**Catalog Number:** API 3161 AA  
**Description:** 6.0 mL, RTU  
**Dilution:** Ready-to-use  
**Diluent:** N/A  

**Intended Use:**  
For In Vitro Diagnostic Use  
CK8/18 (RM) [EP17+EP30] is a cocktail of rabbit monoclonal antibodies that is intended for laboratory use in the qualitative identification of low molecular weight cytokeratin proteins (CK 8, 18) by immunohistochemistry (IHC) in formalin-fixed paraffin-embedded (FFPE) human tissues. The clinical interpretation of any staining or its absence should be complemented by morphological studies using proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist.  

**Summary and Explanation:**  
Clones EP17 and EP30 recognize cytokeratins (CK) 8 and 18, both of which are low molecular weight intermediate filament proteins (52.5 kDa and 45 kDa respectively). In normal tissues, CK8/18 recognizes all simple and glandular epithelium (1). In neoplastic tissues, CK8/18 may prove useful for the identification of most adenocarcinomas and some squamous cell carcinomas. CK8/18 expression patterns may also aid in the classification of tumors of unknown origin and poorly differentiated carcinomas (1-3). CK8/18 rabbit monoclonal may be useful as a staining mask in a multiplex stain with mouse monoclonal antibodies such as Ki-67, PD-1 or CD8. As CK8/18 does not stain stromal components or tumor infiltrating lymphocytes in various carcinomas such as breast or colon cancers, a CK8/18 staining mask may be helpful with these applications.  

**Principle of Procedure:**  
Antigen detection in tissues and cells is a multi-step immunohistochemical process. The initial step binds the primary antibody to its specific epitope. After labeling the antigen with a primary antibody, an enzyme labeled polymer is added to bind to the primary antibody. The detection of the bound antibody is evidenced by a colorimetric reaction.  

**Source:** Rabbit monoclonal  
**Species Reactivity:** Human and mouse (does not stain rat); other species not tested  
**Clone:** EP17+EP30  
**Isotype:** IgG  

**Protocol Recommendations (intelliPATH FLX® and manual use):**  
**Cont’d:**  
**Primary Antibody:** Incubate for 30 minutes at RT.  
**Probe:** N/A  
**Polymer:** Incubate for 30 minutes at RT with a secondary-conjugated polymer.  
**Chromogen:** Incubate for 10 minutes at RT with Warp Red – OR- Incubate for 5 minutes at RT with Biocare’s DAB.  
**Counterstain:** Counterstain with hematoxylin. Rinse with deionized water. Apply Tache’s Bluing Solution for 1 minute. Rinse with deionized water.  

**Technical Note:**  
1. This antibody, for intelliPATH FLX and manual use, has been standardized with MACH 2 Rabbit and MACH 2 Double Stain 2 detection systems. Use TBS for washing steps.  
2. If this reagent is used in combination with other primary antibodies, the antibody incubation time may need to be extended up to 60 minutes, depending upon the particular protocol of the individual investigator.  

**Limitations:**  
The optimum antibody dilution and protocols for a specific application can vary. These include, but are not limited to fixation, heat-retrieval method, incubation times, tissue section thickness and detection kit used. Due to the superior sensitivity of these unique reagents, the recommended incubation times and titers listed are not applicable to other detection systems, as results may vary. The data sheet recommendations and protocols are based on exclusive use of Biocare products. Ultimately, it is the responsibility of the investigator to determine optimal conditions.  

**Quality Control:**  

**Precautions:**  
1. This antibody contains less than 0.1% sodium azide. Concentrations less than 0.1% are not reportable hazardous materials according to U.S. 29 CFR 1910.1200, OSHA Hazard communication and EC Directive 91/155/EC. Sodium azide (NaN₃) used as a preservative is toxic if ingested. Sodium azide may react with lead and copper plumbing to form highly explosive metal azides. Upon disposal, flush with large volumes of water to prevent azide build-up in plumbing. (Center for Disease Control, 1976, National Institute of Occupational Safety and Health, 1976) (4)  
2. Specimens, before and after fixation, and all materials exposed to them should be handled as if capable of transmitting infection and disposed of with proper precautions. Never pipette reagents by mouth and avoid contacting the skin and mucous membranes with reagents and specimens. If reagents or specimens come into contact with sensitive areas, wash with copious amounts of water. (5)  
3. Microbial contamination of reagents may result in an increase in nonspecific staining.  
4. Incubation times or temperatures other than those specified may give erroneous results. The user must validate any such change.  
5. Do not use reagent after the expiration date printed on the vial.  
6. The SDS is available upon request and is located at http://biocare.net.
Troubleshooting:
Follow the antibody specific protocol recommendations according to data sheet provided. If atypical results occur, contact Biocare's Technical Support at 1-800-542-2002.

References:

Produced using Abcam's RabMAB® technology. RabMAB® technology is covered by the following U.S. Patents, No. 5,675,063 and/or 7,429,487.