| Available Product Formats | | | | |
|---------------------------|-----------------|------------------|--------------|------------|
| Format | Catalog Number | Description | Dilution | Diluent |
| Concentrate | CME 324 A, B, C | 0.1, 0.5, 1.0 mL | 1:50 | Renoir Red |
| Predilute | PME 324 AA | 6.0 mL | Ready-to-use | N/A |
| ONCORE Pro | OPAI 324 T60 | 60 tests | Ready-to-use | N/A |

Intended Use:

For In Vitro Diagnostic Use

CD3 [EP41] is a rabbit monoclonal antibody that is intended for laboratory use in the qualitative identification of CD3 protein 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:

This rabbit monoclonal antibody reacts with the intracytoplasmic portion of the CD3 antigen expressed by T-cells. It stains human T-cells in both the cortex and medulla of the thymus and in peripheral lymphoid tissues. It does not react with B-cells, monocytes, granulocytes and platelets. CD3 is regarded as a reliable pan T-cell antibody used in the immunophenotyping of T-cell lymphomas in paraffin sections. Most Tcell lymphomas show positivity for CD3. Used in conjunction, CD3 and UCHL-1 together identified the vast majority of T-cell lymphomas in paraffin sections.

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, a one-step or two-step detection procedure can be applied. A one-step procedure will feature an enzyme labeled polymer that binds the primary antibody. A two-step procedure will feature a linker antibody added to bind to the primary antibody. An enzyme-labeled polymer is then added to bind the linker antibody. These detections of the bound antibodies are evidenced by a colorimetric reaction.

Source: Rabbit monoclonal

Species Reactivity: Human

Clone: EP41 (previously known as EP449E; also identified as E272 in this product)

Isotype: IgG

Protein Concentration: Call for lot specific Ig concentration.

Epitope/Antigen: CD3 (T-cell)

Cellular Localization: Predominantly cell membrane and some cytoplasmic

Positive Tissue Control: Tonsil or T-cell lymphoma **Known Applications:**

Immunohistochemistry (formalin-fixed paraffin-embedded tissues) **Supplied As:** Buffer with protein carrier and preservative

Storage and Stability:

Store at 2°C to 8°C. The product is stable to the expiration date printed on the label, when stored under these conditions. Do not use after expiration date. Diluted reagents should be used promptly; any remaining reagent should be stored at 2°C to 8°C.

Protocol Recommendations (intelliPATH FLX[®] and manual use): Peroxide Block: Block for 5 minutes with Peroxidazed 1.

Pretreatment: Perform heat retrieval using Diva or Reveal Decloaker. Refer to the Diva or Reveal Decloaker product data sheet for specific instructions.

Protein Block (Optional): Incubate for 5-10 minutes at RT with Background Punisher.

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 5 minutes at RT with Biocare's DAB - OR - Incubate for 5-7 minutes at RT with Warp Red.

Counterstain:

Counterstain with hematoxylin. Rinse with deionized water. Apply Tacha's Bluing Solution for 1 minute. Rinse with deionized water. **Technical Note:**

This antibody, for intelliPATH FLX and manual use, has been standardized with MACH 4 detection system. Use TBS for washing steps.

Protocol Recommendations (ONCORE™ Pro Automated Slide Staining System):

OPAI324 is intended for use with the ONCORE Pro. Refer to the User Manual for specific instructions for use. Protocol parameters in the Protocol Editor should be programmed as follows:

Protocol Name: CD3 Rb Protocol Template (Description): Rabbit HRP Template 1 Dewaxing (DS Buffer Option): DS2-50 Antigen Retrieval (AR Option): AR1, high pH; 103°C Block Option: Buffer Reagent Name, Time, Temp.: CD3 Rb, 30 min., 25°C

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:

Refer to CLSI Quality Standards for Design and Implementation of Immunohistochemistry Assays; Approved Guideline-Second edition (I/LA28-A2). CLSI Wayne, PA, USA (www.clsi.org). 2011

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) (2)

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

Biocare Medical 60 Berry Drive Pacheco, CA 94553

USA

ΙΝΣ CE



Westervoortsedijk 60 6827 AT Arnhem The Netherlands

CD3

Concentrated and Prediluted Rabbit Monoclonal Antibody 901-324-052323



Precautions Cont'd:

and specimens. If reagents or specimens come in contact with sensitive areas, wash with copious amounts of water. (3)

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:

1. Rossi S, *et al.* A comparative study between a novel category of immunoreagents and the corresponding mouse monoclonal antibodies. Am J Clin Pathol. 2005; 124(2):295-302.

2. Center for Disease Control Manual. Guide: Safety Management, NO. CDC-22, Atlanta, GA. April 30, 1976 "Decontamination of Laboratory Sink Drains to Remove Azide Salts."

3. Clinical and Laboratory Standards Institute (CLSI). Protection of Laboratory Workers from Occupationally Acquired Infections; Approved Guideline-Fourth Edition CLSI document M29-A4 Wayne, PA 2014.

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.







Westervoortsedijk 60 6827 AT Arnhem The Netherlands