

Special Stains Cleaning Kit

REF 860-016

05279313001

IVD  50

INTENDED USE

VENTANA Special Stains Cleaning Kit is intended for use during the automated cleaning procedure on the VENTANA BenchMark Special Stains automated slide stainer and the VENTANA NexES Special Stains automated slide stainer.

This kit is intended for *in vitro* diagnostic use.

SUMMARY AND EXPLANATION

VENTANA BenchMark Special Stains automated slide stainer and the VENTANA NexES 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. When using this kit with the BenchMark Special Stains automated slide stainer, it must be accompanied by the VENTANA Special Stains Clean Plus vial (860-037 / 06649327001).

PRINCIPLE OF THE PROCEDURE

This kit is optimized for use on VENTANA BenchMark Special Stains automated slide stainers and VENTANA NexES Special Stains automated slide stainers. 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 buffer.

The reagents are aspirated and delivered in the following sequence during the cleaning cycle for the VENTANA NexES Special Stains instrument:

Cleaning Solution A

Cleaning Solution C

Cleaning Solution B

Cleaning Solution C

The reagents are aspirated and delivered in the following sequence during the cleaning cycle for the VENTANA BenchMark Special Stains instrument:

Cleaning Solution A

Cleaning Solution C

Cleaning Solution D

Cleaning Solution C

Cleaning Solution B

Cleaning Solution C

MATERIALS AND METHODS

Reagents Provided

Each kit contains sufficient reagents for 50 cleaning cycles. The reagent vials are supplied in barcode labeled carriers to insert into the reagent tray of the automated slide stainer.

One 27 mL vial of Cleaning Solution A contains 70% alcohol and 1% hydrochloric acid.

One 27 mL vial of Cleaning Solution B contains 2% cetyltrimethylammonium bromide.

One 27 mL vial of Cleaning Solution C contains 0.05% ProClin 300, a preservative.

3 vial inserts with sipping straws.

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 reagents in this kit have been optimally diluted for use on BenchMark Special Stains automated slide stainers and NexES Special Stains automated slide stainers. These reagents may not be optimal for manual procedures or for use on other instruments.

Materials and Reagents Needed

1. BenchMark Special Stains automated slide stainer or NexES 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)
3. Ancillary kit Special Stains Clean Plus (860-037 / 06649327001) for the BenchMark Special Stains automated slide stainer.
4. Bulk reagents for the NexES Special Stains automated slide stainer:
 - Liquid Coverslip (Low Temperature)
 - Special Stains Wash (10X)
5. Deionized or distilled water

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. These reagents may cause irritation. Avoid contact with eyes and mucous membranes. If reagent contacts these areas, rinse with copious amounts of water. Do not ingest or inhale these reagents.
3. Cleaning Solution A is highly flammable and corrosive. Harmful: possible risk of irreversible effects through inhalation, in contact with skin and if swallowed. Causes severe burns. Use protective clothing and gloves.
4. Cleaning Solution B is considered harmful to aquatic organisms and may cause long-term adverse effects in the aquatic environment.
5. Cleaning Solution C contains ProClin 300 as a preservative. ProClin 300 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. If reagent contacts these areas, rinse with copious amounts of water. Use protective clothing and gloves.
6. Disposal of liquid waste resulting from the use of these products should be performed in accordance with all local, state and federal laws.
7. 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 or the NexES Special Stains automated slide stainer 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 onto the reagent tray.
3. If you are using a BenchMark Special Stains automated slide stainer, you must also load the Special Stains Clean Plus vial onto the reagent tray.

4. Select the Clean Icon (scrub brush) on the main screen of the PC to initiate 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.

INTELLECTUAL PROPERTY

BENCHMARK, NexES, VENTANA, and the VENTANA logo are trademarks of Roche. Ventana Medical Systems, Inc. grants to the Purchaser a single use only license under U.S. Pat. Nos. 6045609B1 and any foreign counterparts.

© 2012 Ventana Medical Systems, Inc.

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.ventana.com



Roche Diagnostics GmbH
Sandhofer Strasse 116
D-68305 Mannheim
Germany