PRIMARY ANTIBODY CARTRIDGE (PAC)

Vimentin

Monoclonal Mouse, Anti-Vimentin
Clone V9

REF **014-1029-150**
Ready-to-Use ■ 60 Tests

INSTRUCTIONS FOR USE

INTENDED USE

IVD *For in vitro diagnostic use.*

Monoclonal mouse anti-vimentin, clone V9, is intended for laboratory use to qualitatively identify intermediate filament protein in cells of mesenchymal origin using light microscopy. It may be used with frozen tissue or with formalin-fixed paraffin-embedded tissue.

Positive results aid in the classification of normal and abnormal cells/tissues, and serve as an adjunct to conventional histopathology. The clinical interpretation of any positive staining or its absence should be complemented by morphological and histological studies with proper controls. Evaluations should be made by a qualified individual in conjunction with the patient's clinical history and other diagnostic test results.

Refer to the Celerus Wave® RPD Operator's Manual for additional information about Materials Required but Not Provided; Storage; Staining Procedure; Troubleshooting; Interpretation of Staining; and General Limitations.

SUMMARY AND EXPLANATION

Vimentin antibody specifically binds to antigens in the cytoplasm of mesenchymal cells. Staining will be seen in endothelial cells, vascular smooth muscle cells, myoepithelial cells, peripheral nerve, macrophages, lymphoid cells, fibroblasts, connective tissue, and astrocytes.

PRINCIPLE OF PROCEDURE

Immunohistochemistry is a multi-step process to identify specific cell markers within tissue biopsies or tumor specimens. The sequential steps include antigen retrieval (optional), antibody application, and antibody visualization followed by optional counter-staining. Specimens are then coverslipped and observed under light microscopy by trained personnel. Normally, multiple antibodies are tested to determine lineage and cell cycle markers. The Celerus Wave® RPD is an automated IHC system that produces stained tissue.

Refer to the Celerus Wave® RPD Operator's Manual for additional information about the staining procedure.

MATERIALS AND METHODS

Reagent Provided

CLONE	Ig CLASS	IMMUNOGEN
V9	IgG_1, kappa	Purified vimentin from porcine eye lens.

READY-TO-USE IN PRIMARY ANTIBODY CARTRIDGE

Anti-vimentin is provided with sodium azide as a preservative, in a Primary Antibody Cartridge (PAC), a self-contained dispenser of reagents. Each PAC contains sufficient reagent to complete 60 stained slides. PACs must remain upright to avoid spilling. PAC must be primed before first use.

Refer to the Celerus Wave® RPD Operator's Manual for additional information about the Primary Antibody Cartridge.

SPECIFICITY

Human vimentin intermediate filament.

PRECAUTIONS

For professional users.

Minimize microbial contamination of reagents or an increase in nonspecific staining may occur.

Proper handling procedures should be used.

A Material Safety Data Sheet is available upon request.

Sodium azide deposits in drainage pipes made of lead or copper can result in the formation of highly explosive metallic azides. To avoid such deposits in drainage pipes, sodium azide should be discarded in a large volume of running water.

Sodium azide in the concentration used is not classified as hazardous. The following are the appropriate Risk (**R**) and Safety (**S**) phrases.

R36	Irritating to eyes.
R43	May cause sensitization by skin contact.
S24	Avoid contact with skin.
S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S35	This material and its container must be disposed of in a safe way.
S37/39	Wear suitable gloves and eye/face protection.
S46	If swallowed, seek medical advice immediately and show the product container or label.

WASTE DISPOSAL

Adhere to all local laws when disposing of the PAC.

PACKAGING DAMAGE

DO NOT USE this product if it is leaking, has leaked, has spilled, cannot be primed, or has visually apparent physical damage.

MATERIALS REQUIRED BUT NOT PROVIDED

Celerus Wave® RPD Instrument.

Refer to the Celerus Wave® RPD Operator's Manual for additional information about Materials Required but Not Provided.

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CELERUS DIAGNOSTICS
1005 Mark Avenue
Carpinteria, CA 93013 USA

EC REP **VECTOR LABORATORIES, LTD.**
3 Accent Park, Bakewell Road
Orton Southgate, Peterborough PE2 6XS England

TECHNICAL SUPPORT 888-444-3613
CUSTOMER SERVICE 888-444-8918
www.celerusdiagnostics.com

014-1029-800.05
CDS-0069.02

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STORAGE AND HANDLING

Store at the temperature indicated on the product label. Do not freeze. This product is stable up to the expiration date on the product label. Do not use this product after the expiration date.

To ensure a valid staining assay, the use of positive and negative tissue controls is recommended.

SPECIMEN COLLECTION AND HANDLING

Formalin-fixed paraffin embedded (FFPE) tissues, frozen tissues, or smears are suitable for use. Wave RPD detection kits have been optimized for tissues fixed with 10% formalin.

Slides should be baked overnight at 37 °C, or at 60 °C for one hour.

Use standard histochemical techniques to deparaffinize processed slides. Place slides in the Wave RPD Slide Rack according to the staining grid provided by the instrument software. Avoid drying tissue specimen during this process. After all slides to be stained have been inserted and reagents mounted on the instrument, start the staining run.

When the staining run is complete, remove the slide rack, then slides. Coverslip slides and view under light microscopy.

PRODUCT-SPECIFIC LIMITATIONS

Vimentin antibody, when used on the Wave RPD System, detects antigens that survive routine formalin fixation, tissue processing, and sectioning. Users who deviate from recommended test procedures are responsible for interpretation and validation of patient results.

RESULTS EXPECTED/PERFORMANCE CHARACTERISTICS

Normal Tissues

Clone V9 detected the intermediate filament protein, vimentin, in the cytoplasm of cells of mesenchymal origin. Staining was seen in a variety of cell types, including endothelial cells, fibroblasts, smooth muscle cells, myoepithelial cells, peripheral nerve cells, macrophages, and lymphoid cells (n=55).

Abnormal Tissues

Clone V9 stained 104 of 162 tumors evaluated, including sarcomas, lymphomas, renal cell carcinomas, hepatocellular carcinomas, melanomas, rhabdomyosarcomas, leiomyosarcomas, and some adenocarcinomas and squamous cell carcinomas.

Vimentin V9 is recommended for use as part of an antibody panel for the classification of tumors of mesenchymal origin.

REFERENCES

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Osborn M. Intermediate filaments as histologic markers: an overview. J Invest Dermatol. 81:104s-109s (1983).

Miettinen M, Lehto VP, Virtanen I. Antibodies to intermediate filament proteins in the diagnosis and classification of human tumors. Ultrastruct Pathol. 7:83-107 (1984).

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EXPLANATION OF SYMBOLS

REF *Catalog Number*	*Temperature Limitations*	LOT *Batch Code*	*Sufficient for <n> Tests*	*Harmful, Irritant*	*Warning*
IVD *In Vitro Diagnostic Medical Device*	*Use By*	*European Conformity*	EC REP *EC Representative*	*Manufacturer*	*Refer to Instructions for Use*

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