

PRIMARY ANTIBODY CARTRIDGE (PAC)

Ki67

Monoclonal Mouse, Anti-Ki67
 Clone IVAK-2

REF 014-1139-150

Ready-to-Use ■ 60 Tests

INSTRUCTIONS FOR USE

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INTENDED USE

IVD *For in vitro diagnostic use.*

Monoclonal mouse anti-Ki67, clone IVAK-2, is intended for the identification of human Ki67 using light microscopy. Ki67 is expressed by cells that are undergoing cell division, and is found during late G₁, S, G₂, and M cell cycle phases. Positive staining seen with anti-Ki67 indicates that cells are undergoing replication.

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

Human Ki67 is expressed in all proliferating cells during late G₁, S, G₂ and M phases, but is absent in the G₀ (quiescent) phase.

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
IVAK-2	IgG ₁ , kappa	Recombinant peptide corresponding to a Ki67 cDNA fragment

READY-TO-USE IN PRIMARY ANTIBODY CARTRIDGE

Anti-Ki67 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

Ki67 is found in the nucleus of cells in the active parts of the cell cycle: G₁, S, G₂ and M (mitosis) phase, but not in resting cells (G₀). It may aid in the assessment of proliferation of normal and neoplastic cells.

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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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

Anti-Ki67, 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

Positive staining with anti-Ki67 occurs in the nucleus of the cell.

Normal Tissues

Normal tissue expression of the Ki67 has been reported in tissues that have high cell turnover, including skin, lymphocytic tissue (tonsil and lymph node), testes, ovary, and uterus, as well as gastrointestinal epithelium (esophagus, stomach, small intestine, and colon).

Abnormal Tissues

Ki67 has been used to measure the growth fraction in a variety of tumors. Among the various tumors in which cell division status has been evaluated are glioblastomas, breast and bladder tumors.

REFERENCES

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Torp S. Proliferative activity in human glioblastomas: evaluation of different Ki67 equivalent antibodies. *J Clin Mol Pathol* 1997;50:198-200.

Lee E, Park I, Lee C. Prognostic Markers of intravesical Bacillus Calmette-Guerin therapy for multiple, high-grade stage T1 bladder cancers. *Int J Urol* 1997; 4: 552-556.

EXPLANATION OF SYMBOLS

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

