

PRIMARY ANTIBODY CARTRIDGE (PAC)

Cytokeratin High Molecular Weight (HMW)

Monoclonal Mouse, Anti-Cytokeratin High Molecular Weight
Clone 34βE12

REF 014-1060-150

Ready-to-Use ■ 60 Tests

INSTRUCTIONS FOR USE

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INTENDED USE

IVD *For in vitro diagnostic use.*

Monoclonal mouse anti-cytokeratin high molecular weight, clone 34βE12, is intended for laboratory use in identifying cytokeratins 1, 5, 10, and 14 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

Cytokeratin high molecular weight antibody recognizes keratins with high molecular weights and stains squamous, ductal, and other complex epithelia and carcinomas originating from these tissues. It can be used for characterizing squamous and ductal carcinomas arising from complex epithelia. The antibody also stains small-acinar lesions of the prostate gland and is of value in differentiating benign from malignant lesions.

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
34βE12	IgG ₁ kappa	Solubilized keratin extracted from human stratum corneum

READY-TO-USE IN PRIMARY ANTIBODY CARTRIDGE

Anti-cytokeratin high molecular weight 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

Cytokeratin high molecular weight reacts with cytokeratin proteins 1, 5, 10 and 14.

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.



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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.

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

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

RESULTS EXPECTED / PERFORMANCE CHARACTERISTICS

Normal Tissues

Clone 34BE12 detects cytokeratin intermediate filament proteins 1, 5, 10 and 14. It stained the cytoplasm of squamous epithelium and sweat ducts in skin, some pneumocytes, bronchial epithelium, and mesothelium in normal lung, and bile ducts in normal liver. It also stained ductal cells of the normal pancreas, some acinar and ductal cells of normal breast, basal epithelial cells of prostate, squamous epithelium of tonsil, some kidney tubules, and some epithelia and mesothelium of the normal small and large bowel.

Abnormal Tissues

Clone 34BE12 stained squamous cell carcinomas of the skin, breast, and lung, ductal carcinomas of the breast and pancreas, thymomas, adenosquamous carcinomas of the endometrium, gastrointestinal stromal tumors, and epithelial mesotheliomas. It reacts less strongly with cystadenocarcinomas of the ovary, lung, and colon, and stained adenocarcinomas of the endometrium and renal cell carcinomas only weakly. No staining was seen with small cell carcinomas, leiomyosarcomas, non-Hodgkin's lymphoma, and Hodgkin's lymphoma.

REFERENCES

Gown AM, Vogel AM. Monoclonal antibodies to intermediate filament proteins of human cells: Unique and cross-reacting antibodies. *J Cell Biol* 1982;95(2 Pt 1):414-24.









Moll R, Franke WW, Schiller DL. The catalog of human cytokeratins: Patterns of expression in normal epithelia, tumors and cultured cells. *Cell* 1982;31(1):11-24.

Gown AM, Vogel AM. Monoclonal antibodies to human intermediate filament proteins II. Distribution of filaments in normal human tissues. *Amer J Pathol* 1984;114(2):309-21.

Gown AM, Vogel AM. Monoclonal antibodies to human intermediate filament proteins III. Analysis of tumors. *Amer J Clin Pathol* 1985;84(4):413-24.

Brawer MK, Peehl DM, Stamey TA, Boswick DG. Keratin immunoreactivity in the benign and neoplastic human prostate. *Canc Res* 1985;45(8):3663-7.

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

