

PRIMARY ANTIBODY DILUENT

REF 014-3004-125

125 mL

INSTRUCTIONS FOR USE

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INTENDED USE

IVD For *in vitro* diagnostic use.

The Primary Antibody Diluent is intended for the dilution of primary antibodies and as a negative control for use on the Celerus Wave® RPD System.

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

Use Celerus Primary Antibody Diluent for diluting antibodies or as a negative control for the Celerus Wave® RPD detection system. Diluted antibodies can be transferred into a User-Fillable Primary Antibody Cartridge (Catalog Number 014-2502-150) for use with the Celerus Wave RPD® System.

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

Primary Antibody Diluent.

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.

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.

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.



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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

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.

EXPLANATION OF SYMBOLS

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

