Anti– human Her2 Mouse Monoclonal Primary Antibody

Clone: UMAB36

IVD

REF CE00004

CATALOG NUMBER

C0004MA01-MA 0.1 mL
C0004MA05-MA 0.5 mL

ENGLISH

Intended use

Anti- human Her2 Mouse Monoclonal Primary Antibody is intended for detection of Her2 protein expression in frozen or formalin fixed human tissues and cells. 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 within the context of the patient's clinical history and other diagnostic tests by a qualified pathologist. The antibody is intended for *in vitro* diagnostic (IVD) use.

Background

This Her2/neu/ErbB2 gene encodes a member of the epidermal growth factor (EGF) receptor family of receptor tyrosine kinases. This protein has no ligand binding domain of its own and therefore cannot bind growth factors. However, it does bind tightly to other ligand-bound EGF receptor family members to form a heterodimer, stabilizing ligand binding and enhancing kinase-mediated activation of downstream signaling pathways, such as those involving mitogen-activated protein kinase and phosphatidylinositol-3 kinase. Amplification and/or overexpression of this gene has been reported in numerous cancers, including breast and ovarian tumors. Alternative splicing results in several additional transcript variants, some encoding different isoforms and others that have not been fully characterized. [provided by RefSeq, Jul 2008].

Alternative names: C-erbB-2; HER-2; HER-2/neu; MLN 19; NEU; NGL; TKR1

Reagent provided

Anti- human Her2 Mouse Monoclonal Primary Antibody (Clone: UMAB36) is provided in liquid form in 20mM Sodium phosphate, 150mM Sodium chloride, 0.2% BSA, 0.09% Sodium azide, pH 7.4. The isotype of the antibody is IgG1. The protein concentration is approximately 0.6 +/ - 0.05 mg/mL.

For Immunohistochemistry the primary antibody may be used at a working dilution of 1:100 – 1:200 for formalin-fixed, paraffin-embedded human tissue and this can be dependent upon the detection system used. These are guidelines only and optimal dilutions should be determined by the individual laboratory.

Immunogen

Human recombinant protein fragment corresponding to amino acids 676-1255 of human ERBB2 (NP_004439) produced in HEK293T cell.

Specificity
The specificity of the anti- human Her2 Mouse Monoclonal Primary Antibody was established on known positive human breast cancer and normal human lung tissue. The anti-Her2 presented no staining on formalin fixed Her2 negative lung tissue and positive staining on formalin fixed Her2 positive human breast cancer tissue using immunohistochemical (IHC) test methods.

Materials Required but Not Supplied
Antibody diluent, HIER solution, Antibody detection kits, Chromogen, Staining reagents, negative and positive tissue control slides are not included.

Precautions
1. For use by trained professionals only.
2. This product contains sodium azide (NaN_3), a chemical highly toxic in pure form. At product concentrations, though not classified as hazardous, NaN_3 may react with lead and copper plumbing to form highly explosive build-ups of metal azides. Upon disposal, flush with large volumes of water to prevent metal azide build-up in plumbing.
3. Wear appropriate Personal Protective Equipment to avoid contact with eyes and skin.
4. Unused reagents should be disposed of according to local, State, and Federal regulations.

Storage
Store at 2-8^{o}C. Do not use the product past the expiration date indicated on the label. If reagents are stored under any other conditions, the end user must verify the acceptability of those conditions. There are no obvious signs to indicate instability of this product therefore, positive and negative controls should be run simultaneously with patient specimens.

Specimen Preparation
Paraffin Sections
Anti- human Her2 Mouse Monoclonal Primary Antibody can be used on formalin-fixed, paraffin-embedded tissue sections at a working dilution of 1:100 to 1:200. Anti- human Her2 clone UMAB36 Mouse Monoclonal Primary Antibody working dilution requires 20 minutes of pretreatment with Heat Induced Epitope Retrieval (HIER) for staining. We recommend using HIER EDTA Buffer pH 8.0, which showed optimal staining at a dilution of 1:200 on Her2 positive human breast cancer and negative staining on Her2 negative normal lung. The dilutions are estimates; the actual staining results may vary due to reagents and detection protocols used. Validation of antibody performance and final protocol are the responsibility of the end user.

Staining procedure
Manual Staining Procedure
1. Deparaffinize slides.
2. Submerge slides in peroxidase quenching solution for ~10 minutes and rinse with PBS-T 3 times, 2 minutes each.
3. Heat Induced Epitope Retrieval is required for this antibody.
4. Apply serum blocking solution.[Optional]
5. Apply primary antibody and incubate for 30-60 minutes at room temperature. After incubation wash with PBS-T 3 times, 2 minutes each.
6. Apply secondary antibody and incubate according to the data sheet of the detection system. Wash with PBS-T 3 times, 2 minutes each.
7. Apply enzyme conjugate and incubate according to data sheet of detection system. Wash with PBS-T 3 times, 2 minutes each.
8. Apply chromogen and incubate 5-10 minutes and rinse with distilled water.

Staining interpretation
The cellular staining pattern for Anti- human Her2 Mouse Monoclonal Primary Antibody can be cytoplasmic and membranous.

Performance characteristics
Predicted Staining in Normal Tissue/Cells
Normal human lung was shown to be negative for this antibody.

Predictive Staining in Tumor
Anti- human Her2 Mouse Monoclonal clone UMAB36 produced strong cytoplasmic and membranous positive stain when screened on known Her2 positive human breast cancer tissue.

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