

Special Stains Clean Plus

REF

860-037

06649327001

IVD

 50

INTENDED USE

VENTANA Special Stains Clean Plus is used in conjunction with the VENTANA Special Stains Cleaning Kit (860-016 / 05279313001) and is intended for use during the automated cleaning procedure on the VENTANA BenchMark Special Stains automated slide stainer.

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

SUMMARY AND EXPLANATION

VENTANA BenchMark Special Stains automated slide stainer uses a patented fluid aspiration method to deliver reagents. To keep the aspiration system clean, the automated cleaning procedure must be performed at the end of each working day. Quantities of cleaning solutions and the aspiration and delivery sequences are preprogrammed into the cleaning procedure used on the BenchMark Special Stains automated slide stainer.

PRINCIPLE OF THE PROCEDURE

Special Stains Clean Plus is optimized for use on VENTANA BenchMark Special Stains automated slide stainer and must be used in addition to the VENTANA Special Stains Cleaning Kit. The cleaning kit has been optimized to clean the fluid aspiration system. When the cleaning icon is activated, the slide carousel rotates and is rinsed with warm Wash Solution.

The Special Stains Clean Plus solution is delivered at the end of the Special Stains Cleaning Kit procedure.

MATERIALS AND METHODS

Reagent Provided

Each vial contains sufficient reagents for 50 cleaning cycles. The reagent vial is supplied in a barcode labeled carrier to insert into the reagent tray of the automated slide stainer.

One 27 mL vial of Cleaning Solution D contains 0.56% potassium hydroxide.

1 vial insert with sipping straw.

Reconstitution, Mixing, Dilution, Titration

No reconstitution, mixing, dilution or titration is required. Further dilution of any of the reagents may result in unsatisfactory staining quality. The user must validate any such change.

The reagent in this kit has been optimally diluted for use on BenchMark Special Stains automated slide stainers. This reagent may not be optimal for manual procedures or for use on other instruments.

Materials and Reagents Needed But Not Provided

1. BenchMark Special Stains automated slide stainer.
2. Bulk reagents for the BenchMark Special Stains automated slide stainer:
 - BenchMark Special Stains Deparaffinization Solution (10X)
 - BenchMark Special Stains Liquid Coverslip
 - BenchMark Special Stains Wash Solution (10X)

Storage and Handling

The Special Stains Cleaning Kit should be stored at 15-30°C. See vial label for the proper storage conditions for each component. These reagents are expiration dated. When properly stored, the reagents are stable to the date indicated on the label. Do not use reagents beyond the expiration date for the prescribed storage method.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic (IVD) use.
2. Use protective clothing and gloves when handling laboratory reagents.
3. Cleaning Solution D contains potassium hydroxide, a caustic substance. This reagent may cause irritation. Avoid contact with eyes, skin, and mucous membranes. If reagent contacts these areas, rinse with copious amounts of water. Refer to the Safety Data Sheet for measures to be taken in case of accidental contact with this material.
4. Disposal of liquid waste resulting from the use of these products should be performed in accordance with all local, state and federal laws.
5. For supplementary safety information, refer to the product Safety Data Sheet and the Symbol and Risk Phrase Guide located at www.ventana.com.

INSTRUCTIONS FOR USE

Step by Step Procedure

Refer to the BenchMark Special Stains Operator's Manual for more detailed instructions.

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

1. 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.
2. Place the soft cap into the slot on the reagent holder when the reagent is in use.
3. Use the soft cap to cover the reagent vial when reagent is not in use.

Perform the cleaning procedure at the end of each workday, or more often, if desired.

1. Be sure all slides have been removed from the slide holders before cleaning the reagent delivery system.
2. Load reagents from Special Stains Cleaning Kit and Special Stains Clean Plus onto the reagent tray.
3. Select the Clean Icon (scrub brush) on the main screen of the PC to start the cleaning process.

LIMITATIONS

1. Failure to perform adequate cleaning of the system may result in unsatisfactory staining.
2. Use of the cleaning kit is not a substitute for regular cleaning of the slide holders and fill area. See operator's manual for details.

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