

NKX3.1 (EP356)

Rabbit Anti-Human NKX3.1 Monoclonal Antibody (EP356)

References and presentations¹

- **ready-to-use (manual or LabVision AutoStainer)**
MAD-000771QD-3
MAD-000771QD-7
MAD-000771QD-12
- **Ready-to-use (MD-Stainer)²**
MAD-000771QD-3/V
MAD-000771QD/V
- **concentrated**
MAD-000771Q - 1:50 recommended dilution

Composition: anti-NKX3.1 rabbit monoclonal antibody obtained from supernatant culture and prediluted in a tris buffered solution pH 7.4 containing 0.375mM sodium azide solution as bacteriostatic and bactericidal.

Intended use^{IVD}: Immunohistochemistry (IHC) on paraffin embedded tissues. Not tested on frozen tissues or Western-Blotting

Clone: EP356³

Immunogen: Synthetic peptide corresponding to residues in the human protein of the NKX3.1

Ig isotype: Rabbit IgG

Species reactivity: In vitro diagnostics in humans. Not tested in other species

Description and applications: NKX3.1 is a prostate-specific tumor suppressor protein that is encoded by the homeobox gene NKX3.1 located in chromosome region 8p21 and whose expression is regulated by androgens. The protein acts as an important transcription factor in the normal development of the prostate since it regulates the proliferation of the glandular epithelium and the formation of excretory ducts. For this reason, the protein, which is located in the luminal cells (considered the stem of the prostate epithelium), intervenes in prostate regeneration and is susceptible to oncogenic transformation.

Due to its haplo-insufficient character, the protein NKX3.1 is often negatively regulated during the early stages of carcinogenesis in premalignant lesions and

prostatic intraepithelial neoplasia and, for this reason, loss of heterozygosity is present in 60-80% of prostate tumors. In fact, the loss of activity of the NKX3.1 gene in murine models causes the appearance of intraepithelial prostatic neoplasia similar to human lesions.

The transcription factor NKX3.1 is expressed in the normal prostate epithelium, predominantly located in the cell nucleus. Independently of the prostate epithelium, positive staining has also been observed in the testicular seminal epithelium (spermatogonia), ureter, and mucosecretory glands of the pulmonary bronchial epithelium.

Although in primary and metastatic prostate adenocarcinoma the antibody has a lower staining intensity compared to the normal prostate, when staining is present, the NKX3.1 antibody has a highly sensitive tissue marker specific to prostate adenocarcinoma. Likewise, the EP356 clone against this antigen has been evaluated with optimal results in the NordiQC quality protocols.

Based on the above, the NKX3.1 antibody is useful to differentiate prostate adenocarcinoma from urothelial carcinoma with a sensitivity ranging from 92-94%, together with a specificity of 100%. A recent study has also demonstrated the usefulness of NKX3.1 for the identification of metastatic prostate adenocarcinoma (with sensitivity and specificity of 98% and 99% respectively). Compared to conventional PSA and PSAP markers, the NKX3.1 antibody has greater sensitivity and specificity, especially in the identification of poorly differentiated prostate adenocarcinomas, so that combined in a panel with PSA and PSAP, all metastatic prostate adenocarcinomas were positive for at least one of these markers.

Isolated cases of lobular carcinoma of the breast have been reported with weak and focal positivity.

IHC positive control: Normal prostate

Visualization: Nucleus

IHC recommended procedure:

- 4µm thick section should be taken on charged slides; dry overnight at 60°
- Deparaffinise, rehydrate and HIER (heat induced epitope retrieval) – boil tissue in the Pt Module using Vitro S.A EDTA buffer pH8⁴ for 20 min at 95°C. Upon completion rinse with 3-5 changes of distilled or deionised water followed by cooling at RT for 20 min

¹ These references are for presentation in vials of Low Density Polyethylene (LDPE) dropper. In case the products are used in automated stainers, a special reference is assigned as follows:

- / L: Cylindrical screw-cap vials (QD-3 / L, QD-7 / L, QD-12 / L).

- / N: Polygonal screw-cap vials (QD-3 / N, QD-7 / N, QD-12 / N).

For different presentations (references / volumes) please contact the supplier.

² For Technical specifications for MD-Stainer, please contact your distributor.

³ NKX3.1 clone EP356 is manufactured using Eptomics's RabMAb® technology under U.S. Patent Nos. 5,675,063 and 7,402,409

⁴ Ref: MAD-004072R/D



Vitro S.A



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- Endogenous peroxidase block - Blocking for 10 minutes at room temperature using peroxidase solution (ref. MAD-021540Q-125)
- Primary antibody: incubate for 20 minutes [The antibody dilution (when concentrated) and protocol may vary depending on the specimen preparation and specific application. Optimal conditions should be determined by the individual laboratory]
- For detection use Master Polymer Plus Detection System (HRP) (DAB included; ref. MAD-000237QK)
- Counterstaining with haematoxylin and final mounting of the slide

Storage and stability:  Stored at 2-8°C. Do not freeze.
 Once the packaging has been opened it can be stored until the expiration date of the reagent indicated on the label. If the reagent has been stored under other conditions to those indicated in this document, the user must first check its correct performance taking into account the product warranty is no longer valid.

Warnings and precautions:

1. Avoid contact of reagents with eyes and mucous membranes. If reagents come into contact with sensitive areas, wash with copious amounts of water.
2. This product is harmful if swallowed.
3. Consult local or state authorities with regard to recommended method of disposal.
4. Avoid microbial contamination of reagents.

SAFETY RECOMMENDATIONS

This product is intended for laboratory professional use only. The product is NOT intended to be used as a drug or for domestic purposes. The current version of the Safety Data Sheet for this product can be downloaded by searching the reference number at www.vitro.bio or can be requested at regulatory@vitro.bio.

BIBLIOGRAPHY

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3. Asch-Kendrick RJ, Samols MA, Lilo MT, Subhawong AP, Sharma R, Illei PB, Argani P, Cimino-Mathews A. NKX3.1 is expressed in ER-positive and AR-positive primary breast carcinomas. *J Clin Pathol*. 2014 Sep;67(9):768-71.










4. Bieberich CJ, Fujita K, He WW, Jay G. Prostate-specific and androgen-dependent expression of a novel homeobox gene. *J Biol Chem*. 1996 Dec 13;271(50):31779-82
5. Gelmann EP, Bowen C, Bubendorf L. Expression of NKX3.1 in normal and malignant tissues. *Prostate*. 2003 May 1;55(2):111-7
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LABEL AND BOX SYMBOLS

Explanation of the symbols of the product label and box:

	Expiration date
	Temperature limit
	Manufacturer
	Sufficient content for <n> assays
	Catalog number
	Lot code
	Refer to the instructions of use
	Medical product for <i>in vitro</i> diagnosis.
	Material safety data sheet