

## p63

### Rabbit Monoclonal Antibody

RMAB086

RMPD086

RMPD086-HL

Document #: DS-0646-D  
Effective Date: 12/18/2023

Immunogen	Clone	Species	Isotype	Primary Antibody Diluent
Recombinant human p63 protein fragment	DBR16.1	Rabbit	IgG	K004

*Lot specific Ig concentration available upon request.*

Catalog # Number	Description
RMAB086	Concentrated antibody for use with Diagnostic BioSystems PolyVue™ Plus - Two Step Detection System
RMPD086	Ready to use antibody for use with Diagnostic BioSystems PolyVue™ Plus - Two Step Detection System
RMPD086-HL	Ready to use antibody in RFID tagged vials for use on the HighLighter Staining System

#### Intended Use

##### For In Vitro Diagnostic Use. (For Outside U.S Market)

This product is intended for qualitative immunohistochemistry with normal and neoplastic formalin-fixed, paraffin-embedded tissue sections, to be viewed by light microscopy. Clinical interpretation of staining results should be accompanied by histological studies with proper controls. Patients' clinical histories and other relevant diagnostic tests should be utilized by a qualified person(s) when evaluating and interpreting results.

#### Summary and Explanation

p63 is a homolog of the tumor suppressor p53, it is identified in basal cells in the epithelial layers of a variety of tissues, including epidermis, cervix, urothelium, breast and prostate. p63, vital for the development of the prostate and selectively expressed by normal prostate basal cells, has been shown to be a promising complementary basal cell specific marker to High Molecular Weight-Cytokeratin (HMW-CK), for the differential diagnosis of benign prostatic lesions and prostatic carcinoma. p63 has also been shown to be a sensitive marker for lung squamous cell carcinomas (SqCC), with a sensitivity of ~90%. Specificity for lung SqCC, vs. lung adenocarcinoma (LADC), is approximately 80. In breast tissue, p63 has been identified in myoepithelial cells of normal ducts.

#### Format

This product is supplied as a purified immunoglobulin and contains sodium azide as a preservative.

#### Principles of the Procedures

Antigen detection by immunohistochemistry (IHC) is a two-step process involving first, the binding of a primary antibody to the antigen of interest,

and second, the detection of bound antibody by a chromogen. The primary antibody may be used in IHC using manual techniques or using Diagnostic BioSystems Automated Montage 360™ Staining System or HighLighter Staining System.

#### Dilution of Primary Antibody

Diagnostic BioSystems ready to use antibodies have been optimized for use with the recommended Diagnostic BioSystems Detection System and do not require further dilution. Further dilution may result in loss of sensitivity. The user must validate any such change.

Diagnostic BioSystems concentrated antibodies must be diluted in accordance with the staining procedure when used with the recommended Diagnostic BioSystems detection system. Use of any detection methods other than the recommended systems and protocols require validation by the user. Antibody dilutions should be appropriately adjusted and verified according to the detection system used.

#### Materials Required But Not Provided

Some of the reagents and materials required for IHC are not provided. Pretreatment reagents, detection systems, control reagents and other ancillary reagents are available from Diagnostic BioSystems. Please refer to the Diagnostic BioSystems website at [www.dbiosys.com](http://www.dbiosys.com)

#### Storage and Handling

Store at 2-8°C. This antibody is suitable for use until the expiration date when stored at 2-8°C. Do not use product after the expiration date printed on vial. If reagents are stored under conditions other than those specified here, they must be verified by the user. Diluted reagents should be used promptly. Unused portions of antibody preparation should be discarded after one day.

The presence of precipitate or an unusual odor indicates that the antibody is deteriorating and should not be used.

Positive and negative controls should be run simultaneously with all patient specimens. If unexpected staining is observed which cannot be explained by variations in laboratory procedures and a problem with the antibody is suspected, contact Diagnostic BioSystems Technical Support at (925) 484-3350, extension 2 or [techsupport@dbiosys.com](mailto:techsupport@dbiosys.com).

#### Specimen Collection and Preparation

Tissues fixed in 10% formalin are suitable for use prior to paraffin embedding. Consult references (Kiernan, 1981; Sheehan & Hrapchak, 1980) for further details on specimen preparation.

The user is advised to validate the use of the products with their tissue specimens prepared and handled in accordance with their laboratory practices.

#### Precautions

This product is a single-use, non-sterile, in vitro diagnostic device.

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 (NaN<sub>3</sub>) 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). 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 in contact with sensitive areas, wash with copious amounts of water. Microbial contamination



of reagents may result in an increase in nonspecific staining. Incubation times or temperatures other than those specified may give erroneous results. The user must validate any such change. The MSDS is available upon request.

### Treatment of Tissues Prior to Staining

Place the slides in the recommended antigen retrieval solution using Diagnostic BioSystems Montage Opus™ Antigen Retrieval System if staining is performed manually or with Montage PolyVue Plus™ Auto Detection System. Allow slides to cool down for 20 minutes prior to staining.

### Staining Procedure

Refer to the following table for conditions specifically recommended for this antibody. Refer to the Diagnostic BioSystems PolyVue™ Plus—Two Step Detection System or Montage PolyVue Plus™ Auto Detection System or HighLighter core kit for HighLighter Staining System for guidance on specific staining protocols or other requirements.

Parameter	Diagnostic BioSystems Recommendations
Positive Control	Prostate Ca, Tonsil
Concentrated Dilution	1:50-1:200
Pretreatment	EDTA Buffer pH 8.0 (Manual/ Montage)
Pretreatment for HL	Tris-EDTA Buffer pH 9.0 (EA1, K102-HL)
Incubation Time & Temperature	30 min @ RT
Detection System	PolyVue™ Plus - Two Step Detection System or Montage PolyVue Plus™ Auto Detection System for Montage 360 System or HighLighter core kit for HighLighter Staining System
Tissue Type	FFPE

### 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.

### Troubleshooting

Contact Diagnostic BioSystems Technical Support at (925) 484-3350, extension 2, techsupport@dbiosys.com or your local distributor to report unusual staining.

### Cellular Localization

Nuclear

### Limitations of the Procedure

Immunohistochemistry is a complex technique involving both histological and immunological detection methods. Tissue processing and handling prior to immunostaining can also cause inconsistent results. Variations in fixation and embedding or the inherent nature of the tissue may cause variations in results (Nadji and Morales, 1983). Endogenous peroxidase activity or pseudoperoxidase activity in erythrocytes and endogenous biotin may cause non-specific staining depending on detection system used. Tissues containing Hepatitis B surface Antigen (HBsAg) may give a false positive with horseradish peroxidase systems (Omata et al, 1980). Improper counterstaining and mounting may compromise the interpretation of results.

### Performance Characteristics

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, and 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 Diagnostic BioSystems products. Ultimately, it is the responsibility of the investigator to determine optimal conditions. These products are tools that can be used for interpretation of morphological findings in conjunction with other diagnostic tests and pertinent clinical data by a qualified pathologist.

### References

- I. Yang A, *et al.* p63, a p53 homolog at 3q27–29, encodes multiple products with transactivating, death-inducing, and dominant-negative activities. *Mol Cell.* 1998 Sep; 2(3):305-16.
- II. Mukhopadhyay S, *et al.* Subclassification of non-small cell lung carcinomas lacking morphologic differentiation on biopsy specimens: Utility of an immunohistochemical panel containing TTF-1, napsin A, p63, and CK5/6. *Am J Surg Pathol.* 2011 Jan; 35(1):15-25.
- III. Tacha D, *et al.* A six antibody panel for the classification of lung adenocarcinoma versus squamous cell carcinoma. *Appl Immunohistochem Mol Morphol.* 2012 May; 20 (3):201-7.
- IV. Terry J, *et al.* Optimal immunohistochemical markers for distinguishing lung adenocarcinomas from squamous cell carcinomas in small tumor samples. *Am J Surg Pathol.* 2010 Dec; 34(12):1805-11.
- V. Pu RT, *et al.* Utility of WT-1, p63, MOC31, mesothelin, and cytokeratin (K903 and CK5/6) immunostains in differentiating adenocarcinoma, squamous cell carcinoma, and malignant mesothelioma in effusions. *Diagn Cytopathol.* 2008 Jan; 36(1):20-5.
- VI. Lerwill MF. Current practical applications of diagnostic immunohistochemistry in breast pathology. *Am J Surg Pathol.* 2004 Aug; 28(8):1076-91

