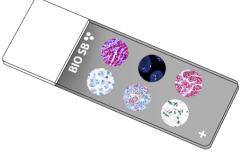


# Cytokeratin MNF116 Control Slides C € IVD



# Intended Use

For In Vitro Diagnostic Use.

# Summary and Explanation

Cytokeratin MNF116 is a broad-spectrum anti-cytokeratin reacting with intermediate and low-molecular-weight keratins, ranging from 40 through 58 kD, corresponding to cytokeratin 5, 6, 8, 17 and 19. It shows a broad pattern of reactivity with human epithelial tissues from simple glandular epithelium to stratified squamous epithelia, like epidermis, mammary gland ducts, and tracheal epithelium.

Cytokeratin MNF116 is a useful aid for the classification of neoplasms of epithelial origin including Squamous Cell Carcinoma, Small Cell Carcinoma, Sarcomatoid Carcinoma, Spindle Cell Carcinoma, Epithelioid and Spindle Cell component of Malignant Mesothelioma and Adenocarcinoma. A wide range of soft tissue tumors are also positive with cytokeratin MNF116: monophasic and biphasic Synovial Sarcoma, vascular neoplasms including Epithelioid Hemangioendothelioma, Epithelioid Angiosarcoma, Epithelioid Sarcoma. Desmoplastic Small Round Cell Tumors require cytokeratin positivity for diagnosis. Smooth muscle tumors and Plasmacytoma may demonstrate aberrant expression of cytokeratin MNF116.

# Presentation

Five slides of Cytokeratin, MNF116 positive tissues, each mounted on Hydrophilic Plus Slides, provided in a plastic mailer.

Catalog No.	Quantity		
BSB-9159-CS	5 slides		
BSB 3538	5 slides		

# Storage Store at 20-25°C

# Precautions

1. For professional users only. Results should be interpreted by a qualified medical professional.

2. Ensure proper handling procedures are used with this reagent.

3. Always wear personal protective equipment such as a laboratory coat, goggles, and gloves when handling reagents.

4. Dispose of unused solution with copious amounts of water.

5. Follow safety precautions of the heating device used for epitope retrieval (TintoRetriever Pressure Cooker or similar).

8. For additional safety information, refer to Safety Data Sheet for this product.

9. 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" (see References in this document).

# Stability

**This product is stable up to the expiration date on the product label.** Do not use after expiration date listed on package label.

# IHC Protocol

1. Subject tissues to heat induced epitope retrieval (HIER) using a suitable retrieval solution such as ImmunoDNA Retriever with Citrate (BSB 0020-BSB 0023) or EDTA (BSB 0030-BSB 0033).

2. 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 on trivet 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.

 After heat treatment, transfer slides in ImmunoDNA Retriever with Citrate or EDTA to room temperature and let stand for 15-20 minutes.
For manual staining, perform antibody incubation at ambient temperature. For automated staining methods, perform antibody incubation according to instrument manufacturer's instructions.

5. Wash slides with ImmunoDNA washer or DI water.

6. Continue IHC staining protocol. Wash slides between each step with ImmunoDNA washer solution.

#### Abbreviated Immunohistochemical 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 / Coverslip	Varies	Varies	Varies	

#### Abbreviated IF Protocol

Step	Incubation Time		
Rinse slides in IF wash buffer	5 minutes		
Drain and wipe excess IF wash buffer off slide			
Conduct remaining steps in the dark			
Apply Antibody	30-60 minutes		
Rinse with 3 changes of IF wash buffer	3x15 minutes each		
Coverslip with IF mounting medium			

#### **Mounting Protocols**

For detailed instructions using biodegradable permanent mounting media such as XyGreen PermaMounter (BSB 0169-0174) or organic solvent based resin such as PermaMounter (BSB 0094-0097), refer to PI0174 or PI0097.

#### **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 qualified medical professional.

#### References

1. Prieto VG, Lugo J, McNutt NS. Intermediate- and low-molecular-weight keratin detection with the monoclonal antibody MNF116. An immunohistochemical study on 232 paraffin-embedded cutaneous lesions. J Cutan Pathol 1996;23:234-41.

 Mocanu L, et. Al. Expression of cytokeratin MNF116 and vimentin in pleural serous effusions. Rom J Morphol Embryol. 2007;48(3):291-4.
Miettinen M., Keratin immunohistochemistry: update of applications and pitfalls, Pathol Annu, 1993, 28(Pt 2):113–143.

4. Mentzel T., et al. Epithelioid haemangioendothelioma of skin and soft tissue: clinicopathologic and immunohistochemical study of 30 cases, Am J Surgical Pathol, 1997, 21(4):363–374.

5. Evans H. L., Baer S. C., Epithelioid sarcoma: a clinicopathologic and prognostic study of 26 cases, Semin Diagn Pathol, 1993, 10(4):286–291. 6. Guillou L., et al. "Proximal-type" epithelioid sarcoma, a distinctive aggressive neoplasm showing rhabdoid feature. Clinicopathologic, immunohistochemical, and ultrastructural study of a series, Am J Surg Pathol, 1997, 21(2):130–146.

 Ramaeckers F. C., et al. Cytokeratins in smooth muscle cells and smooth muscle tumors, Histopathology, 1988, 12(5):558–561.
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. https://www.cdc.gov/mmwr/pdf/other/su6101.pdf

#### Symbol Key / Légende des symboles/Erläuterung der Symbole

	egenae acs symboles/Endaterang acr.						
EC RE	QAdvis EAR AB Ideon Science Park Scheelevägen 17 SE-223 70 Lund, Sweden	ł	Storage Temperature Limites de température Zulässiger Temperaturbereich		Manufacturer Fabricant Hersteller	REF	Catalog Number Référence du catalogue Bestellnummer
IVD	In Vitro Diagnostic Medical Device Dispositif médical de diagnostic in vitro In-Vitro-Diagnostikum	[]i	Read Instructions for Use Consulter les instructions d'utilisation Gebrauchsanweisung beachten	$\square$	Expiration Date Utiliser jusque Verwendbar bis	LOT	Lot Number Code du lot Chargenbezeichnung
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5385 Hollister Avenue, Bldg. 8, Ste. 108, Santa Barbara, CA 93111, USA Tel. (805) 692-2768 | Tel. (800) 561-1145 | Fax. (805) 692-2769

E-mail: sales@biosb.com | Website: www.biosb.com