ULTRA Cell Conditioning Solution (ULTRA CC2)

REF 950-223

05424542001

IVD

INTENDED USE

ULTRA Cell Conditioning Solution (ULTRA CC2) is a prediluted solution intended for laboratory use as a pretreatment step in the processing of formalin-fixed, paraffin-embedded tissue samples during immunohistochemistry and in situ hybridization applications on the BenchMark ULTRA and BenchMark ULTRA PLUS instruments.

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

PRINCIPLE OF THE PROCEDURE

Fixation of tissue by formalin results in the formation of covalent bonds between the aldehyde and amino groups present in the tissue. The formation of these bonds denatures protein and can result in the loss of accessibility of epitopes or target nucleic acids. In addition, the formaldehyde can form methylene bridges cross linking tissue proteins thus reducing the penetration of the tissue to large molecules such as antibodies and nucleic acid probes.

ULTRA 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 or probe accessibility. Often these changes result in significant gains in antibody or probe binding and improved signal to noise ratios. The BenchMark ULTRA or BenchMark ULTRA PLUS instrument automatically applies ULTRA CC2 from the appropriate position (ULTRA CC2 bottle) of the automated fluidics module on the instrument as required by the procedure being run. The BenchMark ULTRA or BenchMark ULTRA PLUS instrument then automatically heats the slide to the appropriate temperature and time as selected by the user.

ULTRA CC2 is used with probes, antibodies, accessory reagents and BenchMark ULTRA and BenchMark ULTRA PLUS instruments to achieve appropriate immunohistochemistry (IHC) or in situ hybridization (ISH) staining.

Material PROVIDED

One 1 L bottle of ULTRA CC2 contains a citrate-based buffer, with 5% ethylene glycol, and 0.05% 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.

MATERIALS REQUIRED BUT NOT PROVIDED

Additional reagents including but not limited to VENTANA primary antibodies, probes, detection and staining 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 ULTRA instrument
3. BenchMark ULTRA PLUS instrument

STORAGE AND STABILITY

Upon receipt and when not in use, store at 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.

Throughout the shelf life of ULTRA CC2, pH may drift outside the manufacturing specifications in the Certificate of Analysis. The functional pH range of ULTRA CC2 is validated between pH 5.20 and 6.20. Internal studies demonstrate pH in this range does not affect staining performance.

WARNINGS AND PRECAUTIONS

1. For in vitro diagnostic (IVD) use.
2. For professional use only.
3. 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.
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 ULTRA or BenchMark ULTRA PLUS 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
Warning 	H317	May cause an allergic skin reaction.
	P261	Avoid breathing mist or vapours.
	P272	Contaminated work clothing should not be allowed out of the workplace.
	P280	Wear protective gloves.
	P333 + P313	If skin irritation or rash occurs: Get medical advice/ attention.
	P362 + P364	Take off contaminated clothing and wash it before reuse.
	P501	Dispose of contents/ container to an approved waste disposal plant.

This product contains CAS # 55965-84-9, reaction mass of 5-chloro-2-methyl-2H-isothiazol-3-one and 2-methyl-2H-isothiazol-3-one (3:1).

INSTRUCTIONS FOR USE

Refer to the appropriate primary antibody, probe, staining kit, or detection kit method sheet for the recommended staining protocol and to the instrument User Guide for detailed instructions and additional protocol options.

ULTRA CC2 is poured into the appropriate bulk fluid bottle of the automated fluidics module on the BenchMark ULTRA and BenchMark ULTRA PLUS instruments. ULTRA CC2 is applied automatically as required for the procedure being run.

PERFORMANCE CHARACTERISTICS

ANALYTICAL PERFORMANCE

ULTRA 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 or nucleic acid, in conjunction with the BenchMark ULTRA and BenchMark ULTRA PLUS 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.

Multiple VENTANA primary antibodies and probes have been developed with ULTRA CC2 in IHC and ISH applications. As part of the testing for those assays, the following performance characteristics were demonstrated for ULTRA CC2:

1. Within-run, between-day, and between-instrument precision on the BenchMark ULTRA and BenchMark ULTRA PLUS instruments.
2. Sensitivity and specificity of staining across a range of normal and neoplastic tissue types and assay-specific target tissues.

All studies met their acceptance criteria.

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):

GTIN	Global Trade Item Number
UDI	Unique Device Identifier
	Indicates the entity importing the medical device into the European Union

REVISION HISTORY

Rev	Updates
J	Added functional pH acceptance range. Updated hazard table.

INTELLECTUAL PROPERTY

CONTACT INFORMATION

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