

## PRIMARY ANTIBODY CARTRIDGE (PAC)

### CD117

Monoclonal Rabbit, Anti-CD117  
Clone YR145

**REF** 014-1147-150

Ready-to-Use ■ 60 Tests

INSTRUCTIONS FOR USE

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### INTENDED USE

**IVD** *For in vitro diagnostic use.*

Monoclonal rabbit anti-CD117, clone YR145, is intended for laboratory use to identify CD117 by light microscopy in both normal and pathological human paraffin-embedded tissue. Tissue should be processed in neutral buffered formalin using immunohistochemical procedures.

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

CD117 is a tyrosine kinase receptor found on a variety of normal and abnormal cell types. The antibody is an effective marker for mast cell disorders and gastrointestinal stromal tumors (GIST), and for immunotyping blast cells in bone marrow. It can also be used to differentiate gastrointestinal stromal tumors from Kaposi's sarcoma and tumors of smooth muscle 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
YR145	IgG	A synthetic peptide corresponding to residues in the C-terminus of human c-kit.

### READY-TO-USE IN PRIMARY ANTIBODY CARTRIDGE

Anti-CD117 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 CD117, also known as stem cell factor receptor or c-kit.

### 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.

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

CD 117 antibody, when used on the Wave instrument, 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.

Staining from poorly fixed tissue specimens, decalcified specimens treated with proteolytic digestion, or specimens handled without regard to tissue preservation may yield nonspecific staining of non-lymphoid tissues particularly in epithelium and smooth muscle.

### RESULTS EXPECTED / PERFORMANCE CHARACTERISTICS

Positive staining for CD 117 occurs in the cytoplasm and cell membrane.

#### Normal Tissues

In normal cells, the CD 117 antibody stains breast epithelium, skin basal cells, melanocytes, germ cells, mast cells and stem cells.

#### Abnormal Tissues

CD 117 is expressed in gastrointestinal stromal tumors, plus certain other malignancies such as endometrial carcinomas, papillary and follicular thyroid carcinomas, small cell carcinomas, ovarian epithelial carcinomas, melanomas, seminomas and leukemias.

### REFERENCES

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### 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

