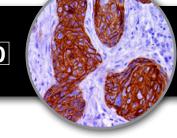
PI 2892 Rev. A - Cytokeratin 16, RMab DCN: 2131 Effective Date: 05/04/2017

Cytokeratin 16, RMab Clone: EP297 CE Rabbit Monoclonal

CE IVD



Inset: IHC of Cytokeratin 16 on a FFPE Anal Carcinoma Tissue

Intended Use

For In Vitro Diagnostic Use.

This antibody is intended for use in Immunohistochemical applications on formalinfixed paraffin-embedded tissues (FFPE), frozen tissue sections and cell preparations. Interpretation of results should be performed by a qualified medical professional.

* The Cytokeratin 16 antibody, clone EP297, has been manufactured using Epitomics RabMab[®] technology covered under Patent No.'s 5,675,063 and 7,402,409.

Immunogen

A synthetic peptide corresponding to residues of human Cytokeratin 16 protein

Summary and Explanation

Cytokeratin 16 (CK16) is a protein that in humans is encoded by the KRT16 gene. Cytokeratin 16 is a type I cytokeratin. It is paired with cytokeratin 6 in a number of epithelial tissues, including nail bed, esophagus, tongue, and hair follicles. Mutations in the gene encoding this protein are associated with the genetic skin disorders pachyonychia congenita, non-epidermolytic palmoplantar keratoderma and unilateral palmoplantar verrucous nevus.

Studies have proposed a modulatory role of CK16 in cell proliferation, suggesting its utility as a marker for proliferation. Rapid induction of CK16 expression near the edge of wounds, upregulation in response to epidermal growth factor stimulus, and overexpression in hyperproliferative disorders, including psoriasis and chronic contact dermatitis, support this assertion. In psoriasis, the severity of disease is correlated with the amount of CK16. Additionally, CK16 expression has been described in neoplasms of multiple tissues. Progressive CK16 abundance and intensity were observed with increased grade of severity of cervical intraepithelial neoplasia lesions. Furthermore, 10% of invasive carcinomas were diffusely or focally positive. In keratocystic odontogenic tumors, CK16 was observed in 79% of cases. These observations support CK16 as a marker of hyperproliferation.

Antibody Type	Rabbit Monoclonal	Clone	EP297
lsotype	IgG	Reactivity	Paraffin, Frozen
Localization	Cytoplasmic	Control	Skin, Prostate, Breast, Cervix, Salivary Gland, SCC
Species Reactiv	ity	Human	

Presentation

Cytokeratin 16 is a rabbit monoclonal antibody derived from cell culture supernatant that is concentrated, dialyzed, filter sterilized and diluted in buffer pH 7.5, containing BSA and sodium azide as a preservative.

Catalog Num.	Antibody Type	Dilution	Volume/Qty
BSB 2887	Tinto Prediluted	Ready-to-Use	3.0 mL
BSB 2888	Tinto Prediluted	Ready-to-Use	7.0 mL
BSB 2889	Tinto Prediluted	Ready-to-Use	15.0 mL
BSB 2890	Concentrated	1:50 - 1:200	0.1 mL
BSB 2891	Concentrated	1:50 - 1:200	0.5 mL
BSB 2892	Concentrated	1:50 - 1:200	1.0 mL
BSB 2893	Control Slides	Not Applicable	5 slides

Precautions

Presentations

For professional users only. Ensure results are interpreted by a medical professional.
 This product contains sodium azide (NaN3), a toxic chemical which may react with plumbing to form highly explosive build-ups of metal azides. Upon disposal, flush with large volumes of water to prevent sodium azide build-up.

3. Ensure proper handling procedures are used with reagent. Always wear proper laboratory equipment such as laboratory coat and gloves when handling reagents.
4. Unused solution should be disposed of according to local and federal regulations.
5. Do not ingest reagent. If reagent ingested, contact a poison control center immediately.

6. For complete recommendations for handling biological specimens please refer to the CDC document, "Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories." (5)

Storage

Store at 2-8 °C. Do not use after expiration date listed on package label. Temperature fluctuations should be avoided. Store appropriately when not in use, and avoid prolonged exposure to room temperature conditions.

Specimen Preparation

Paraffin sections: The antibody can be used on formalin-fixed paraffin-embedded (FFPE) tissue sections. Ensure tissue undergoes appropriate fixation to ensure best results. Pre-treatment of tissues with heat-induced epitope retrieval (HIER) is recommended using Bio SB ImmunoDNA Retriever with Citrate (BSB 0020-BSB 0023), ImmunoDNA Retriever with EDTA (BSB 0030-BSB 0033) or ImmunoDNA Digestor (BSB 0108-0112). See reverse side for complete protocol. Tissue should remain hydrated via use of Bio SB Immuno/DNA Washer solutions (BSB 0029 & BSB 0042).

Frozen sections and cell preparations: The antibody can be used for labeling acetone-fixed frozen sections and acetone-fixed cell preparations.

Staining Procedure

1. Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positive charged slides such as Bio SB Hydrophilic Plus Slides (BSB 7028).

2. Air dry for 2 hours at 58° C.

3. Deparaffinize, dehydrate and rehydrate tissues.

4. Subject tissues to heat epitope retrieval using a suitable retrieval solution such as ImmunoDNA Retriever with Citrate (BSB 0020-BSB 0023) or EDTA (BSB 0030-BSB 0033). 5. Any of three heating methods may be used:

a. TintoRetriever Pressure Cooker or Equivalent

Place tissues/slides in a staining dish or coplin jar containing the ImmunoDNA Retriever with Citrate or EDTA, and place in the pressure cooker. Add 1-2 inches of distilled water to the pressure cooker and turn heat to high. Incubate for 15 minutes. Open and immediately transfer slides to room temperature.

b. TintoRetriever PT Module or Water Bath Method

Place tissues/slides in a pre-warmed staining dish or coplin jar containing the ImmunoDNA Retriever with Citrate or EDTA at 95°-99° C. Incubate for 30-60 minutes.

c. Conventional Steamer Method

Place tissues/slides in a pre-warmed staining dish or coplin jar containing the ImmunoDNA Retriever with Citrate or EDTA in a Steamer, cover and steam for 30-60 minutes.

6. After heat treatment, transfer slides in ImmunoDNA Retriever with Citrate or EDTA to room temperature and let stand for 15-20 minutes.

7. For manual staining, perform antibody incubation at ambient temperature. For automated staining methods, perform antibody incubation according to instrument manufacturer's instructions.

8. Wash slides with IHC wash buffer or DI water.

9. Continue IHC staining protocol.

Recommended IHC Protocol

Step	ImmunoDetector AP/HRP	PolyDetector AP/HRP	PolyDetector Plus HRP	
Peroxidase/AP Blocker	5 min.	5 min.	5 min	
Primary Antibody	30-60 min.	30-60 min.	30-60 min.	
1st Step Detection	10 min.	30-45 min.	15 min.	
2nd Step Detection	10 min.	Not Applicable	15 min.	
Substrate-Chromogen	5-10 min.	5-10 min.	5-10 min.	
Counterstain	Varies	Varies	Varies	

Product Limitations

Due to inherent variability present in immunohistochemical procedures (including fixation time of tissues, dilution factor of antibody, retrieval method utilized and incubation time), optimal performance should be established through the use of positive and negative controls. Results should be interpreted by a medical professional.

References

1. Rosenberg M, et al. A group of type I keratin genes on human chromosome 17: characterization and expression. Mol. Cell. Biol. 1988; 8 (2): 722–36.

2. Rosenberg M, et al. Three epidermal and one simple epithelial type II keratin genes map to human chromosome 12. Cytogenet. Cell Genet. 1991; 57 (1): 33–8.

3. Schweizer J, et al. New consensus nomenclature for mammalian keratins. J. Cell Biol. 2006; 174(2): 169–74.

4. Shamsher MK, et al. Novel mutations in keratin 16 gene underlie focal non-epidermolytic palmoplantar keratoderma (NEPPK) in two families. Hum. Mol. Genet. 1995; 4 (10): 1875–81.

5. U.S. Department of Health and Human Services: Centers for Disease Control and Prevention. Guidelines for Safe Work Practices in Human and Animal Medical Diagnostic Laboratories. Supplement / Vol. 61, January 6, 2012.

Symbol Key / Légende des symboles/Erläuterung der Symbole

EC REP EC REP EXERCISE The Hague The Netherlands	2°C	Storage Temperature Limites de température Zulässiger Temperaturbereich		Manufacturer Fabricant Hersteller	REF	Catalog Number Référence du catalogue Bestellnummer
In Vitro Diagnostic Medical Device Dispositif médical de diagnostic in vitro In-Vitro-Diagnostikum	Ĺ	Read Instructions for Use Consulter les instructions d'utilisation Gebrauchsanweisung beachten	2	Expiration Date Utiliser jusque Verwendbar bis	LOT	Lot Number Code du lot Chargenbezeichnung





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