

Cell Conditioning Solution (CC2)

REF

950-123

05279798001

IVD

INTENDED USE

Cell Conditioning Solution (CC2) from Ventana Medical Systems, Inc. (Ventana) is a prediluted solution used as a pretreatment step in the processing of tissue samples during immunohistochemistry (IHC) and *in situ* hybridization (ISH) on VENTANA BenchMark, BenchMark GX, and BenchMark XT instruments.

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

PRINCIPLE OF THE PROCEDURE

CC2 is a citrate buffer at a slightly acidic pH, which, at elevated temperatures, is capable of hydrolyzing the covalent bonds formed by formalin and formaldehyde fixed tissue. Removing these bonds allows renaturation of protein molecules and increases antibody accessibility. Often these changes result in significant gains in antibody binding and improved signal to noise ratios.

MATERIALS AND METHODS

Reagent Provided

One 1 L bottle of CC2 contains a citrate-based buffer and ProClin 300, a preservative.

Reconstitution, Mixing, Dilution, Titration

No reconstitution, mixing, dilution, or titration is required. Further dilution may result in loss of staining specificity. The user must validate any such changes.

Materials Required But Not Provided

Additional reagents including but not limited to VENTANA primary antibodies, probes, detection kits, and ancillary components, are not provided.

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

Storage and Handling

Store at room temperature (15-30°C). Do not freeze or refrigerate as precipitate may form at storage temperatures below those recommended. If precipitate is noted due to cold temperatures, allow the bottle to return to room temperature and shake to dissolve precipitate.

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.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic (IVD) use.
2. For professional use only.
3. Take reasonable precautions when handling reagents. Avoid contact of reagents with eyes, skin, and mucous membranes. Use protective clothing and gloves.
4. 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.
5. Avoid microbial contamination of product, as this could produce incorrect results.
6. Consult local or state authorities with regard to recommended method of disposal.
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

Refer to the appropriate probe or detection kit package insert for the recommended staining protocol and to the instrument Operator's Manual for detailed instructions and additional protocol options.

CC2 is poured into the appropriate position (CC2 bottle) of the automated fluidics module, on the VENTANA BenchMark, BenchMark GX, and BenchMark XT instruments. CC2 is applied automatically as required for the procedure being run. Refer to the instrument Operator's Manual for detailed instructions and additional protocol options.

PERFORMANCE CHARACTERISTICS

CC2 is applied to tissue specimens following the removal of paraffin for paraffin-embedded sections and prior to the application of reagents used in the detection of the target antigen, in conjunction with the VENTANA BenchMark, BenchMark GX, and BenchMark XT instruments. Expected results are quantitative only when testing the sensitivity and specificity of each specific antigen or target nucleic acid sequence. As a standalone reagent, this product cannot be tested for specificity or sensitivity.

TROUBLESHOOTING

For corrective action, refer to the primary antibody or probe package insert, the automated slide stainer Operator's Manual, or contact your local support representative.

INTELLECTUAL PROPERTY

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