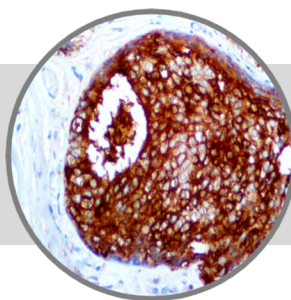


GCDFP-15, RMAb

Clone: EP95

Rabbit Monoclonal


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Inset: IHC of GCDFP-15 on a FFPE Breast Carcinoma Tissue

Intended Use

For In Vitro Diagnostic Use.

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

Immunogen

A synthetic peptide corresponding to residues near the N-terminus of human GCDFP.

Summary and Explanation

Gross Cystic Disease is a common premenopausal disorder in which gross cysts are the predominant pathologic lesion. It is characterized by production of a fluid secretion which accumulates in the breast cysts. Gross Cystic Disease fluid is a pathologic secretion from breast composed of several glycoproteins, including a unique 15 kDa monomer protein, GCDFP-15. The cells within the body that produce GCDFP-15 appear to be restricted primarily to those with apocrine function such as breast cysts and in apocrine glands in the axilla, vulva, eyelid, and ear canal.

Studies have found GCDFP-15 to be a highly specific and sensitive marker for breast cancer. Approximately 70% of breast carcinomas stain positive with antibody to GCDFP-15. In contrast, Colorectal Carcinomas, as well as Mesotheliomas, do not stain with this antibody. Lung Adenocarcinomas rarely stain with this antibody.

Antibody Type	Rabbit Monoclonal	Clone	EP95
Isotype	IgG	Reactivity	Paraffin, Frozen
Localization	Cytoplasmic	Control	Breast, Salivary Gland, Sweat Glands in Skin, Breast Carcinoma
Species Reactivity		Human	

Precautions

1. For professional users only. Results should be interpreted by a qualified medical professional.
2. This product contains <0.1% sodium azide (NaN₃) as a preservative. Ensure proper handling procedures are used with this reagent.
3. Always wear personal protective equipment such as laboratory coat, goggles and gloves when handling reagents.
4. Dispose of unused solution with copious amount of water.
5. Do not ingest reagent. If reagent is ingested, seek medical advice immediately.
6. Avoid contact with eyes. If contact occurs, flush with large quantities of water.
7. 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).

Presentation

GCDFP-15 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.

<i>Catalog No.</i>	<i>Antibody Type</i>	<i>Dilution</i>	<i>Volume/Qty</i>
BSB 6765	Tinto Prediluted	Ready-to-Use	3.0 mL
BSB 6766	Tinto Prediluted	Ready-to-Use	7.0 mL
BSB 6767	Tinto Prediluted	Ready-to-Use	15.0 mL
BSB 6768	Concentrated	1:50 - 1:200	0.1 mL
BSB 6769	Concentrated	1:50 - 1:200	0.5 mL
BSB 6770	Concentrated	1:50 - 1:200	1.0 mL

Control Slides Available

<i>Catalog No.</i>	<i>Quantity</i>
BSB 6771	5 slides

Storage Store at 2-8°C (Control Slides: Store at 20-25°C)

Stability

This product is stable up to the expiration date on the product label. 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 for 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

- Cut and mount 3-5 micron formalin-fixed paraffin-embedded tissues on positively charged slides such as Bio SB Hydrophilic Plus Slides (BSB 7028).
- Air dry for 2 hours at 58° C.
- Deparaffinize, dehydrate and rehydrate tissues.
- 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).
- Any of three heating methods may be used:
 - 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.
 - 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.
 - 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.
- Wash slides with ImmunoDNA washer or DI water.
- 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

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

Normal Tissues	
Positive (+)	
Breast 2/3; Glandular and ductal cells, cytoplasmic	
Salivary gland 2/2; Serous glands, cytoplasmic	
Skin 3/3; Sweat glands, cytoplasmic	
Negative (-)	
Adrenal 0/2	Bone Marrow 0/1
Brain/Cerebellum 0/3	Brain/Cerebrum 0/3
Cervix 0/3	Colon 0/3
Esophagus 0/2	Kidney 0/3
Lung 0/3	Mesothelial Cell 0/2
Nerve, Peripheral 0/2	Ovary 0/2
Pancreas 0/3	Parathyroid 0/1
Pituitary 0/3	Prostate 0/3
Small Intestine 0/2	Stomach 0/3
Thyroid 0/3	Tonsil 0/2
Uterus 0/3	
Abnormal Tissues	
Positive (+)	
24/58 (41%) primary and metastatic breast carcinomas, with an additional 25 case demonstrating weak and/or focal staining, bringing the overall sensitivity to 84.5%.	
In breast carcinoma tissue microarrays, the antibody demonstrated moderate to strong diffuse or patchy staining on 4/63 cores (6%), with an addition 8 cores exhibiting weak and/or focal staining with an overall sensitivity of 22%.	









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

- Mazoujian G, Mrgolis R, Am J Dermatopathol. 1988;Feb;10(1):28-35
- Ansaï S, Kosiki S, Hozumi Y, Kondo S, Am J Dermatopathol. 1995;Jun;17(3):249-55
- Mazoujian G, Pinkus GS, Davis S, Haagensen DE Jr, Am J Pathol. 1983;Feb;110(2):105-12
- Wich MR, Lillemoë TJ, Copland GT, Swanson PE, Manivel JC, Kiang DT, Hum Pathol. 1989;Mar;20(3):281-7
- 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

	EMERGO EUROPE Prinsessegracht 20 2514 AP The Hague The Netherlands		Storage Temperature Limites de température Zulässiger Temperaturbereich		Manufacturer Fabricant Hersteller		Catalog Number Référence du catalogue Bestellnummer
	In Vitro Diagnostic Medical Device Dispositif médical de diagnostic in vitro In-Vitro-Diagnostikum		Read Instructions for Use Consulter les instructions d'utilisation Gebrauchsanweisung beachten		Expiration Date Utiliser jusque Verwendbar bis		Lot Number Code du lot Chargenbezeichnung