


Special Stains Tartrazine CS

REF	860-051
	10284838001
IVD	 75

INTENDED USE

Special Stains Tartrazine CS is intended for laboratory use in staining non-target tissue components and providing contrast with target stains in sections of formalin-fixed, paraffin-embedded (FFPE) tissue on a BenchMark Special Stains instrument.

This reagent is intended as a counterstain in special stains applications.

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

PRINCIPLE OF THE PROCEDURE

Special Stains Tartrazine CS (counterstain) can be used with several Special Stains core kits. The process will vary depending on the kit. Special Stains Tartrazine CS provides a contrasting yellow background.

This reagent is optimized for use on BenchMark Special Stains instruments. The reagent is applied to tissue on microscope slides and mixed over the entire specimen.

MATERIAL PROVIDED

One 27 mL vial of Special Stains Tartrazine CS contains approximately 0.1% tartrazine and approximately 0.3% acetic acid reagent.

One vial insert with sipping straw.

Reconstitution, Mixing, Dilution, Titration

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

This reagent has been optimally diluted for use on the BenchMark Special Stains instrument.

MATERIALS REQUIRED BUT 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. Recommended control tissue
2. BenchMark Special Stains instrument
3. Compatible BenchMark Special Stains core kits
4. BenchMark Special Stains Deparaffinization Solution (10X) (Cat. No. 860-036 / 06523102001)
5. BenchMark Special Stains Liquid Coverslip (Cat. No. 860-034 / 06523072001)
6. BenchMark Special Stains Wash II (Cat. No. 860-041 / 08309817001)
7. General purpose laboratory equipment

STORAGE AND STABILITY

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

When properly stored, unopened reagents are stable to the date indicated on the label. Do not use reagent beyond the expiration date indicated on the kit.

When properly stored, open reagents are stable to the expiration date indicated on the kit.

There are no obvious signs to indicate instability of these reagents; therefore, controls should be run simultaneously with unknown specimens. Contact your local support representative if positive control material shows a decrease in staining as it could indicate reagent instability.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic (IVD) use.
2. For professional use only.
3. 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}
4. Avoid contact of reagents with eyes and mucous membranes. If reagents come in contact with sensitive areas, wash with copious amounts of water.

5. Avoid microbial contamination of product as it may cause incorrect results.
6. 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 navifyportal.roche.com.
7. Consult local and/or state authorities with regard to recommended method of disposal.
8. Product safety labeling primarily follows EU GHS guidance. Safety data sheet available for professional user on request.
9. 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.
10. This product contains Tartrazine. May produce an allergic reaction.

EUH208: Contains trisodium 5-hydroxy-1-(4-sulphophenyl)-4-(4-sulphophenylazo)pyrazole-3-carboxylate. May produce an allergic reaction.

INSTRUCTIONS FOR USE

Refer to the compatible core kit method sheet for the recommended staining protocol and to the instrument User Guide for detailed instructions and additional protocol options. Special Stains Tartrazine CS is applied as required for the procedure being run.

Prepare Reagent Vial

Before first use, a vial insert and sipping straw must be placed in the reagent vial.

Remove the shipping cap from the vial and place the insert and straw into the vial. The insert and sipping straw should be left in the vial, once the vial has been opened.

Use the soft cap to cover the reagent vial when reagent is not in use.

After use, store the reagents according to the recommended storage conditions.

LIMITATIONS

Excessive or incomplete counterstaining may compromise proper interpretation of results.

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 24 June 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 elabdoc.roche.com/symbols for more information).



Global Trade Item Number

Rx only

For USA: Caution: Federal law restricts this device to sale by or on the order of a physician.

INTELLECTUAL PROPERTY

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For USA: Rx only

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