PI 5433 Rev. D - Cytokeratin Cocktail AE1/AE3 DCN: 2296 Effective Date: 05/04/2017

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Cytokeratin Cocktail AE1/AE3 Clone: AE1/AE3 Mouse Monoclonal



Inset: IHC of CK AE1 & AE3 on a FFPE Colon 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.

# Immunogen

Purified human epidermal keratin.

# **Summary and Explanation**

Cytokeratins are intermediate-filament keratins found in the intracytoplasmic cytoskeleton of epithelial tissue. There are two types of cytokeratins: the low-weight, acidic Type I cytokeratins and the high-weight, basic or neutral Type II cytokeratins. Cytokeratins are usually found in pairs comprising a Type I cytokeratin and a Type II cytokeratin. Expression of these cytokeratins is frequently organ or tissue-specific.

Cytokeratin cocktail AE1/AE3 is well suited to distinguish Epithelial Carcinoma from Non-epithelial malignancies and is used to aid Epithelial Tumor classification. This antibody has been used to characterize the source of various neoplasms and to study the distribution of keratin-containing cells in epithelia during normal development and during the development of epithelial neoplasms. This antibody stains cytokeratins present in normal and abnormal human tissues. This antibody has shown high sensitivity and specificity in recognizing epithelial cells of neoplastic origin.

Antibody Type	Mouse Monoclonal	Clone	AE1/AE3	
lsotype	lgG1	Reactivity	Paraffin, Frozen	
Localization	Cytoplasmic	Control	Prostate, Skin, Colon, Stomach, Salivary Gland	
Species Reactivity		Human, Dog, Cat, Mouse, Rat, Mon- key, Rabbit, Chicken, Horse		

# Presentation

Cytokeratin AE1/AE3 is a cocktail of mouse monoclonal antibodies 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.

Antibody Type	Dilution	Volume/Qty
Tinto Prediluted	Ready-to-Use	3.0 mL
Tinto Prediluted	Ready-to-Use	7.0 mL
Tinto Prediluted	Ready-to-Use	15.0 mL
Concentrated	1:100 - 1:500	0.1 mL
Concentrated	1:100 - 1:500	0.5 mL
Concentrated	1:100 - 1:500	1.0 mL
Control Slides	Not Applicable	5 slides
	Antibody Type Into Prediluted Into Prediluted Concentrated Concentrated Concentrated	Antibody TypeDilutionTinto PredilutedReady-to-UseTinto PredilutedReady-to-UseTinto PredilutedReady-to-UseConcentrated1:100 - 1:500Concentrated1:100 - 1:500Concentrated1:100 - 1:500Control SlidesNot Applicable

## 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.

 Ensure proper handling procedures are used with reagent. Always wear proper laboratory equipment such as laboratory coat and gloves when handling reagents.
Unused solution should be disposed of according to local and federal regulations.
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" (6).

## 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

**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	

### References

- 1. Battifora H, Am J Surg Pathol. 1988;12:24
- 2. Gown AM, et al. Am J Clin Pathol. 1985;84:413
- 3. Knapp AC, et al. Cell. 1989;59:67-79
- 4. Sunn TT, et al. J Invest Dermatol. 1983;81:109s-115s
- 5. Eichner R, et al. J Cell Biol. 1984;98:1388-1396

6. 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.

## **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.

Symbol Key / Légende des symboles/Erläuterung der Symbole

# Columnar Epithelium (Cytoplasm) - Cervix, Colon, Esophagus, Skin, Small Intestine, Stomach and Tonsil

**Normal Tissues** 

**Performance Characteristics** 

Glandular Tissue	Mammar	y, Parathyroid, Prostate Sweat and Thyroid		
Astrocyte		White Matter (cerebellum)		
Glial Filaments (cereb	rum)	Distal Tubule (kidney)		
Bowman's Capsule (kid	lney)	Bile Duct		
Pneumocytes		Bronchi		
Mesothelium		Interlobular duct (pancreas)		
Anterior Pituitary Cell (saliv	ary gland)	Acinar cells (salivary gland)		
Reticular Cells (thym	us)	Hassall's bodies (thymus)		
Endometrium (uter	us)	Smooth muscle (uterus)		
Keratinized Epidermis (56.	5/65-67)	Corneal epidermis (55/64)		
Stratified Squamous Epithe nal organs) (51/59	elia (inter-	Stratified epithelia (50/58)		

Positive (+)

Squamous Epithelium (Cytoplasm) - Cervix, Colon, Esophagus, Skin, Small Intes-

tine, Stomach and Tonsil

Hyperproliferative Keratinocytes (48/56) Simple epithelia (45/52 and 46/54)

Negative (-)			
Adrenal	Bone Marrow		
Pericardium	Peripheral Nerve		
Skeletal Muscle	Spleen		
Heart	Testis		

## Epidermis (Adult) Abnormal Tissues

Positive (+)				
Small Carcinoma 2/6	Transitional Cell Carcinoma 3/5			
Epithelial Neoplasms 34/34	Sarcomatoid (Spindle-Cell) 30/30			
Chonroid Chordoma 3/3	Lymphoma 1/8			
Transitional Cell Carcinomas Weak,	diffuse cytoplasmic or perinuclear staining			
Neoplasms 33% of	ms 33% of the cases more reliably than the anti-EMA			
Adenocarcinomas (various types) 33% of the cases more reliably than the anti-EN				
Nega	ntive (-)			
Spindle cell neoplasms 0/49	Non-epithelial melanoma 0/4			
Non-epithelial glioblastoma 0/4	Nonepithelial tumors 0/8			
Melanoma	Lymphoma			
Neurofibroma	Sarcoma			
Non-epithelial neoplasms 0/25				

EC REP	EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands	2°C	Storage Temperature Limites de température Zulässiger Temperaturbereich	***	Manufacturer Fabricant Hersteller	REF	Catalog Number Référence du catalogue Bestellnummer
IVD Dis	In Vitro Diagnostic Medical Device spositif médical de diagnostic in vitro In-Vitro-Diagnostikum	<b></b>	Read Instructions for Use Consulter les instructions d'utilisation Gebrauchsanweisung beachten	$\mathbf{\Sigma}$	Expiration Date Utiliser jusque Verwendbar bis	LOT	Lot Number Code du lot Chargenbezeichnung

