Direttiva 98/79/CE *"Dispositivi Medico-Diagnostici In Vitro" e s.m.i.*
according to Annex III of the Directive 98/79/EC on "In Vitro Diagnostic Medical Devices" as amended

fabbricante / *manufacturer*: ***VACUTEST KIMA S.r.l. - articoli per laboratori analisi disposable labware***

indirizzo / *address*: ***Via dell'Industria, 12 35020 Arzergrande (PD) - Italia***

telefono / *phone* **+39-049-9720624** fax / *fax* **+39-049-9720182** posta elettronica / *e-mail* **info@vacutestkima.it**

identificazione dei prodotti / *product identification*: **Autoanalizzatore per provette KIMASED**

KIMASED Tubes AUTOANALYZER

nome commerciale / *brand name*: **"KIMASED AUTO 60" "KIMASED AUTO 20"**

classificazione dei prodotti / *product classification*: **dispositivi diversi da quelli elencati nell'Allegato II della Direttiva 98/79/CE e s.m.i.**
devices other then those mentioned in Annex II of the Directive 98/79/EC as amended

Si dichiara

sotto la propria responsabilità che tutti i dispositivi sopraelencati rispettano le disposizioni applicabili della Direttiva 98/79/CE e s.m.i."*Dispositivi Medico-Diagnostici In Vitro".*
Tutta la documentazione tecnica richiesta dall'Allegato III della succitata Direttiva e comprovante il rispetto dei Requisiti Essenziali di cui all'Allegato I della Direttiva, è conservata a cura del Fabbricante

Hereby we declare

under our sole responsibility that the above mentioned devices meet the applicable provisions of the Directive 98/79/EC as amended on "In Vitro Diagnostic Medical Devices".

All the supporting documents, as required by Annex III of the 98/79/EC Directive, in order to prove conformity to the Essential Requirements as listed in Annex I, are retained under the premises of the Manufacturer

luogo e data / *place and date*: **Arzergrande, 02/09/2013**

firma / *signature*: **Assicuratore Qualità / Quality Manager**
Giovanni Chiarin

VACUTEST kima

www.vacutestkima.it

DICHIARAZIONE DI CONFORMITÁ CE
EC DECLARATION OF CONFORMITY

conforme all'Allegato III della Direttiva 98/79/CE *"Dispositivi Medico-Diagnostici In Vitro" e s.m.i.*
according to Annex III of the Directive 98/79/EC on "In Vitro Diagnostic Medical Devices" as amended

fabbricante / *manufacturer*: ***VACUTEST KIMA S.r.l. - articoli per laboratori analisi***
disposable labware

indirizzo / *address*: ***Via dell'Industria, 12***
35020 Arzergrande (PD) - Italia

telefono / *phone* **+39-049-9720624** fax / *fax* **+39-049-9720182** posta elettronica / *e-mail* **info@vacutestkima.it**

identificazione dei prodotti / *product identification*:

Sistema di prelievo di sangue e altri liquidi biologici mediante provette con vuoto predeterminato in plastica "VACUTEST KIMA".

"VACUTEST KIMA" vacuum blood and biological liquids collection tubes in plastic.

nome commerciale / *brand name*: **"VACUTEST KIMA"**

classificazione dei prodotti / *product classification*: **dispositivi diversi da quelli elencati nell'Allegato II della Direttiva 98/79/CE e s.m.i.**
devices other then those mentioned in Annex II of the Directive 98/79/EC as amended

Si dichiara
sotto la propria responsabilità che tutti i dispositivi sopraelencati rispettano le disposizioni applicabili della Direttiva 98/79/CE e s.m.i."*Dispositivi Medico-Diagnostici In Vitro*".
Tutta la documentazione tecnica richiesta dall'Allegato III della succitata Direttiva e comprovante il rispetto dei Requisiti Essenziali di cui all'Allegato I della Direttiva, è conservata a cura del Fabbricante

Hereby we declare
under our sole responsibility that the above mentioned devices meet the applicable provisions of the Directive 98/79/EC as amended on "In Vitro Diagnostic Medical Devices".
All the supporting documents, as required by Annex III, in order to prove conformity to the Essential Requirements as listed in Annex I, are retained under the premises of the Manufacturer

luogo e data / *place and date*: **Arzergrande, 01/01/2015**

firma / *signature*: **Assicuratore Qualità / Quality Manager**
Giovanni Chiarin

CERTIFICATE OF REGISTRATION

Lorne Laboratories Ltd

Unit 1 Cutbush Park Industrial Estate
Danehill
Lower Earley
Berkshire RG6 4UT UNITED KINGDOM

UL LLC®(UL) issues this certificate to the Firm named above, after assessing the Firm's quality system and finding it in compliance with:

ISO 13485:2016
EN ISO 13485:2016

The manufacture of in vitro diagnostic blood grouping reagents. The purchase for resale of in vitro diagnostic serology test kit.

Authorized by

Michael J. Windler, P.E.
Manager of Global Regulatory Service
Distinguished Member of the Technical Staff
UL Life and Health Sciences
UL LLC

Check Certificate Status: here

4426

File Number	A12241
Certificate	1458.180626
Initial Issue	June 26, 2018
Cycle Start Date	June 26, 2018
Effective Date	June 26, 2018
Expiry Date	May 22, 2020

This quality system registration is included in UL's Directory of Registered Firms and applies to the provision of goods and/or services as specified in the scope of registration from the address(es) shown above. By issuance of this certificate the firm represents that it will maintain its registration in accordance with the applicable requirements. This certificate is not transferable and remains the property of UL LLC.

UL LLC
333 Pfingsten Road
Northbrook, IL 60062-2096
USA

LORNE
LABORATORIES

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product Name	Catalogue Number
Anti-D Duoclone Monoclonal	740010

has been classified as List A (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC) and the Commission Decision on Common Technical Specifications 2009/108/EC.

and is in conformity with the national standards transposing harmonised standards:

- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 15223-1:2016
- BS EN ISO 18113-2:2011
- BS EN ISO 23640:2015

The conformity assessment procedure performed was in accordance with Annex IV of Directive 98/79/EC and was carried out by UL International (UK) Ltd, Wonersh House, The Guildway, Old Portsmouth Road, Guildford, Surrey GU3 1LR, United Kingdom, Notified Body Number 0843.

The certificates issued by UL-UK Ltd to show compliance are numbers 354.170425 and 355.130523.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 23 May 2017.

Eddy Velthuis
Technical Director

Lorne Laboratories Limited | Tel: +44 (0) 118 921 2264
Unit 1 Cutbush Park Industrial Estate | Fax: +44 (0) 118 986 4518
Danehill, Lower Earley | Email: info@lornelabs.com
Berkshire RG6 4UT United Kingdom | www.lornelabs.com

File No A12241;
ISO 13485:2003; ISO 9001:2008

МЕДИКЛОН

ООО "Медиклон"

127276 Москва, Ботаническая ул, 35 , т\ф (495) 231-2272, (499) 502-12-14
e-mail : Mediclone@mediclone.ru

ИНН 7719191607 Р/с **40702810038040106975** в ПАО Сбербанк г.Москва, К/С 30101810400000000225 КПП 771501001 БИК 044525225 ОКПО 51203590 ОГРН 1027700153766

Исх 74-19
24.12.2019

СВИДЕТЕЛЬСТВО
НА ЭКСКЛЮЗИВНОЕ ПРАВО ПРОДАЖИ

Общество с ограниченной ответственностью «МЕДИКЛОН» 127276 Россия Москва ул.Ботаническая, 35, ОГРН 1027700153766 - производитель реагентов для трансфузиологии (Цоликлонов) в лице генерального директора Викторова Н.А. официально удостоверяет, что фирма IM «GBG-MLD» SRL , расположенная по адресу : MD-2001 г Кишинёв, ул.Тигина , 65 , оф. 607 , Республика Молдова , является официальным дистрибьютором (авторизованным дилером) всей продукции производства ООО «МЕДИКЛОН» на всей территории Республики Молдова.

IM «GBG-MLD» SRL имеет право на распространение (реализацию), продвижение (рекламу) а также поддержку продукции, выпускаемой фирмой ООО «МЕДИКЛОН» в Республике Молдова.

IM «GBG-MLD» SRL имеет право участвовать от имени фирмы ООО «Медиклон» в частных и Государственных тендерах и тем самым действовать как официальный представитель фирмы ООО «Медиклон» на всей территории Республики Молдова

ООО «Медиклон» распространяет свои полные гарантии на продукцию, проданную фирмой IM «GBG-MLD» SRL .

Генеральный
директор ООО «Медиклон» Н.А.Викторов

МЕДИКЛОН

ООО "Медиклон"

127276 Москва, Ботаническая ул., 35 , т\ф +7495 231-2272 +7499 502-1214

ПАСПОРТ – СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009

(ЦОЛИКЛОНЫ Анти-А, Анти-В и Анти-АВ)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-А во флаконах по 10 мл с красными крышками

Серия: 096111 **Единица:** 100 мл

Изготовлен: 05.11.2019 **Количество единиц** 40

Годен до: 05.11.2021 **Объем серии:** 10000 мл.

Паспорт: А096111 от 05.11.2019

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид 1.1 Цоликлон анти-А 1.2 Цоликлон анти-В 1.3 Цоликлон анти-АВ	Прозрачная жидкость красного цвета. Прозрачная жидкость синего цвета. Прозрачная бесцветная жидкость.	Соответствует
2. Серологические свойства 2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и О(I) Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(III) и О(I) Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы О(I)	Соответствует Соответствует Соответствует
2.1 Гемагглютинирующая способность	Агглютинация на плоскости эритроцитов А1 и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует 10 секунд
2.3 Титр	Титр Цоликлона анти-А в реакции агглютинации на плоскости с эритроцитами группы А(II) 1:32 - 1:64 Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы В(III) 1 : 64	Соответствует 1:32 - 1: 64
	Титр Цоликлона анти-АВ в реакции агглютина-ции на плоскости с эритроцитами групп А(II) 1:32 - 1: 64 и В(III) 1 : 64	Соответствует 1:64 Соответствует 1:32 - 1: 64

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» М.С. Орлова

МЕДИКЛОН

ООО "Медиклон"

127276 Москва, Ботаническая ул., 35 , т\ф +7495 231-2272 +7499 502-1214

ПАСПОРТ – СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009

(ЦОЛИКЛОНЫ Анти-А, Анти-В и Анти-АВ)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г.

Наименование: Цоликлон Анти-В во флаконах по 10 мл с синими крышками

Серия: 095810 **Единица:** 100 мл

Изготовлен: 21.10.2019 **Количество единиц** 40

~~**Годен до:** 21.10.2021~~ ~~**Объем серии:** 10000 мл.~~

Паспорт: В095810 от 21.10.2019

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид 1.1 Цоликлон анти-А 1.2 Цоликлон анти-В 1.3 Цоликлон анти-АВ	Прозрачная жидкость красного цвета. Прозрачная жидкость синего цвета. Прозрачная бесцветная жидкость.	Соответствует
2. Серологические свойства 2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и О(I) Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(II) и О(I) Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы О(I)	Соответствует Соответствует Соответствует
2.1 Гемагглютинирующая способность	Агглютинация на плоскости эритроцитов А1 и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует 10 секунд
2.3 Титр	Титр Цоликлона анти-А в реакции агглютинации на плоскости с эритроцитами группы А(II) 1:32 - 1:64 Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы В(III) 1 : 64	Соответствует 1:32 - 1: 64
	Титр Цоликлона анти-АВ в реакции агглютина-ции на плоскости с эритроцитами групп А(II) 1:32 - 1: 64 и В(III) 1 : 64	Соответствует 1:64 Соответствует 1:32 - 1: 64

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» М.С. Орлова

МЕДИКЛОН

ООО "Медиклон"

127276 Москва, Ботаническая ул., 35 , Т\ф +7495 231-2272 +7499 502-1214

ПАСПОРТ – СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009

(ЦОЛИКЛОНЫ Анти-А, Анти-В и Анти-АВ)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-АВ

Серия: 098611 **Единица:** 100 мл

Изготовлен: 05.11.2019 **Количество единиц** 10

Годен до: 05.11.2021 **Объем серии:** 10000 мл.

Паспорт: АВ098611 от 05.11.2019

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид		
1.1 Цоликлон анти-А	Прозрачная жидкость красного цвета.	Соответствует
1.2 Цоликлон анти-В	Прозрачная жидкость синего цвета.	
1.3 Цоликлон анти-АВ	Прозрачная бесцветная жидкость.	
2. Серологические свойства		
2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и О(I)	Соответствует
	Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(III) и О(I)	Соответствует
	Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы О(I)	Соответствует
2.1 Гемагглютинирующая способность	Агглютинация на плоскости эритроцитов А1 и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует 10 секунд
2.3 Титр	Титр Цоликлона анти-А в реакции агглютинации на плоскости с эритроцитами группы А(II) 1:32 - 1:64	Соответствует 1:32 - 1: 64
	Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы В(III) 1 : 64	Соответствует 1:64
	Титр Цоликлона анти-АВ в реакции агглютина-ции на плоскости с эритроцитами групп А(II) 1:32 - 1: 64 и В(III) 1 : 64	Соответствует 1:32 - 1: 64

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» М.С. Орлова

МЕДИКЛОН
127276 Москва, Ботаническая ул., 35, т\ф (495) 231-2272 (499) 502-1214

ООО "Медиклон"

ПАСПОРТ–СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ
на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009
(ЦОЛИКЛОН Анти-D Супер)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-D Супер во флаконах по 10 мл с зелеными крышками

Серия: 292711 **Единица:** 100 мл

Изготовлен: 05.11.2019 **Количество единиц** 40

Годен до: 05.11.2021 **Объем серии:** 10000 мл.

Паспорт: Дс292711 от 05.11.2019

Наименование показателя	Характеристика нормы по ТУ	Результаты испытаний
1. Внешний вид	Прозрачная жидкость светло-бежевого цвета	Соответствует
2. Серологические свойства		
2.1 Специфичность	Цоликлон Анти-D Супер не должен агглютинировать D(–) эритроциты.	Соответствует
2.2 Гемагглютинирующая способность	Четкая реакция агглютинации должна наступать в течение 30 сек. после смешивания реагента с D(+) эритроцитами	Соответствует 30 сек.
2.3 Титр	Титр Цоликлона Анти-D Супер в реакции агглютинации на плоскости с D(+) эритроцитами 1:32 Титр Цоликлона Анти-D Супер в реакции прямой агглютинации с D(+) эритроцитами в микропланшете не ниже 1:256	Соответствует 1:32 1:256

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» М.С.Орлова

ООО "Медиклон"
МЕДИКЛОН
127276 Москва, Ботаническая ул., 35 , т\ф (495) 231-2272 (499) 502-1214

ПАСПОРТ – СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009

(ЦОЛИКЛОН Анти-D (IgG))

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-D(IgG)

Серия: 292110 **Единица:** 100 мл

Изготовлен: 28.10.2019 **Количество единиц** 10

Годен до: 28.10.2021 **Объем серии:** 10000 мл.

Паспорт: Дж292110 от 28.10.2019

Наименование показателя	Характеристика нормы	Результаты испытаний
1. Внешний вид	Прозрачная жидкость светло-бежевого цвета	Соответствует
2. Серологические свойства		
2.1 Специфичность	Цоликлон Анти-D не должен агглютинировать D(-) эритроциты.	Соответствует
2.2 Гемагглютинирующая способность	Агглютинация эритроцитов D+ с Цоликлоном в пробирочном тесте с желатином должна появляться не позднее 15 мин.	Соответствует
2.3 Титр	Титр Цоликлона анти-D в пробирочном тесте с желатином 1:128. Титр Цоликлона в непрямом антиглобулиновом тесте : 1:512	Соответствует

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» М.С.Орлова

МЕДИКЛОН
127276 Москва, Ботаническая ул., 35 , т\ф (495) 231-2272 (499) 502-1214

ООО "Медиклон"

ПАСПОРТ–СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ
на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009
(ЦОЛИКЛОН Анти-Kell Супер)
Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-Kell Супер

Серия: 196410 **Единица:** 100 мл

Изготовлен: 21.10.2019 **Количество единиц** 10

Годен до: 21.10.2021 **Объем серии:** 10000 мл.

Паспорт: К196410 от 21.10.2019

Наименование показателя	Характеристика нормы по ТУ	Результаты испытаний
1.Внешний вид	Прозрачная желтоватая или розоватая жидкость	Соответствует
2. Серологические свойства		
2.1 Специфичность	Цоликлон Анти-Kell супер не должен агглютинировать эритроциты К(-)	Соответствует
2.2 Гемагглютинирующая способность	Четкая реакция агглютинации на плоскости должна наступать в течение 30 сек. после смешивания	Соответствует
2.2 Активность	Титр Цоликлона Анти-Kell Супер в реакции прямой агглютинации в микропланшете не ниже 1:16	Соответствует 1:16

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» М.С.Орлова

Declaration of Conformity

HL-7-0664DC DOI 2015/08 (1)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5267L	Thromboplastin L	55983

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson Title: Managing Director

Signed: Date: 06 Aug 2015

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7- 0511 DC DOI 2013/08 (3)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5376	Clauss Fibrinogen 100	55997
5376H	Clauss Fibrinogen 100	55997

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson Title: Managing Director

Signed: Date: 05 Aug 2013

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7- 0137 DC DOI 2013/10 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5186	Routine Control N	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:

Date: 31st October 2013

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe,
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7- 0138 DC DOI 2013/10 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5187	Routine Control A	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:

Date: 31st October 2013

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7- 0135 DC DOI 2013/10 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5183	Routine Control SA	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:

Date: 31st October 2013

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Coagulation

Behnk Elektronik

CERTIFICATE

Mr. Sergey Sorokovitsch

actively and successfully participated

in

SERVICE AND APPLICATION TRAINING

for

Thrombolyzer Systems

from 26th November to 30th November 2012

location

Kommanditgesellschaft
Behnk Elektronik GmbH & Co.
Hans-Böckler-Ring 27
22851 Norderstedt
Germany

Holger Behnk, Director

Abbott Products Romania S.R.L.
Green Court Bucharest
Gara Herastrau 4C
Corp B, etaj 2, sector 2
Bucuresti, Romania

C.U.I. RO 15910608
R.C.: J40/15462/18.11.2003
Capital Social: 595002 lei
Banca: Citibank
IBAN: RO22CITI000000724585043

Tel: +40-21-529 30 00
Fax: +40-21-529 30 01

NOTIFICARE

Catre: **S.C. GLOBAL Biomarketing Group – Moldova SRL**

Noi, ABBOTT PRODUCTS ROMANIA SRL, reprezentant autorizat in Romania (Strada Gara Herastrau, numarul 4C, sector 2, Bucuresti, inreg. la MEC sub nr. 1069/22) al companiei Abbott Laboratories, producator de instrumente de biochimie si imunologie ARCHITECT, hematologie Cell-Dyn Emerald si Cell-Dyn Ruby, precum si de reactivi, controale, calibratori si consumabile pentru acestea, avand capacitatile de productie in SUA, Abbott Park 60064, Illinois,Santa Clara California, Germania –Wiesbaden, Marea Britanie- Dartford, declaram ca analizoarele mai sus mentionate functioneaza in sistem inchis, numai cu reactivi dedicati si produsi de firma Abbott.

Data completarii:
10.09.2019

Producator:

ABBOTT PRODUCTS ROMANIA SRL

Customer Experience Manager,
Camelia Pirvulescu

ABBOTT PRODUCTS ROMANIA S.R.L. BUCURESTI

SOCIETATEA CU RASPUNDERE LIMITATA S.R.L. IDNO 1003600 REPUBLICA MOLDOVA

Abbott
A Promise for Life

Customer Service Organization Certificate of Technical Competence

Abbott

This is to acknowledge that

Sergiu Sorocovici

has met Abbott's Service Certification Criteria for

CELL-DYN Ruby Field Service Certifcation Exam

Certificate is valid for two years from printed completion date

29/06/2018

Manager
I certify that this individual has completed the program requirements

I certify that on the dates above, this individual has completed the program requirements for Instrument Certification

Customer Service Organization Certificate of Technical Competence

Abbott

This is to acknowledge that

Ion Negru

has met Abbott's Service Certification Criteria for

CELL-DYN Ruby Field Service Certifcation Exam

Certificate is valid for two years from printed completion date

29/06/2018

Manager
I certify that this individual has completed the program requirements

I certify that on the dates above, this individual has completed the program requirements for Instrument Certification

Abbott Diagnostics Division
Abbott Laboratories 2016

Abbott

Declaration of Conformity

Certificate Identification: SC-01H73

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
01H73-01	58237	CELL-DYN Sapphire and CELL-DYN Ruby Systems DILUENT/SHEATH	Self-declared

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:		Signature:	
Full Name:	Barry Simpson	Full Name:	Marcy Jaqua
Position:	Site Quality Manager	Position:	Director, Regulatory Affairs
Date of Approval:	29 Jun 2015	Date of Approval:	30 June 2015
Date Issued:	JUN 30 2015	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V2 January 10, 2014	Effective (Date or Lot Number):	JUL 06 2015

Abbott

Declaration of Conformity

Certificate Identification: SC-08H52

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
08H52-01	61165	CELL-DYN Ruby, CELL-DYN 3200 Systems WBC LYSE	Self-declared

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:		Signature:	
Full Name:	Barry Simpson	Full Name:	Marcy Jaqua
Position:	Site Quality Manager	Position:	Director, Regulatory Affairs
Date of Approval:	29. Jun. 2015	Date of Approval:	30 June 2015
Date Issued:	JUN 30 2015	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V2, January 10, 2014	Effective (Date or Lot Number):	JUL 06 2015

Abbott

Declaration of Conformity

Certificate Identification: SC-03H80

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

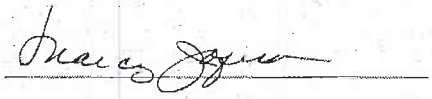
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
03H80-02	61165	CELL-DYN Ruby, CELL-DYN 3200 Systems CN-FREE HGB/NOC LYSE	Self-declared

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:		Signature:	
Full Name:	Barry Simpson	Full Name:	Marcy Jaqua
Position:	Site Quality Manager	Position:	Director, Regulatory Affairs
Date of Approval:	29. Jun. 2015	Date of Approval:	30 June 2015
Date Issued:	JUN 30 2015	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V2 January 10, 2014	Effective (Date or Lot Number):	JUL 06 2015

Abbott

Declaration of Conformity

Certificate Identification: SC-08H59

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
08H59-01	55866	CELL-DYN 26 Plus Control, Full Pack	Self-declared
08H59-02	55866	CELL-DYN 26 Plus Control, Half Pack	Self-declared

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:		Signature:	
Full Name:	Barry Simpson	Full Name:	Marcy Jaqua
Position:	Site Quality Manager	Position:	Director, Regulatory Affairs
Date of Approval:	18 June 2015	Date of Approval:	30 June 2015
Date Issued:	JUN 30 2015	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V5 February 26, 2015	Effective (Date or Lot Number):	JUL 06 2015

Abbott

Declaration of Conformity

Certificate Identification: SC-99644
Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
99644-01	59058	CELL-DYN ENZYMATIC CLEANER CONCENTRATE	**Self-declared**
93641-01	59058	CELL-DYN ENZYMATIC CLEANER CONCENTRATE	**Self-declared**

Authorized European Representative (name and address)	ABBOTT Max-Planck-Ring 2 65205 Wiesbaden, Germany
Storage site of technical documentation (name and address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054 USA
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.
This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:		Signature:	
Full Name:	Barry Simpson	Full Name:	Marcy Jaqua
Position:	Quality Manager	Position:	Regulatory Affairs , Director
Date of Approval:	04. Sept. 2015	Date of Approval:	04 Sep 2015
Date Issued:	SEP 04 2015	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V4, January 10, 2014	Effective (Date or Lot Number):	SEP 11 2015

Abbott

Declaration of Conformity

Certificate Identification: SC-09H46

Legal Manufacturer's Name: Abbott Laboratories
Diagnostics Division

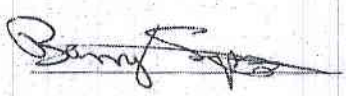
Legal Manufacturer's Address: Abbott Park, IL 60064 USA

List Numbers and Size Code of Devices	GMDN Code	Names and Description of Devices	Classification
09H46-02	58236	CELL-DYN Emerald CLEANER	Self-declared
09H47-02	61165	CELL-DYN Emerald CN-FREE LYSE	Self-declared
09H48-02	58237	CELL-DYN Emerald DILUENT	Self-declared

Authorized European Representative (Name and Address)	ABBOTT Max-Planck-Ring-2 65205 Wiesbaden, Germany
Storage site of technical documentation (Name and Address)	Abbott Laboratories 4551 Great America Parkway Santa Clara, CA 95054
Harmonized Standards	Listed in the Technical Documentation

We, the undersigned, hereby declare that the in vitro diagnostic medical devices described above and bearing the CE marking, conform with the applicable provisions of the EC Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In Vitro Diagnostic Medical Devices as they are transposed into the laws of the member states.

This declaration is made in accordance with Annex III of the IVD Directive and is issued under the sole responsibility of the manufacturer.

Signature:		Signature:	
Full Name:	Barry Simpson	Full Name:	Marcy Jaqua
Position:	Site Quality Manager	Position:	Director, Regulatory Affairs
Date of Approval:	02-Dec-2015	Date of Approval:	01 DEC 2015
Date Issued:	DEC 02 2015	Place Issued:	Abbott Santa Clara
Supersedes:	IRIS V6 July 6, 2015	Effective (Date or Lot Number):	DEC 03 2015

TO WHOM IT MAY CONCERN

This declaration has been established for GBG-MLD Moldova

We, MACHEREY-NAGEL GMBH & CO KG, Neumann-Neander-Str. 6-8, 52355Düren, GERMANY, are Original Manufacturers of

- *Filtration products*
- *Rapid Test products*
- *MEDI-TEST products*
- *Chromatography products*

Our Authorized / *(Non-)Exclusive* Distributor in Moldova
for the above mentioned products under MACHEREY-NAGEL brand, is the company

"GBG-MLD" S.R.L.
Tighina str.65, office 607
MD-2001,Chisinau,
Republic of Moldova

Explicitly, GBG-MLD is allowed to take part and submit bids in official tenders for the goods manufactured by us in GBG-MLD`s own name, risk and on their own account. MACHEREY-NAGEL gives no warranty regarding the fulfilment of any signed contracts or conditions granted by GBG-MLD

This declaration will remain valid up to 31.12.2020 and will automatically end this date without any termination or expiration notice given. In no event shall this declaration be extended automatically.

Düren, 20.01.2020
MACHEREY-NAGEL GMBH & CO. KG

Dr. Christos Evangelakakis
International Sales Manager

MACHEREY-NAGEL DÜREN

SOCIETATEA CU RĂSPUNDERE LIMITATĂ "GBG-MLD" S.R.L. IDNO 1003600117382 REPUBLICA MOLDOVA, MUN. CHIȘINĂU

TÜVRheinland®

Certificate

The Certification Body of
TÜV Rheinland LGA Products GmbH

hereby certifies that the organization

Macherey-Nagel GmbH & Co. KG
Neumann-Neander-Str. 6-8
52355 Düren
Deutschland

has established and applies a quality management system for medical devices for the following scope:

Discription see attachment

Proof has been furnished that the requirements specified in

EN ISO 13485:2016

are fulfilled. The quality management system is subject to yearly surveillance.

Effective Date:	2018-08-21
Certificate Registration No.:	SX 60129407 0001
An audit was performed. Report No.:	21265422 003
This Certificate is valid until:	2020-05-28

Certification Body

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

Date 2018-08-21

Dipl.-Ing. Sven Hoffmann

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
Tel. +49 221 806-1371 Fax: +49 221 806-3935 e-mail:cert-validity@de.tuv.com http://www.tuv.com/safety

EC Declaration of Conformity

EC Declaration of Conformity for In-vitro Diagnostic Products

The procedure for EC declaration of conformity was established on the basis of a full quality assurance system according to EN ISO 13485:2016 according to the IVD directive 98/79/EC Annex IV, except chapters 4 and 6.

CE

We

Name of manufacturer	MACHEREY-NAGEL GmbH & Co. KG
Address:	MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Strasse 6-8 D - 52355 Dueren Germany

confirm that the following product for professional use

Name of product	**Reference numbers**
NucleoSpin Dx Virus	740895
Type:	A generic system for isolation and purification of viral nucleic acids from human serum or plasma samples for subsequent in-vitro diagnostic purposes. No EDMS nomenclature.
Registration number:	DE/CA21/MACHEREY/2002/11/IVD/0011
Notified body:	TÜV Rheinland LGA Products GmbH Tillystr. 2. 90431 Nürnberg

is manufactured in compliance with the European Directive 98/79/EC. The manufacturer is exclusively responsibility for the declaration of conformity.

Düren, 10.09.2018

ppa. Dr. Markus Meusel
(QAM, Manager Reg. Affairs)

www.mn-net.com

MACHEREY-NAGEL GmbH & Co. KG · Neumann-Neander-Str. 6–8 · 52355 Düren · Germany
DE/international: Tel.: +49 24 21 969-0 Fax: +49 24 21 969-199 E-mail: info@mn-net.com
CH: Tel.: +41 62 388 55 00 Fax: +41 62 388 55 05 E-mail: sales-ch@mn-net.com
FR: Tel.: +33 388 68 22 68 Fax: +33 388 51 76 88 E-mail: sales-fr@mn-net.com
US: Tel.: +1 484 821 0984 Fax: +1 484 821 1272 E-mail: sales-us@mn-net.com

EC Declaration of Conformity

EC Declaration of Conformity for In-vitro Diagnostic Products

The procedure for EC declaration of conformity was established on the basis of a full quality assurance system according to EN ISO 9001:2008 and EN ISO 13485:2012+AC:2012 according to the IVD directive 98/79/EC Annex IV, except chapters 4 and 6.

CE

We

Name of manufacturer	MACHEREY-NAGEL GmbH & Co. KG
Address:	MACHEREY-NAGEL GmbH & Co. KG Neumann-Neander-Strasse 6-8 D - 52355 Dueren Germany

confirm that the following test strips for professional use

Name of product	Reference numbers
Medi-Test Glucose PN	93017; 930965
Medi-Test Glucose	93001; 93024
Medi-Test Glucose 3	93003; 93026
Medi-Test Glucose/Keton	93020; 93025
Medi-Test Protein 2	93004; 93027
Medi-Test Keton	93005; 93028
Medi-Test Nitrit	93006; 93029
Medi-Test Combi 2	93015; 93037
Medi-Test Urbi	93012
Medi-Test Combi 3	93050
Medi-Test Combi 3A	93007; 93030
Medi-Test Combi 5	93009; 93032
Medi-Test Combi 5N	93035; 93036
Medi-Test Combi 5S	93055
Medi-Test Combi 6	93018; 93078
Medi-Test Combi 6A	93013; 93034
Medi-Test Combi 7	93010; 93022
Medi-Test Combi 7L	93031
Medi-Test Combi 8L	93021
Medi-Test Combi 9	93011; 93023
Medi-Test Combi 10	93056
Medi-Test Combi 10L	93058; 93079
Medi-Test Combi 10 SGL	93067; 93077
Medi-Test URYXXON Stick 10	93068; 930872
Medi-Test Combi 11	93060; 930871
Medi-Test Mikroalbumin	930874

MACHEREY-NAGEL GmbH & Co. KG · Neumann-Neander-Str. 6-8 · 52355 Düren · Germany

DE / International:
Tel.: +49 24 21 969-0
Fax: +49 24 21 969-199
E-mail: info@mn-net.com

CH:
Tel.: +41 62 388 55 00
Fax: +41 62 388 55 05
E-mail: sales-ch@mn-net.com

FR:
Tel.: +33 388 68 22 68
Fax: +33 388 51 76 88
E-mail: sales-fr@mn-net.com

US:
Tel.: +1 484 821 0984
Fax: +1 484 821 0272
E-mail: sales-us@mn-net.com