CELERUS DIAGNOSTICS

LRM System
Red Universal

REF **014-2009**
Wave Red Universal Detection Kit

INTENDED USE

IVD For in vitro diagnostic use.

The Wave LRM (Linear Reagent Magazine) system is intended for laboratory use to detect mouse and rabbit 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 Wave Instrument Operator's Manual for additional information concerning Materials Required but Not Provided; Storage; Staining Procedure; Troubleshooting; Interpretation of Staining; and General Limitations.

SUMMARY AND EXPLANATION

The Unviersal Red LRM system is based on alkaline phosphatase and can detect both mouse and rabbit primary antibodies. This system contains the necessary reagents for the sequential steps of immunohistochemistry following application of the primary antibody. These reagents include the anti-mouse and anti-rabbit secondary antibodies, chromogen, substrate buffer, hematoxylin and wash buffer. The LRM system is ready-to-use, and is packaged for direct insertion onto the Wave instrument. Together with Celerus Diagnostic primary antibodies, these reagents make up a complete immunohistochemical test system when used on the Wave instrument.

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 counterstaining. 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 is an automated instrument that performs immunohistochemistry stains. For further information on the staining procedure, refer to the Celerus Wave Operator's Manual.

MATERIALS PROVIDED

The Red Universal LRM system contains separate compartments which hold secondary antibody/Polymer, Alkaline Phosphatase Substrate and Chromogen components, Hematoxylin counterstain, and Wash Buffer respectively. The reagents supplied are sufficient to stain 80 slides. The system does not allow for reuse or refilling after the 80 slides have been stained.

MATERIALS REQUIRED BUT NOT PROVIDED

1. Wave instrument
2. Wave slide rack
3. Positively-charged microscope slides, appropriately labeled
4. Timer
5. Celerus Riptide for antigen retrieval (or equivalent)
6. Celerus Target Retrieval Solution (or equivalent)
7. Slide drying chamber
8. Xylene or xylene substitute
9. Reagent alcohol or ethyl alcohol
10. Distilled or deionized water
11. TBS wash buffer, pH 7.6
12. Positive and negative tissue controls
13. Celerus Negative Control Reagent (or equivalent)
14. Mounting Medium
15. Cover slips

STORAGE AND HANDLING

Store LRM at 2-8 °C. Do not freeze. The reagents are stable up to the expiration date on the container. Do not use LRM after the expiration date, as the activity cannot be ensured.

There are no signs to indicate instability of these reagents. To ensure a valid staining assay, the use of positive and negative tissue controls is recommended. Contact your Celerus representative if there are stability concerns prior to the expiration date.

PRECAUTIONS

1. For professional users.
2. Minimize microbial contamination of reagents or an increase in nonspecific staining may occur.
3. As with any product derived from biological sources, proper handling procedures should be used.
4. A Material Safety Data Sheet is available for professional users on request.
5. ProClin 300 and sodium azide (NaN3), used for stabilization, are not considered toxic in the concentrations used. ProClin 300 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. The following are the appropriate Risk (R) and Safety (S) phrases.

R22 Harmful if swallowed
R36/37/38 Irritating to eyes, respiratory system and skin
R40 Limited evidence of carcinogenic effect
R43 May cause sensitization by skin contact
R68 Possible risk of irreversible effects
S24/25 Avoid contact with skin and eyes
S26 In case of contact with eyes, rinse immediately with plenty of water and seek medical advice
S29/56 Do not empty into drains; dispose of this material and its container in a safe way
S37/39 Wear suitable gloves and eye/face protection
S46 If swallowed seek medical advice immediately and show this container or label
S49 Keep only in original container

WASTE DISPOSAL

Adhere to all local laws when disposing of the LRM.

PACKAGING DAMAGE

DO NOT USE an LRM if it is leaking, has leaked, has spilled, cannot be primed, or has visually apparent physical damage.

SPECIMEN COLLECTION AND HANDLING

Formalin-fixed paraffin embedded (FFPE) tissues, frozen tissues, or smears are suitable for use. Wave detection kits have been optimized for tissues fixed with 10% formalin. Ideally, each 4-6µ tissue section should be placed on charged slides on the lower 2/3 of the slide. Very large sections should be placed 1/4 inch below the lower end of the slide label.

Slides should be baked overnight at 37 °C, or at 60 °C for one hour.

Use standard histochemical techniques to deparaffinize processed slides. For uniformity of staining results, it is recommended that target retrieval be performed using the Celerus Riptide and Celerus Target Retrieval Solution (or equivalent) at 112 °C for 5 minutes. Avoid drying of the 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 slides have completed the staining run, remove them from the instrument, coverslip, and view under light microscopy.

MOUNTING FINISHED SLIDES

The Red Universal chromogen resists organic solvents, such as alcohols, xylenes and may be permanently mounted. However, for optimal signal, minimize exposure of finished slides to organic solvents and mount as quickly as possible. Alternatively rinse finished slides with distilled water and let completely air dry. Dried slides can be directly mounted without exposure to alcohol and xylene.

RESULTS EXPECTED

The Red Universal LRM system provides a red stain of antigen-antibody complexes, and a blue stain of cell nuclei to aid in assessment of cellular structures. Any unwanted staining or overstaining may require repeat testing. If retesting is required, follow the staining procedure outlined in the Wave user manual, with special care taken for deparaffinization and antigen retrieval. Over or under-fixed tissue may give erroneous results.

CELERUS DIAGNOSTICS

CE

EC REP Vector Laboratories, Ltd.
3 Accent Park, Bakewell Road
Orton Southgate, Peterborough
PE2 6XS, England

Celerus Diagnostics
1005 Mark Avenue
Carpinteria, CA 93013 USA

TECHNICAL SUPPORT 888-444-3613
CUSTOMER SERVICE 888-444-8918

www.celerusdiagnostics.com