

anti-c-MYC (Y69) Rabbit Monoclonal Primary Antibody

REF 790-4628

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IVD Σ 50

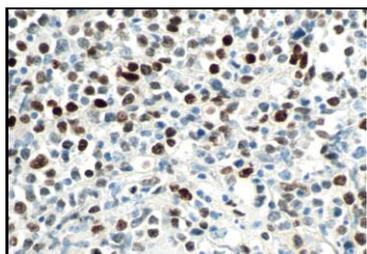


Figure 1. Anti-c-MYC (Y69) nuclear staining of lymphoma tissue.

INTENDED USE

Anti-c-MYC (Y69) Rabbit Monoclonal Primary Antibody (anti-c-MYC (Y69)) is directed against the transcription factor c-MYC, an important factor in cell cycle regulation. The anti-c-MYC (Y69) antibody exhibits a nuclear staining pattern and may be used to aid in the characterization of lymphoma. This antibody is intended for qualitative staining of sections of formalin-fixed, paraffin-embedded tissue.

This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls.

This antibody is intended for *in vitro* diagnostic (IVD) use.

SUMMARY AND EXPLANATION

Anti-c-MYC (Y69) is a rabbit monoclonal antibody produced against the N-terminus of the 64 kDa c-MYC protein.

c-MYC acts as a DNA binding protein and is part of the MYC/MAD/MAX family of helix-loop-helix zipper motif proteins.^{1,2} c-MYC expression has been described in a variety of cancers including breast cancer, prostate cancer, lymphomas, lung, and colon cancers. c-MYC amplification and overexpression in these cancers has been shown on the gene and mRNA levels using in-situ hybridization and RT-PCR methods. The gene is located at t(8q24), which is involved in translocations in Burkitt's lymphoma, where the c-myc gene is placed under the IgG loci for heavy or light chains.³ The most common translocation being t(8;14)(q24;q32), but translocations t(2;8)(p12;q24) and t(8;22)(q24;q11) have also been described for lymphomas.^{4,5}

REAGENT PROVIDED

Anti-c-MYC (Y69) contains sufficient reagent for 50 tests.

One 5 mL dispenser of anti-c-MYC (Y69) contains approximately 120 µg of a rabbit monoclonal antibody.

The antibody is diluted in a TBS buffer containing 0.3% carrier protein.

Total protein concentration of the reagent is approximately 3.0 mg/mL. Specific antibody concentration is approximately 24 µg/mL.

Anti-c-MYC (Y69) is a rabbit monoclonal antibody produced as purified cell culture supernatant.

Refer to the appropriate VENTANA detection kit package insert for detailed descriptions of: (1) Principles of the Procedure, (2) Materials and Reagents Needed but Not Provided, (3) Specimen Collection and Preparation for Analysis, (4) Quality Control Procedures, (5) Troubleshooting, (6) Interpretation of Results, and (7) General Limitations.

MATERIALS REQUIRED BUT NOT PROVIDED

Staining reagents, such as VENTANA detection kits and ancillary components, including negative and positive tissue control slides, are not provided.

STORAGE

Store at 2-8°C. Do not freeze.

To ensure proper reagent delivery and the stability of the antibody, replace the dispenser cap after every use and immediately place the dispenser in the refrigerator in an upright position.

Every antibody dispenser is expiration dated. When properly stored, the reagent is stable to the date indicated on the label. Do not use reagent beyond the expiration date.

SPECIMEN PREPARATION

Routinely processed, formalin-fixed, paraffin-embedded tissues are suitable for use with this primary antibody when used with VENTANA detection kits and a VENTANA BenchMark XT and BenchMark ULTRA automated slide stainer. The recommended tissue fixative is 10% neutral buffered formalin.⁶ Slides should be stained immediately, as antigenicity of cut tissue sections may diminish over time.

It is recommended that positive and negative controls be run simultaneously with unknown specimens.

WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic (IVD) use.
2. Materials of human or animal origin should be handled as biohazardous materials and disposed of with proper precautions.
3. Avoid contact of reagents with eyes and mucous membranes. If reagents come in contact with sensitive areas, wash with copious amounts of water.
4. Avoid microbial contamination of reagents as it may cause incorrect results.
5. Consult local and/or state authorities with regard to recommended method of disposal.
6. For supplementary safety information, refer to the product Safety Data Sheet and the Symbol and Risk Phrase Guide located at www.ventana.com.

STAINING PROCEDURE

VENTANA primary antibodies have been developed for use on a VENTANA BenchMark XT and BenchMark ULTRA automated slide stainer in combination with VENTANA detection kits and accessories. Refer to Table 1 and Table 2 for recommended staining protocols.

This antibody has been optimized for specific incubation times but the user must validate results obtained with this reagent.

The parameters for the automated procedures can be displayed, printed and edited according to the procedure in the instrument's Operator's Manual. Refer to the appropriate VENTANA detection kit package insert for more details regarding immunohistochemistry staining procedures.

Table 1. Recommended Staining Protocol for anti-c-MYC (Y69) with VENTANA *ultraView* Universal DAB Detection Kit on a BenchMark XT instrument and BenchMark ULTRA instrument.

Procedure Type	Method
Deparaffinization	Selected
Cell Conditioning (Antigen Unmasking)	Cell Conditioning 1, Standard
Antibody (Primary)	BenchMark XT instrument 16 minutes, 37°C BenchMark ULTRA instrument 16 minutes, 36°C
Amplification	BenchMark XT instrument, Selected BenchMark ULTRA instrument, Selected
Counterstain	Hematoxylin II, 4 minutes
Post Counterstain	Bluing, 4 minutes

Table 2. Recommended Staining Protocol for anti-c-MYC (Y69) with OptiView DAB IHC Detection Kit on a BenchMark XT instrument and BenchMark ULTRA instrument.

Procedure Type	Method
Deparaffinization	Selected
Cell Conditioning (Antigen Unmasking)	Cell Conditioning 1, 64 minutes
Antibody (Primary)	BenchMark XT instrument 16 minutes, 37°C BenchMark ULTRA instrument 16 minutes, 36°C
Counterstain	Hematoxylin II, 4 minutes
Post Counterstain	Bluing, 4 minutes

Due to variation in tissue fixation and processing, as well as general lab instrument and environmental conditions, it may be necessary to increase or decrease the primary antibody incubation, cell conditioning or protease pretreatment based on individual specimens, detection used, and reader preference. For further information on fixation variables, refer to "Immunohistochemistry Principles and Advances".⁷

POSITIVE TISSUE CONTROL

An example of a positive control tissue for this antibody is skin.

STAINING INTERPRETATION / EXPECTED RESULTS

The cellular staining pattern for anti-c-MYC (Y69) is nuclear.

SPECIFIC LIMITATIONS

This antibody may demonstrate cross-reactivity to mucin in the small intestine. This non-specific staining does not interfere with staining interpretation.

PERFORMANCE CHARACTERISTICS

Staining tests for specificity, sensitivity, and repeatability were conducted and the results are listed in Table 3 and Table 4 and in the Repeatability section.

Specificity

Table 3. Specificity of anti-c-MYC (Y69) was determined by testing formalin-fixed, paraffin-embedded normal tissues.

Tissue	# positive / total cases	Tissue	# positive / total cases
Cerebrum	0/6	Thymus	0/3
Cerebellum	0/3	Myeloid (bone marrow)	0/3
Adrenal gland	0/3	Lung	0/3
Ovary	2/2	Heart	0/3
Pancreas	0/3	Esophagus	1/3
Hypophysis	0/3	Stomach	0/3
Testis	0/3	Small intestine	3/3
Thyroid	0/4	Colon	0/3
Breast	1/3	Liver	0/3
Spleen	1/3	Salivary gland	1/3
Tonsil	0/3	Kidney	1/3
Endometrium	1/6	Prostate	0/3
Skeletal muscle	0/3	Cervix	1/4
Nerve (sparse)	1/6	Skin	3/6

Tissue	# positive / total cases	Tissue	# positive / total cases
Lymph Node	0/6	Mesothelium and lung	0/3

Sensitivity

Table 4. Sensitivity of anti-c-MYC (Y69) was determined by testing a variety of formalin-fixed, paraffin-embedded neoplastic tissues.

Pathology	# positive / total cases
Glioblastoma	1/1
Atypical meningioma	0/1
Malignant ependymoma	0/1
Malignant oligodendroglioma	0/1
Serous adenocarcinoma	1/1
Ovarian adenocarcinoma	2/2
Islet cell carcinoma	0/1
Pancreatic adenocarcinoma	0/2
Seminoma	1/2
Embryonal carcinoma	1/2
Medullary carcinoma	0/1
Papillary carcinoma	0/1
Breast intraductal carcinoma	0/1
Breast invasive ductal carcinoma	2/2
Lung small cell undifferentiated carcinoma	1/1
Lung squamous cell carcinoma	1/1
Lung adenocarcinoma	0/1
Esophageal squamous cell carcinoma	0/1
Esophageal adenocarcinoma	1/1
Gastric mucinous adenocarcinomas	1/1
Gastrointestinal adenocarcinoma	0/1
GIST	1/1
Hepatocellular carcinoma	0/1
Hepatoblastoma	0/1
Renal clear cell carcinoma	0/1
Prostatic adenocarcinoma	0/2
Leiomyoma	0/1
Endometrial adenocarcinoma	0/1
Endometrial clear cell carcinoma	0/1
Uterine squamous cell carcinoma	1/2
Embryonal rhabdomyosarcoma	0/1
Anal malignant melanoma	0/1

Pathology	# positive / total cases
Basal cell carcinoma	0/1
Squamous cell carcinoma	1/1
Neurofibroma	0/1
Retroperitoneal neuroblastoma	0/1
Epithelial malignant mesothelioma	1/1
Burkitt's lymphoma	3/3
B-cell lymphoma	70/175
Follicular lymphoma	1/4
Hodgkin lymphoma	4/11
Large cell anaplastic lymphoma	0/1
Small lymphocytic lymphoma	0/2
T-cell lymphoma	12/22
Plasma cell myeloma	1/8
Bladder transitional cell carcinoma	0/1
Low grade leiomyosarcoma	0/1
Osteosarcoma	0/1
Spindle cell rhabdomyosarcoma	0/1
Intermediate grade leiomyosarcoma	0/1

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Repeatability

Repeatability studies for anti-c-MYC (Y69) were completed to demonstrate:

- Inter-lot reproducibility of the antibody.
- Intra-run and Inter-run reproducibility on a BenchMark XT instrument.
- Intra-platform reproducibility on the BenchMark XT instrument and the BenchMark ULTRA instrument.
- Inter-platform reproducibility between the BenchMark XT instrument and BenchMark ULTRA instrument.

All studies met their acceptance criteria ($\geq 90\%$).

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