

## PRIMARY ANTIBODY CARTRIDGE (PAC)

### CD4

Monoclonal Rabbit, Anti-CD4  
Clone SP35

**REF** 014-1150-150

Ready-to-Use ■ 60 Tests

INSTRUCTIONS FOR USE

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### INTENDED USE

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

Monoclonal rabbit anti-CD4, clone SP35, is intended for laboratory use in identifying CD4 in normal or neoplastic tissue using light microscopy. It may be used with frozen or 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

CD4 is a glycoprotein expressed on the surface of T helper cells. The antibody can be used in the characterization of T cell disorders.

### 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
SP35	IgG	Synthetic peptide corresponding to internal region of human CD4 protein

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

Anti-CD4 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 CD4 antigen.

### 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.

### 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

The CD4 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

Positive staining with CD4 antibody is localized to the cell membrane.

#### Normal Tissues

The CD4 antibody reacts with CD4 antigen on the cell surface of the helper/inducer sub-population of normal T cells.

#### Abnormal Tissues

Most post-thymic T cell neoplasms are CD4 positive. As with other T cell antigens, CD4 may be aberrantly deleted in neoplastic T cells so that the evaluation of such tumors requires the application of a panel of markers in order to identify tumors with such anomalous antigenic expression.

### REFERENCES

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### EXPLANATION OF SYMBOLS

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

