CE
EC REP Emergo Europe, Prinsessegracht 20, 2514AP The Hague, The Netherlands

# Anti-CD30 (Ki-1 Antigen) [Ber-H2]

| Catalog No. | Description |
|---|---|
| AM327-5M | 6 ml of Ready-to-Use Antibody for use with BioGenex Super Sensitive™ Detection Systems OR equivalent detection system |
| AM327-10M | 10 ml of Ready-to-Use Antibody in a barcode labeled vial for use with BioGenex Super Sensitive™ Detection Systems and i6000™ Automated Staining Systems |
| AX327-YCD | Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx® Elite/Ultra Staining System, 200 tests |
| AX327-50D | Ready-to-Use Antibody in Barcode labeled vial for use on the Xmatrx® Elite/Ultra Staining System, 50 tests |

| Clone | Species | Ig Class |
|---|---|---|
| Ber-H2 | Mouse | IgG1, kappa |

## Intended Use

**For In Vitro Diagnostic Use.** This antibody is designed for the specific localization of CD30 (Ki-1) in formalin-fixed, paraffin-embedded (FFPE) tissue sections. Evaluation must be performed by a qualified pathologist.

## Summary and Explanation

CD30 (Ki-1 antigen), a 120 kD single chain glycoprotein, is expressed in only a small population of normal lymphoid tissue. By contrast, it is expressed in approximately 50% of all malignant lymphomas including all cases of Hodgkin's disease and a vast majority of Ki-1 positive anaplastic large cell lymphomas. Ki-1 antigen can be detected in sera from lymphoma patients, but not in sera from normal individuals with systemic infection.

## Storage and Handling

**Store at 2-8°C.** Fresh dilutions, if required, should be prepared prior to use and are stable and steady for up to one day at room temperature (20-26°C). Diluted antibody preparations can be refrigerated or frozen for extended shelf life.

## Principles of the Procedure

Antigen detection by immunohistochemistry (IHC) is a two-step process wherein the primary antibody binds to the antigen of interest and that binding is detected by a chromogen. The primary antibody may be used in IHC using manual techniques or BioGenex Automated Staining System. Positive and negative controls should always be run simultaneously with all patient specimens.

## Reagents Provided

Mouse Monoclonal Antibody to CD30 (Ki-1) is affinity purified and diluted in PBS, pH 7.2, containing 1% BSA and 0.09% sodium azide.

## Dilution of Primary Antibody

BioGenex Ready-to-Use antibodies have been optimized for use with the recommended BioGenex Detection System and should not require further dilution.

BioGenex concentrated antibodies must be diluted in accordance with the recommended protocol when used with the recommended BioGenex Detection System.

## Recommended Protocol

Refer to the following table for conditions specifically recommended for this antibody. Refer to the BioGenex website for guidance on specific staining protocols or other requirements.

| Parameter | BioGenex Recommendations |
|---|---|
| Control Tissue | Hodgkin's Lymphoma as available with Biogenex FB-327M* & FG-327M* |
| Recommended Pretreatment (Manual/i6000)** | EZ-AR2 (HK522-XAK) |
| Recommended Pretreatment (Xmatrx) | EZ-AR2 Elegance (HX032-YCD) |
| Antibody Incubation (Manual/i6000) | 30-60 min at RT |
| Antibody Incubation (Xmatrx) | 30-60 min at 25°C |
| Detection System for Manual, Xmatrx & i6000 systems*** | Use BioGenex Two-Step **OR** One-Step Super Sensitive™ Polymer-HRP IHC Detection System/DAB; see p. 2 for more information |

*FB: positive control barrier slides, FG: positive control non-barrier slides. Xmatrx requires barrier slides.
**Pretreatment times will vary based on individual microwave power.
***For automation systems (Xmatrx-Elite, Xmatrx-Ultra & i6000 Diagnostics), refer to the factory protocols provided with the instrument.



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| Detection System | Two-Step HRP Kit | One-Step HRP Kit | Link and Label Kit |
|---|---|---|---|
| Manual | QD440-XAKE (1000 Test) | QD630-XAKE (1000 Test) | QP300-XAKE (1000 Test) |
| | QD430-XAKE (1000 Test) | | |
| | QD420-YIKE (500 Test) | QD620-XAKE (500 Test) | QP900-9LE (500 Test) |
| | QD400-60KE (60 Test) | | |
| Xmatrx - Automation | QD550-YCDE (200 Test) | QD610-YADE (200 Test) | N/A |
| i6000 - Automation | QD410-YAXE (200 Test) | QD610-YAXE (200 Test) | N/A |
| For more information, visit www.biogenex.com. | | | |

## Precautions

This product contains sodium azide at concentrations of less than 0.1%. Sodium azide is not classified as a hazardous chemical at the product concentrations, but proper handling protocols should be observed. For more information, a Safety Data Sheet (SDS) for sodium azide is available upon request. Dispose of unused reagents according to Local, State and Federal Regulations. Wear suitable Personal Protective Equipment, do not pipette reagents by mouth, and avoid contact of reagents and specimens with skin and mucous membranes. If reagents or specimens come in contact with sensitive area, wash with copious amounts of water.

## Quality Control

Refer to BioGenex detection system documents for guidance on general quality control procedures.

## Troubleshooting

Refer to the troubleshooting section in the documentation for BioGenex Detection Systems (or equivalent detection systems) for remedial actions on detection system related issues, or contact BioGenex Technical Support Department at 1-800-421-4149 or support@biogenex.com or your local distributor to report unusual staining.

## Expected Results

This antibody stains nucleus/cytoplasm in positive cells in formalin-fixed, paraffin embedded tissue sections. An example image of a tissue section stained with this antibody can be found on the product page on the BioGenex website. Interpretation of the staining result is solely the responsibility of the user. Experimental results should be confirmed by a medically-established diagnostic product or procedure.

## Limitations of the Procedure

Improper tissue handling and processing prior to immunostaining can lead to inconsistent results. Variations in embedding and fixation or the nature of the tissue may lead to variations in results. Endogenous peroxidase activity or pseudo peroxidase activity in erythrocytes and tissue biotin may result in non-specific staining based on the detection system employed. Tissues containing Hepatitis B Surface Antigen (HBsAg) may give false positive with horseradish peroxidase systems. Improper counterstaining and mounting may compromise the interpretation of results.

## Bibliography

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2. Schwarting R, et al. Blood 74:1678-1689, 1989.
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7. Omata M, Liew CT, Ashcavai M, Peters Rl. Nonimmunologic binding of horseradish peroxidase to hepatitis B surface antigen. A possible source of error in immunohistochemistry. Am J Clin Pathol. May, 1980; 73(5):626-632.
8. U.S. Congress. Clinical Laboratory Improvement Amendments of 1988: Final Rule, 57 FR 7163, February 28, 1992.
9. National Institute for Occupational Safety and Health, (NIOSH), Rockville, MD. Explosive azide hazard, Publication No. 78-127, 1976.

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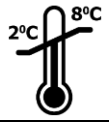
|   | Temperature Limitation | | In Vitro Diagnostic Medical Device |
| | Use By Date | | Batch Code |
| | Non-Sterile | | Consult Instructions for Use |
| | Representative in the European Community | | Manufacturer |

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