

PRIMARY ANTIBODY CARTRIDGE (PAC)

Cytokeratin 7

Monoclonal Mouse Anti-Cytokeratin 7
Clone OV-TL 12/30

REF 014-1137-150

Ready-to-Use ■ 60 Tests

INSTRUCTIONS FOR USE

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INTENDED USE

IVD For *in vitro* diagnostic use.

Monoclonal mouse anti-cytokeratin 7, clone OV-TL 12/30, is intended for laboratory use in identifying the cytokeratin 7 intermediate filament protein 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 7 is found in many ductal, glandular and transitional epithelia, including lung and breast. It is not found in hepatocytes, stratified squamous epithelia, colon or prostate. The cytokeratin 7 antibody is recommended for use as part of an antibody panel to characterize neoplasms of epithelial origin.

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
OV-TL 12/30	IgG ₁ , kappa	OTN 11 ovarian carcinoma cell line

READY-TO-USE IN PRIMARY ANTIBODY CARTRIDGE

Anti-cytokeratin 7 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 cytokeratin 7 intermediate filament protein; may cross-react weakly with endothelial cell walls.

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 7 antibody, when used on the Celerus 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

Cells staining with Cytokeratin 7 antibody display a cytoplasmic staining pattern.

Normal Tissues

Cytokeratin 7 antibody stains most simple epithelial cells other than those in the intestine and stomach.

Abnormal Tissues

Cholangiocellular carcinoma, ductal carcinoma of the breast, and transitional carcinoma of the bladder stain positive with this antibody, as do adenocarcinomas of the ovary, breast, and lung. Colorectal carcinoma, hepatocellular carcinoma, and prostate carcinoma do not stain with this antibody.

REFERENCES

van Niekerk CC, Jap PHK, Ramaekers FCS, van de Molengraft F, Poels LG. Immunohistochemical demonstration of keratin 7 in routinely fixed paraffin-embedded human tissues. *J Pathol* 165:145-152 (1991).









Leroy X, Moukassa D, Copin MC, Saint F, Mazeman E, Gosselin B. Utility of cytokeratin 7 for distinguishing chromophobe renal cell carcinoma from renal oncocytoma. *Eur Urol* 37:484-487 (2000).

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

Moll R. Cytokeratins as markers of differentiation in the diagnosis of epithelial tumors. In: Hermann, Harris, editors. *Subcellular biochemistry*. Volume 31, New York: Plenum Press, p. 205-262 (1998).

Ramaekers F, van Niekerk C, Poels L, Schaafsma E, Huijsmans A, Robben H, et al. Use of monoclonal antibodies to keratin 7 in the differential diagnosis of adenocarcinomas. *Am J Pathol* 136:641-55 (1990).

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

