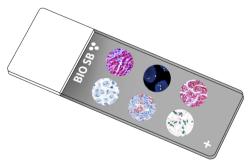


Cytokeratin 7 & CDX2 Control Slides C € IVD



Intended Use

For In Vitro Diagnostic Use.

Summary and Explanation

Cytokeratin 7 (CK7) reacts with proteins that are found in most ductal, glandular and transitional epithelium of the urinary tract and bile duct epithelial cells. CK7 distinguishes between lung and breast epithelium that stain positive, and colon and prostate epithelial cells that are negative. CDX2 is a caudal-type homeobox gene that encodes an intestine-specific transcription factor expressed early in intestinal development and that may be involved in the regulation of proliferation and differentiation of intestinal epithelial cells.

The Cytokeratin 7 antibody has been shown to label the rete epithelium in the testis, epididymis epithelium, and the surface epithelium of the stomach and duodenum. Transitional-cell Carcinomas are positive and Prostate Cancers are negative. Anti-CDX2 antibody has been useful in distinguishing the gastrointestinal origin of Metastatic Adenocarcinomas and carcinoids. A high percentage of Mucinous Carcinomas of the Ovary also stain positively with this antibody, as well as Carcinomas from the upper gastrointestinal tract.

Presentation

Five slides of Cytokeratin 7 & CDX2 positive tissues, each mounted on Hydrophilic Plus Slides, provided in a plastic mailer.

Catalog No.	Quantity
BSB-9150-CS	5 slides
BSB 6659	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 the 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 the after expiration date listed on the 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.

- 3. After heat treatment, transfer slides in ImmunoDNA Retriever with Citrate or EDTA to room temperature and let stand for 15-20 minutes.
- 4. 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

IVD

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. Van de Molengraft FJJM, et al. Histopathology. 1993;22:35-38
- 2. Van Niekerk CC, et al. Am J Pathology. 1991;138:455-463
- 3. Levine PH, et al. Diagn Cytopathology. 2006; Mar; 34(3):191-5
- 4. Mazziotta RM, et al. App Immunohistochem Mol Morphol. 2005;Mar;13(1):55-60
- 5. Sagi A, et al. Am J Clin Pathol. 2005; Mar; 123(3):394-404
- 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.

https://www.cdc.gov/mmwr/pdf/other/su6101.pdf

Symbol Key / Légende des symboles/Erläuterung der Symbole OAdvis EAR AB Storage Temperature Manufacturer Catalog Number Ideon Science Park EC **REP** REF Limites de température **Fabricant** Référence du catalogue Scheelevägen 17 Zulässiger Temperaturbereich Hersteller Bestellnummer SE-223 70 Lund, Sweden

In Vitro Diagnostic Medical Device
Dispositif médical de diagnostic in vitro
In-Vitro-Diagnostikum

Read Instructions for Use
Consulter les instructions
d'utilisation

Consulter les instructions d'utilisation
Gebrauchsanweisung beachten

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