Universal Negative Control Serum

For In Vitro Diagnostic Use (IVD)
Instructions For Use

INTENDED USE

Universal Negative Control Serum is intended for use in immunohistochemistry (IHC) staining protocols as a negative reagent/ antibody control.

SUMMARY AND EXPLANATION

Universal Negative Control Serum reagent is a solution of non-immune serum diluted in a buffered saline solution containing carrier protein. It aids in the identification of cells, tissues or tissue components which may non-specifically bind antibodies within tested tissues.

PRINCIPLES AND PROCEDURES

The negative control reagent is applied in place of an anti-human primary antibody onto tissue that has been designated as the corresponding negative control. The section under test and the corresponding negative control should be serial sections off the same paraffin-embedded block.

MATERIALS AND METHODS

Reagents Supplied As:

Reagent Cat. No.	Contents	Vol. (ml)
939B-01	Predilute ready-to-use	7.0 mL
939B-02	Predilute ready-to-use	25.0 mL
939B-03	Predilute ready-to-use	100.0 mL
939B-09	Predilute ready-to-use	1000.0 mL

Materials and Reagents Needed But Not Provided

1. Primary antibody(ies)
2. TBS or PBS wash buffer*
3. Volumetric flask/graduated cylinder
4. Microscope slides, positively charged
5. Drying oven
6. Positive and negative controls
7. Clearing agent (xylene, Clearene, etc.)
8. Ethanol or reagent alcohol
9. Slide rack*
10. Staining dishes*
11. Pressure cooker*
12. Pretreatment reagents*
13. Proteolytic enzyme
14. Peroxidase block
15. Detection kits*
16. Chromogen*
17. Hematoxylin*
18. Mounting medium

**See Cell Marque Catalog for product numbers. Some of the reagents listed are based on specific applications and detection system used.*

Storage and Stability
Store at 2-8°C, up to 36 months from date of manufacture *(see product label for expiration date)*.

Reagent Preparation
This product is a ready to use reagent.

INTERPRETATION OF RESULTS

The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls. Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

QUALITY CONTROL PROCEDURES

Refer to NCCLS Quality Assurance for Immunocytochemistry approved guidelines, December 1999 MM4-A Vol.19 No.26 for more information on tissue controls.

WARNINGS AND PRECAUTIONS

1. This product is for *in vitro* diagnostic use by professionals only.
2. This is a ready to use reagent. Do not dilute prior to use.
3. Do not use after expiration date printed on product labels. The user must validate any storage conditions other than those specified in the package insert.
4. Bring all reagents, slides, and specimens to room temperature (18-24° C) prior to use.
5. Cross contamination of reagents or samples may give false results.
6. Avoid microbial contamination of reagents, as this could produce incorrect results.
7. Avoid contact of reagents with eyes and mucous membranes. If reagents come in contact with sensitive areas, wash with copious amounts of water.
8. Do not smoke, eat, or drink in areas where specimens or kit reagents are handled.
9. Avoid splashing or generation of aerosols at all times.
10. Reusable glassware must be washed and thoroughly rinsed free of detergents prior to use. All glassware must be clean and dry before use.
11. Never pipette by mouth and avoid contact of reagents and specimens with skin and mucous membranes. If contact occurs, wash with a germicidal soap and copious amounts of water.

12. Refer to product SDS.
13. When used according to instructions, this product is not classified as a hazardous substance. The preservative in the reagent is less than 0.1% sodium azide and does not meet the OSHA (USA) criteria for hazardous substance at the stated concentration. See SDS. Sodium azide may react with lead or copper plumbing and form explosive metal azide salts. When disposing of reagents, flush with ample volumes of tap water to prevent potential residues in plumbing. Sodium azide is a poison and may be toxic if ingested.

LIMITATIONS

Immunohistochemistry is a multiple step diagnostic process that requires specialized training and selection of appropriate reagents and controls. The protocols for a specific application can vary. It is the responsibility of the end user to determine optimal conditions.

TROUBLESHOOTING

For further help, feel free to contact Cell Marque's Technical Support at +1-800-665-7284.

REFERENCES

1. NCCLS Quality Assurance for Immunocytochemistry approved guideline, December 1999 MM4-A Vol. 19 No.26 for more information on tissue controls.

DISCLAIMERS

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