

BenchMark Special Stains Deparaffinization Solution (10X)

REF 860-036

06523102001

IVD

INTENDED USE

BenchMark Special Stains Deparaffinization Solution (10X) is intended for laboratory use to solubilize paraffin during the deparaffinization process for slides containing formalin-fixed, paraffin-embedded (FFPE) tissues during special stains procedures on a BenchMark Special Stains instrument.

This product is intended for in vitro diagnostic (IVD) use.

PRINCIPLE OF THE PROCEDURE

BenchMark Special Stains Deparaffinization Solution (10X) is used with BenchMark Special Stains reagent kits, ancillary reagents, and BenchMark Special Stains instruments to achieve the appropriate histochemistry staining. During the staining process, appropriately diluted BenchMark Special Stains Deparaffinization Solution (10X) is used in combination with heat and vortex mixing for removal of paraffin on the slide.

MATERIAL PROVIDED

One 2 L bottle of BenchMark Special Stains Deparaffinization Solution (10X) contains an aqueous-based detergent solution with 0.5% ProClin 300, a preservative.

Reconstitution, Mixing, Dilution, Titration

BenchMark Special Stains Deparaffinization Solution (10X) must be diluted with nine parts of deionized water prior to use.

1. Ensure the 20 L graduated carboy and Deparaffinization Solution bulk bottle are clean to avoid microbial contamination. (Refer to the BenchMark Special Stains instrument User Guide for instructions.)
2. Check the spigot of the carboy to ensure it is in the off position.
3. Add deionized water until the carboy is approximately three quarters full.
4. Pour the entire contents of the 2 L bottle of BenchMark Special Stains Deparaffinization Solution (10X) into the carboy.
5. Fill the carboy to the 20 L graduation mark with deionized water. If large quantities of bubbles form during the filling procedure, allow the solution to sit until the bubbles have dissipated.
6. Place the cap on the container and mix the solution well to ensure that the concentrate is thoroughly mixed with the water. The diluted BenchMark Special Stains Deparaffinization Solution (1X) solution is ready to use.

MATERIALS REQUIRED BUT NOT PROVIDED

Additional reagents including but not limited to BenchMark Special Stains reagent kits and ancillary components are not provided.

Not all products listed in the method sheet may be available in all geographies. Consult your local support representative.

The following reagents and materials may be required for staining but are not provided:

1. Deionized water
2. General purpose laboratory equipment
3. BenchMark Special Stains instrument

STORAGE AND STABILITY

Upon receipt and when not in use, store at 15-30°C. Do not freeze.

This reagent is expiration dated. When properly stored, the reagent is stable to the date indicated on the label. Do not use reagent beyond the expiration date.

BenchMark Special Stains Deparaffinization Solution (10X) must be examined for microbial contamination prior to use. The signs indicating contamination or instability of this product are turbidity of the solution, odor development, or precipitation. At the first sign of possible reagent contamination or instability, contact your local support representative.

1X Dilute

Store at 15-30°C. Keep out of direct sunlight.

Prepared as directed, testing has shown the 1X solution is stable up to three months or to the expiration date indicated in the original package label, whichever happens first. Once diluted, the solution should be examined for microbial contamination prior to use. The signs indicating contamination or possible instability of the product include turbidity of the solution, development of an odor characteristic of bacterial growth, or presence of precipitate in the solution.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic (IVD) use.
2. For professional use only.
3. ProClin 300 solution is used as a preservative in this solution. It is classified as an irritant and may cause sensitization through skin contact. Take reasonable precautions when handling. Avoid contact of reagents with eyes, skin, and mucous membranes. Use protective clothing and gloves.
4. Materials of human or animal origin should be handled as biohazardous materials and disposed of with proper precautions. In the event of exposure, the health directives of the responsible authorities should be followed.^{1,2}
5. Avoid contact of reagents with eyes and mucous membranes. If reagents come in contact with sensitive areas, wash with copious amounts of water.
6. Avoid microbial contamination of product as it may cause incorrect results.
7. For further information on the use of this device, refer to the BenchMark Special Stains instrument User Guide, and instructions for use of all necessary components located at dialog. Roche.com.
8. Consult local and/or state authorities with regard to recommended method of disposal.
9. Product safety labeling primarily follows EU GHS guidance. Safety data sheet available for professional user on request.
10. To report suspected serious incidents related to this device, contact the local Roche representative and the competent authority of the Member State or Country in which the user is established.

This product contains components classified as follows in accordance with the Regulation (EC) No. 1272/2008:

Table 1. Hazard information.

Hazard	Code	Statement
	H317	May cause an allergic skin reaction.
	H318	Causes serious eye damage.
	H412	Harmful to aquatic life with long lasting effects.
	P261	Avoid breathing dust/ fume/ gas/ mist/ vapours/ spray.
	P273	Avoid release to the environment.
	P280	Wear protective gloves/ eye protection/ face protection.
	P305 + P351 + P338 + P310	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Immediately call a POISON CENTER/doctor.
	P333 + P313	If skin irritation or rash occurs: Get medical advice/ attention.
	P362 + P364	Take off contaminated clothing and wash it before reuse.

INSTRUCTIONS FOR USE

The diluted BenchMark Special Stains Deparaffinization Solution (10X) solution is poured directly into the appropriate bulk fluid bottle of the Automated Fluidics Module (AFM) on the BenchMark Special Stains instrument. The diluted BenchMark Special Stains Deparaffinization Solution (10X) is applied automatically as required for the procedure being run.

Reagents have been developed for use on a BenchMark Special Stains instrument in combination with BenchMark Special Stains reagents and accessories. The parameters for the automated procedures can be displayed, printed, and edited according to the

procedure in the instrument User Guide. Other operating parameters for the instrument have been preset at the factory.

Refer to the appropriate staining kit method sheet for the recommended staining protocol and to the instrument User Guide for detailed instructions and additional protocol options.

PERFORMANCE CHARACTERISTICS

ANALYTICAL PERFORMANCE

BenchMark Special Stains Deparaffinization Solution (10X) is used for removal of paraffin on tissue samples for special stains performed exclusively on BenchMark Special Stains instrument. The diluted BenchMark Special Stains Deparaffinization Solution (10X) was tested at various incubation times with specific tissue types.

LIMITATIONS

BenchMark Special Stains Deparaffinization Solution (10X) has been optimally formulated for use on BenchMark Special Stains instruments.

BenchMark Special Stains Deparaffinization Solution (10X) and 1X dilute must be examined for microbial contamination prior to use. The signs indicating contamination or instability of this product are turbidity of the solution, odor development, or precipitation. At the first sign of possible reagent contamination or instability, contact your local support representative.

TROUBLESHOOTING

For corrective action, refer to the instrument User Guide or contact your local support representative.

REFERENCES

1. Occupational Safety and Health Standards: Occupational exposure to hazardous chemicals in laboratories. (29 CFR Part 1910.1450). Fed. Register.
2. Directive 2000/54/EC of the European Parliament and Council of 18 September 2000 on the protection of workers from risks related to exposure to biological agents at work.

NOTE: A point (period/stop) is always used in this document as the decimal separator to mark the border between the integral and the fractional parts of a decimal numeral. Separators for thousands are not used.

Symbols

Ventana uses the following symbols and signs in addition to those listed in the ISO 15223-1 standard (for USA: see dialog.roche.com for definition of symbols used):



Global Trade Item Number



Unique Device Identifier



Indicates the entity importing the medical device into the European Union

INTELLECTUAL PROPERTY

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