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Universal Negative Control Serum

For In Vitro Diagnostic Use (IVD)
Instructions for use

INTENDED USE

The Cell Marque Universal Negative Control Serum is intended for qualified laboratories to qualitatively identify by light microscopy the presence of non-specific staining in formalin-fixed, paraffin-embedded tissue using IHC test methods. Use of this reagent is indicated, as an aid in the identification of cells or tissue components which may nonspecifically bind to antigen-specific antibodies within tested tissues.

SUMMARY AND EXPLANATION

The Universal Negative Control Serum reagent is used in IHC assays where both mouse and rabbit primary antibodies produce antigen specific recognition and binding. These reagents aid in the identification of cells, tissues or tissue components which may nonspecifically bind antibodies and thereby facilitate interpretation.

PRINCIPLES AND PROCEDURES

A control reagent should be tested with each specimen to ensure proper function of the reagents and proper function of staining techniques. Universal Negative Control Serum reagent is applied in place of a mouse or rabbit anti-human primary antibody onto IHC test tissue.

MATERIALS AND METHODS

Cat. No.	Contents
939B-01	7.0 ml, predilute ready-to-use
939B-02	25.0 ml, predilute ready-to-use
939B-03	100.0 ml, predilute ready-to-use
939B-09	1000.0 ml, predilute ready-to-use

Materials and Reagents Needed But Not Provided

1. Primary and secondary antibodies
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. Avidin-Biotin block†
15. Peroxidase block
16. Negative control reagents†
17. Detection kits†
18. Hematoxylin†
19. 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 (see product label for expiration date).

INTERPRETATION OF RESULTS

The clinical interpretation of any positive staining, or its absence, must be evaluated within the context of clinical history and morphology, and must be complemented by proper controls and other diagnostic tests. It is the responsibility of a qualified pathologist to be familiar with the antibodies, reagents, and methods used to produce the stained preparation. Staining must be performed in a certified licensed laboratory under the supervision of a pathologist who is responsible for reviewing the stained slides and assuring the adequacy of positive and negative controls.

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. 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.
3. Tissue staining is dependent on the handling and processing of the tissue prior to staining. Improper fixation, freezing, thawing, washing, drying, heating, sectioning, or contamination with other tissues or fluids may produce artifacts, loss of tissue, false positive or false negative results.

LIMITATIONS AND WARRANTY

Immunohistochemistry is a multi-step process that is dependent on the pre-analytical variables involved in specimen processing prior to IHC staining. It is the responsibility of the end user to determine optimal conditions.

There are no express or implied warranties which extend beyond this datasheet. Cell Marque is not liable for personal injury, property damage, or economic loss caused by this product.

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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