

BenchMark Special Stains Liquid Coverslip

REF

860-034

06523072001

IVD

INTENDED USE

BenchMark Special Stains Liquid Coverslip is a prediluted coverslip solution intended for laboratory use as a barrier between the aqueous reagents and the air. This barrier prevents evaporation, thereby providing a stable aqueous environment for special stains reactions on a BenchMark Special Stains instrument.

BenchMark Special Stains Liquid Coverslip is also used to solubilize paraffin during the deparaffinization process for slides containing formalin-fixed, paraffin-embedded (FFPE) tissues when using the AFB staining procedure on a BenchMark Special Stains instrument.

This product is intended for in vitro diagnostic use.

PRINCIPLE OF THE PROCEDURE

BenchMark Special Stains Liquid Coverslip is used with BenchMark Special Stains reagent kits, ancillary reagents, and BenchMark Special Stains instruments to achieve the appropriate histochemistry staining. It is composed of organic oil molecules having a density significantly less than that of water. When applied to an aqueous solution pool the surface tension causes the lighter oil to spread out over the surface of the solution forming a chamber. This results in an effective barrier between the solution and the air preventing evaporation of the aqueous reagent pool. In addition, the surface layer of BenchMark Special Stains Liquid Coverslip solution allows the addition of other aqueous reagents from above to pass through and enter the solution pool on the slide. The BenchMark Special Stains instrument automatically applies BenchMark Special Stains Liquid Coverslip solution as needed throughout the various staining protocols.

MATERIAL PROVIDED

One 2 L bottle of BenchMark Special Stains Liquid Coverslip contains a low density, paraffinic hydrocarbon.

Reconstitution, Mixing, Dilution, Titration

No reconstitution, mixing, dilution, or titration is required. Further dilution may result in unsatisfactory staining quality.

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. General purpose laboratory equipment
2. 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 Liquid Coverslip solution 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.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic (IVD) use.
2. For professional use only.
3. Avoid spilling this reagent. If this precaution is not taken, the user risks a slip and fall.

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
	H304	May be fatal if swallowed and enters airways.
	P301 + P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor.
	P331	Do NOT induce vomiting.
	P405	Store locked up.
	P501	Dispose of contents/ container to an approved waste disposal plant.

This product contains CAS # 90622-46-1, alkanes C14-16.

INSTRUCTIONS FOR USE

BenchMark Special Stains Liquid Coverslip is poured directly into the appropriate bulk fluid bottle of the Automated Fluidics Module (AFM) on the BenchMark Special Stains instrument. BenchMark Special Stains Liquid Coverslip solution is applied automatically as required for the procedure being run.

Reagents have been developed for use on BenchMark Special Stains instruments in combination with BenchMark Special Stains reagents and accessories. The parameters for 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 Liquid Coverslip is used to provide a barrier between the aqueous solutions and the air on samples for BenchMark Special Stains instruments. BenchMark Special Stains Liquid Coverslip was tested with a variety of BenchMark Special Stains reagent kits at various incubation times with specific tissue types.

LIMITATIONS

BenchMark Special Stains Liquid Coverslip has been optimally formulated for use on BenchMark Special Stains instruments.

BenchMark Special Stains Liquid Coverslip solution 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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CONTACT INFORMATION



Ventana Medical Systems, Inc.
1910 E. Innovation Park Drive
Tucson, Arizona 85755
USA
+1 520 887 2155
+1 800 227 2155 (USA)

www.roche.com



Roche Diagnostics GmbH
Sandhofer Strasse 116
D-68305 Mannheim
Germany
+800 5505 6606

