LCS (Predilute)

REF 650-010

05264839001

IVD

INTENDED USE

LCS (Predilute) is a prediluted coverslip solution intended for laboratory use as a barrier between the aqueous reagents and the air. This barrier prevents evaporation, thereby providing a stable aqueous environment for the immunohistochemistry, immunocytochemistry, or in situ hybridization reactions on BenchMark GX and BenchMark XT instruments.

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

PRINCIPLE OF THE PROCEDURE

LCS (Predilute) reagent is composed of organic oil molecules having a density significantly less than that of water. When applied to an aqueous buffer pool the surface tension causes the lighter oil to spread out over the surface of the buffer forming a chamber. This results in an effective barrier between the buffer and the air preventing evaporation of the aqueous reagent pool. In addition, the surface layer of LCS (Predilute) reagent allows the addition of other aqueous reagents from above to pass through and enter the buffer pool on the slide. The instrument automatically applies LCS (Predilute) reagent as needed throughout the various immunohistochemistry (IHC), immunocytochemistry (ICC), or in situ hybridization (ISH) staining protocols.

REAGENT PROVIDED

One 2 liter bottle of LCS (Predilute) reagent contains a low density, paraffinic hydrocarbon and mineral oil.

Reconstitution, Mixing, Dilution, Titration

This reagent is ready to use directly from the bottle and must not be diluted. 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 method sheet may be available in all geographies. Consult your local support representative.

1. General purpose laboratory equipment
2. BenchMark GX instrument
3. BenchMark XT instrument

STORAGE AND STABILITY

Store at room temperature 15-30°C. Do not freeze.

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. Avoid spilling this reagent. If this precaution is not taken, the user risks a slip and fall.
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. Use protective clothing and gloves. Do not inhale.
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 IHC/ISH 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
Danger 	H304	May be fatal if swallowed and enters airways.
	P301 + P310	IF SWALLOWED: Immediately call a POISON CENTER/doctor.
	P331	Do NOT induce vomiting.
	P405	Store locked up.
	P501	Dispose of contents/ container to an approved waste disposal plant.

This product contains CAS # 90622-46-1, Alkanes, C14-16.

INSTRUCTIONS FOR USE

LCS (Predilute) reagent is poured directly into the 2 liter LCS bottle in the appropriate position (LCS) of the automated fluidics module. The instrument automatically applies LCS (Predilute) reagent as required by the selected staining protocol.

Prior to the initial use of the LCS (Predilute) solution in the user's laboratory, appropriate staining should be verified by staining a number of positive and negative controls.

This product has been developed for use on the BenchMark XT and BenchMark GX instruments in combination with VENTANA detection kits, primary antibodies, probes and accessories. Recommended staining protocols for the instrument are described in the method sheet of the primary antibody or probe of interest. The staining protocols can be displayed, printed and edited according to the procedure in the instrument User Guide.

PERFORMANCE CHARACTERISTICS

ANALYTICAL PERFORMANCE

LCS (Predilute) reagent is used to provide a barrier between the aqueous solutions and the air during IHC, ICC and ISH applications on the BenchMark XT and BenchMark GX instruments. LCS (Predilute) reagent has been tested with a variety of VENTANA primary antibodies and probes at various incubation times with specific tissue types.

LIMITATIONS

1. LCS (Predilute) reagent must be examined for microbial contamination prior to use. The signs indicating contamination or instability of this product are: turbidity of the solution, odor development or precipitation. At the first sign of possible reagent contamination or instability, call your local support representative.
2. LCS (Predilute) reagent has been optimally formulated for use on the BenchMark XT and BenchMark GX instruments. Dilution of this product will result in poor instrument performance and possible loss of staining.
3. LCS constituents, as expected with petroleum derivatives, have been reported to aid in the sample deparaffinization process. The suitability for this purpose is sample dependent and application specific and must be validated by the end user.

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

INTELLECTUAL PROPERTY

Additions, deletions or changes are indicated by a change bar in the margin.

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