EN – Instruction for use

ProClean™

CE IVD

APPLICABLE PRODUCTS

QTY REF

Description	Pack Size	Cat. No.
ProClean™	5 L	3900
ProClean™, Micros	1 L	3768.1000

INTENDED PURPOSE

The product is used in cleaning of cell counters of samples derived from the human body. The functionality of the product is limited to cleaning of cell counters and is suitable for the preparation of diagnostic analyses. It is only meant for laboratory use by healthcare professionals. The intended patient population are human patients in need of such examinations.

COMPOSITION

The product is composed of propylene glycol (< 10), sodium sulphate (< 1%), proteolytic enzyme (< 1%), sodium hydrogen phosphate (< 0,5%), disodium phosphate (< 0,5%), surfactant (< 0,5%), sodium chloride (< 0,5%), EDTA (< 0,1%) and preservative (< 0,05%).

PRINCIPLE

Haematology cell analysers must be cleaned daily with a suitable cleaning reagent to prevent the instruments of pollution with blood proteins and cell debris. Even cleaners are needed in emergency cases, such as aperture clogging and tubing blockage. Cleaning and rinsing solutions are needed to keep the instrument in perfect state. It will contribute to a high level of accuracy and precision.

ProClean™ is an enzymatic regular cleaning solution, which contains proteolytic enzymes to remove proteineous pollution and cell debris. ProClean contains a harmless purple dye visualizing the reagent in the tubing of the instrument. In daily routine ProClean is connected to the instrument as an on-line cleaner.

LIMITATIONS OF USE

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

Please refer to operator's manual for instrument for information about any additional limitation of use.

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

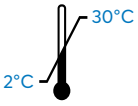
SPECIMENS

Not applicable.

REAGENT PREPARATION

This reagent is ready to use and can be applied straight from the container. No special reagent preparation is needed unless operator's manual for used instrument includes it.

STORAGE CONDITIONS AND SHELF LIFE



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

APPLICATION

ProClean should be used according to instrument manufacturer's instructions for use and should be connected as listed in the operator's manual for the instrument.

For further information on special methods, please refer to the Annex.

DISPOSAL

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.

WARNINGS AND PRECAUTIONS

The substance is classified as not hazardous according to the regulation in force.

For further information please refer to Safety Data Sheet.

J.T.Baker®

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SYMBOLS USED

Symbol	Symbol title and description
CE	CE marking of conformity
REF	Catalogue number
	Fragile, handle with care
	Do not use if the packaging is damaged
	Consult instructions for use
	Use-by date

Symbol	Symbol title and description
IVD	In vitro diagnostic medical device
QTY	Product Quantity in the box
	Manufacturer
UDI	Unique Device Identification
	Date of manufacture
LOT	Batch code

Symbol	Symbol title and description
	Made in Poland
	Keep dry
	Keep away from sunlight
	Caution
	Temperature limit

ANNEX

ProClean should be used according to instrument manufacturer's instructions for use and should be connected as listed in the operator's manual for instrument.

Recommended models of instruments:

Model of instrument*	Description	Reagent	REF
	Diluent	Diluid™ III Diff	**3963**
Abbott Cell-Dyn® Emerald 18	Cleaner	ProClean™	**3900**
	Diluent	Diluid™ III Diff	**3963**
	Cleaner	ProClean™	**3900**
Beckman Coulter® AcT Diff™, AcT Diff 2™	Emergency Cleaner	Hypochlorite 0.5%	**3917**
Drew Excell 18 (BT2100) HTI® micros CC18	Hematology Control	3-Diff Control L/N/H	**3433/3434/3435** **3502/3503/3504**
	Diluent	Diluid™ III Diff	**3963**
Beckman Coulter® AcT 8™, AcT 10™	Cleaner	ProClean™	**3900**
SEAC H12	Emergency Cleaner	Hypochlorite 0.5%	**3917**
	Diluent	Diluid™ III Diff	**3963**
	Cleaner	ProClean™	**3900**
	Emergency Cleaner	Hypochlorite NR	**3941**
Drew D3	Hematology Control	3-Diff Control L/N/H	**3433/3434/3435** **3502/3503/3504**
	Diluent	Diluid™ ERMA	**3459.9020**
	Cleaner	ProClean™	**3900**
	Emergency Cleaner	Hypochlorite 0.5%	**3917**
Erma PCE-210	Hematology Control	3-Diff Control L/N/H	**3433/3434/3435** **3502/3503/3504**
	Diluent	Diluid™ III Diff	**3963**
	Cleaner	ProClean™	**3900**
Orphée Mythic™ 18	Hematology Control	3-Diff Control L/N/H	**3433/3434/3435** **3502/3503/3504**
	Diluent	Diluid™ 22	**2990.9010PC**
Orphée Mythic™ 22	Cleaner	ProClean™	**3768.1000**
	Diluent	Diluid™ III Diff	**3963**
	Cleaner	ProClean™	**3900**
	Emergency Cleaner	Hypochlorite 0.5%	**3917**
SEAC H20 Genius	Hematology Control	CD-Diff Control L/N/H	**3452/3453/3454**

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

DISCLAIMER

We pay the utmost attention to the quality of our products. In case of any malfunction or dissatisfaction please use the complaints form on the contact page of your local **vwr.com** website and indicate the reference and batch number of the product concerned.

The attention of the users is drawn to the possible risks when the product is used for purposes other than what it is intended for. This IFU does not exempt the user from knowing and implementing all the information regulating their activity. The user will take under their responsibility the relevant precautions needed in the use that they make of this product.

CHANGE LOG

This instruction for use was established on June 2023 and cancels all previous instructions. The information is based on our knowledge and our experience on this day.

VERSION 02

Changes regarding latest IFU version:

- General update of the layout
- Minor corrections and clarifications

CONTACT

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Any serious incident that has occurred in relation to this product must be reported to the manufacturer and the Competent Authority of the Member State in which the user and/or the patient is established. Please contact Avantor's customer service department.

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