

## LINEAR REAGENT MAGAZINE (LRM)

### Wave RPD Universal DAB

**REF** 014-2018-100

100 Tests

**INSTRUCTIONS FOR USE**

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#### INTENDED USE

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

The Wave RPD Universal Detection LRM is intended for laboratory use with the Celerus Wave® RPD System, to detect antibodies bound to antigens on test tissues using immunohistochemistry.

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 tests.

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

The Universal DAB LRM contains the necessary reagents for the sequential steps of immunohistochemistry starting with the pretreatment needed for paraffin removal and antigen retrieval prior to the primary antibody application and including the detection reagents following primary antibody application. The LRM, together with Celerus Diagnostics primary antibodies, make up a complete immunohistochemical test system when used on the 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

The Universal DAB LRM contains separate compartments which hold proprietary reagents such as primary antibody enhancer, Polymer, DAB Substrate Buffer, DAB Chromogen, Hematoxylin Counterstain and Wash Buffers. The reagents supplied are sufficient to stain 100 slides. The system does not allow for reuse or refilling after 100 slides have been stained.

##### LRM Preparation and Priming

Refer to the Celerus Wave® RPD Operator's Manual for additional information about preparing and priming the LRM.

#### 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.

ProClin 950 and sodium azide (NaN<sub>3</sub>), used for stabilization, are not considered toxic in the concentrations used. ProClin 950 is classified per applicable European Community (EC) Directives as: Irritant (Xi).

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>R22</b>	Harmful if swallowed.
<b>R36/37/38</b>	Irritating to eyes, respiratory system and skin.
<b>R40</b>	Limited evidence of carcinogenic effect.
<b>R43</b>	May cause sensitization by skin contact.
<b>R68</b>	Possible risk of irreversible effects.
<b>S24/25</b>	Avoid contact with skin and eyes.
<b>S26</b>	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
<b>S29/56</b>	Do not empty into drains; dispose of this material and its container 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.
<b>S49</b>	Keep only in original container.



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### WASTE DISPOSAL

Adhere to all local laws when disposing of the Universal DAB LRM.

### 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.

### 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

Staining from poorly fixed tissue specimens, decalcified specimens treated with proteolytic digestion, or specimens handled without regard to tissue preservation may yield nonspecific staining.

### 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

