

EN – Instruction for use

UltraClear™



APPLICABLE PRODUCTS	QTY	REF
Description	Pack Size	Cat. No.
UltraClear™	2,5 L	3905.2500PE
UltraClear™	5 L	3905.5000PE
UltraClear™	10 L	3905.9010PE

INTENDED PURPOSE

The product is used as a clearing agent during tissue embedding and deparaffination processes of samples derived from the human body. The functionality of the product is limited to histological examinations and is suitable for the preparation of diagnostic analyses. It is only meant for laboratory use by healthcare professionals. The intended patient population are humans in need of such examinations.

COMPOSITION

The product is composed of hydrocarbons, C11-C12, isoalkanes (< 100%).

PRINCIPLE

Tissue that has been fixed must be embedded in paraffin to make sectioning in thin slices possible. First, the water in the tissue must be removed. This is normally done with a series of alcohols (70– 95–100%). The next step is called "clearing" and consists of removal of the dehydrant, or water-removing agent, with a clearing reagent. UltraClear™ clearing agent is an iso-paraffin based clearing agent for tissue embedding and deparaffination. It works with all kinds of paraffin and no methanol is needed during dehydration. Iso-paraffins are considered to be more environmentally friendly when compared to traditional solvent containing clearing agents. After clearing, the tissue is infiltrated with paraffin, sectioned, and put on a microscopic slide. The embedding process must be reversed to get the paraffin wax out of the tissue and allow water soluble dyes to penetrate the sections. The slides are deparaffinized by running them through UltraClear™ clearing agent and then through alcohols and then water and finally the slides are stained. The stained slide is taken through a series of alcohols to remove the water, then through UltraClear™ clearing agent to a point at which the cover glass can be mounted with UltraKitt™ mounting media.

UltraClear™ clearing agent is an isoparaffin-based clearing agent that can be used as an environmentally friendly xylene replacement during tissue embedding, deparaffination and staining processes. Not only is UltraClear™ clearing agent odourless, less toxic and less flammable when compared to xylene, it is also easy to adapt with existing working protocols.

LIMITATIONS OF USE

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

UltraClear™ clearing agent cannot be used in combination with Eukit/DPX or Entellan. Neither UltraKitt™ mounting media nor UltraClear™ clearing agent can be used with cover slipping machines using a tape, as the glue of the tape will only dissolve in xylene, not in UltraClear™ clearing agent.

To be aware of performance limits, reference must be made to the technique used.

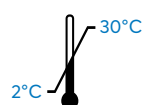
SPECIMENS

The product is supposed to be used with samples of examinations of sections fixed in formalin, paraffin embedded tissues and histological and bacteriological smear specimens.

REAGENT PREPARATION

This reagent is ready to use and can be applied straight from the container, no special reagent preparation is needed.

STORAGE CONDITIONS AND SHELF LIFE



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



APPLICATION

When regular laboratory procedures are used but xylene is replaced by UltraClear™ clearing agent in tissue processing, the following steps should be considered:

- Frequent refreshment of ethanol 100%. Xylene still can dissolve small amounts of water while UltraClear™ clearing agent cannot. Ethanol 100% helps to complete the dehydration of the tissue.
- Time of clearing should be increased by 30 minutes. Penetration of xylene in tissue is faster than with UltraClear™ clearing agent; however, UltraClear™ clearing agent hardens fragile tissue material much less than xylene (examples are lymph nodes and testis). This is a major advantage to using UltraClear™ clearing agent over xylene.

UltraClear™ clearing agent is recommended and optimized for methods for tissue embedding on Shandon Hypercentre and the Sakura VIP 3000. Recommendations were made for deparaffination and cover slipping using both UltraClear™ clearing agent and UltraKitt™ mounting media during HE-staining and PAP staining procedures. In all cases it should be noted that all recommendations are subject to individual changes and these recommendations should be used as a guideline.

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 characteristics at time of disposal.

WARNINGS AND PRECAUTIONS



H226: Flammable liquid and vapour.

H304: May be fatal if swallowed and enters airways.

P331: Do NOT induce vomiting

PREVENTION

P210: Keep away from heat, hot surfaces, sparks, open flames, and other ignition sources. No smoking.

RESPONSE

P301+P310: IF SWALLOWED: Immediately call a POISON CENTER/doctor.

For further information please refer to Safety Data Sheet.

ANNEX

PROGRAM ON HYPERCENTER OF SHANDON

Reagent sequence	Time
Formalin 10% v/v	5 min., 45°, 0, drain=2 min.
Ethanol 90%	5 min., 45°, 0, drain=2 min.
5x Ethanol 100%	5 min., 45°, 0, drain=2 min.
2x UltraClear™	10 min., 45°, 0, drain=2 min.
UltraClear™	15 min., 45°, 0, drain=2 min.
Paraffin	20 min., 60°, 0, drain=2 min.
Paraffin	30 min., 60°, 0, drain=2 min.

Reagent sequence	Time
Formalin 10% v/v	10 min., 0, drain=2 min.
Ethanol 90%	20 min., 0, drain=2 min.
Ethanol 100%	30 min., 0, drain=2 min.
4x Ethanol 100%	60 min., 0, drain=2 min.
2x UltraClear™	90 min., 0, drain=2 min.
UltraClear™	120 min., 0, drain=2 min.
2x Paraffin	150 min., 0, drain=2 min.

Reagent sequence	Time
Formalin 10% v/v	24h 10 min., N, drain=2min.
Ethanol 90%	20 min., 0, drain=2 min.
Ethanol 100%	30 min., 0, drain=2 min.
4x Ethanol 100%	60 min., 0, drain=2 min.
2x UltraClear™	90 min., 0, drain=2 min.
UltraClear™	120 min., 0, drain=2 min.
2x Paraffin	150 min., 0, drain=2 min.

PROGRAM ON VIP 3000

Reagent sequence	Minutes	Temperature
Formalin 10% v/v	30	40 °C
Formalin 10% v/v	60	40 °C
Ethanol 50%	30	40 °C
Ethanol 70%	30	40 °C
Ethanol 100%	30	40 °C
Ethanol 100%	60	40 °C
Ethanol 100%	60	40 °C
Ethanol 100%	120	40 °C
UltraClear™	40	40 °C
UltraClear™	80	40 °C
Paraffin	60	56 °C
Paraffin	60	56 °C
Paraffin	60	56 °C
Paraffin	120	56 °C

SYMBOLS USED

Symbol	Symbol title and description	Symbol	Symbol title and description	Symbol	Symbol title and description
	CE marking of conformity		In vitro diagnostic medical device		Made in Poland
	Catalogue number		Product Quantity in the box		Keep dry
	Fragile, handle with care		Manufacturer		Keep away from sunlight
	Do not use if the packaging is damaged		Unique Device Identification		Caution
	Consult instructions for use		Date of manufacture		Temperature limit
	Use-by date		Batch code		

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 in 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.