IVD In Vitro Diagnostic Medical Device
For professional use only

Leukolyse 3200

REF	Name	Packaging size
3475.5000PC	Leukolyse 3200	5 l

Intended purpose

LeucoLyse 3200 is a specially filtered, non-sterile blood stabilising reagent fluid for use in cell counting and sizing. Intended to be used in vitro for the examination of specimens derived from the human body. The reagent is designed for Abbott® Cel-Dyn 3200, capable to monitor a five-part WBC differential. LeucoLyse should be used in combination with Diluid/Sheath 3200-4000.

Principle

LeucoLyse 3200 is a reagent that is developed for use in the Abbott Cell-Dyn 3200, a 5-part differential instrument that uses the Abbott MAPPS technology. Using the MAPSS™ (for Multi-Angle Polarized Scatter Separation) technology, blood cells are measured by usage of a laser beam and flow cell and a special sheath fluid. When a cell comes in front of the laser beam, light will be scattered in different directions. The intensity of light scattered in these different directions is measured. Various combinations of four measurements are used to classify the WBC subpopulations and provide morphological flagging. The information from all four measurements is used to differentiate the WBCs into five subpopulations: Neutrophils, Lymphocytes, Monocytes, Eosinophils, Basophils.

The reagent is used prior to counting and sizing of WBC. The reagent stabilizes WBC for counting and sizing.

Specimens (collection and preparation)

Whole blood collected on a coagulant.

Reagent preparation

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

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

Procedure (instruction for use)*

LeucoLyse 3200 should be used according to instrument manufacturer`s instructions for use and should be connected as listed in the Operators manual for instrument.
Reagent may be used with Diluid™/Sheath 3200-4000

Recommended models of instruments:

Model of instrument*			
Abbott Cell-Dyn® 3200	**Description**	**Reagent**	**REF**
	Diluent	Diluid™/Sheath 3200-4000	3832.9020
	Scatter reagent	LeucoLyse 2000	3475.5000PC
	Hematology Control	CD-Diff Control L/N/H	3452/3453/3454

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

Composition (in water)

Component	**Concentration**
2-Butoxyethanol	< 1%
2-Phenoxethanol	< 0.1%
Sodium Chloride	< 0.05%
TRIS buffer	< 0.05%
Surfactant	< 0.05%

Storage and shelf life



Store in temperature 2-30°C.

The shelf life of LeukoLyse 3200 is 2 years from manufacturing date, if stored at the prescribed temperature range.
Do not use reagent beyond the expiration date printed on label.

Warnings and precautions

For in vitro diagnostic use
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LeukoLyse 3200 meeting the criteria for classification in accordance with Regulation (EC) No 1272/2008.

For further information please refer to Master Safety Data Sheet.

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Limitations of use

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

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

Disposal information

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

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