



BRST-2 (GCDFP-15) Monoclonal Antibody, Purified

Catalog# / Size 915103 / 6 mL

915102 / 6 mL 915101 / 1 mL

Clone D6

Isotype Mouse IgG2a, κ

Description The BRST-2 antigen is expressed by apocrine sweat glands, eccrine glands (variable), minor

salivary glands, bronchial glands, metaplasmic epithelium of the breast, benign sweat gland tumors of the skin and the serous cells of the submandibular gland. Breast carcinomas (primary and metastatic lesions) with apocrine features express the BRST-2 antigen.

This antibody is effective in immunohistochemistry (IHC).

The BRST-2 clone D6 recognizes a 15 kD glycoprotein known as Gross Cystic Disease Fluid

Protein-15 (GCDFP-15).

Concentrated Format:

Cat. No. 915101 (Formerly: SIG-3611-1000) [1 mL]

Prediluted Formats:

Cat. No. 915102 (Formerly: SIG-3611-16) [6 mL Level 1] is ready to use with with automated strainers with Biotin-based detection systems such as USA Ultra Streptavidin Detection (Cat.

No. 929501).

Cat. No. 915103 (Formerly: SIG-3611-26) [6 mL Level 2] is ready-to-use with Biotin-based

detection systems such as USA Ultra Streptavidin Detection (Cat. No. 929501).

Product Details

Product Information Intended Use:

In Vitro Diagnostic (IVD). Use in immunohistochemistry (IHC) test methods only.

The monoclonal antibody D6 is used for the in vitro examination of paraffin-embedded tissue sections of human breast carcinoma samples using immunohistochemistry (IHC) methods for the qualitative identification of GCDFP-15. The clinical interpretation of any staining or its absence should be complemented by morphological studies and proper controls and should be evaluated within the context of the patient's clinical history and other diagnostic tests by a qualified

pathologist.

Reactivity Human

Immunogen This antibody was generated against a gross cystic disease fluid protein 15.

Formulation Phosphate-buffered solution with BSA + 0.1% NaN3.

Preparation The antibody was purified by affinity chromatography.

Storage & Handling Store between 2°C and 8°C.

Recommended Usage Each lot of this antibody is quality control tested by immunohistochemical staining of formalin-fixed

paraffin-embedded breast cancer tissue sections.

The optimal working dilution should be determined for each specific assay condition.

• IHC: ≥1:40 (concentrated format) with Biotin based detection systems such as USA Ultra

Streptavidin Detection (Cat. No. 929501).

Positive tissue (human): Axilla or breast carcinoma

Tissue Sections: Formalin-fixed, paraffin-embedded tissues

Pretreatment: Not required. The BRST-2 epitope is heat-sensitive; paraffin sections that have been

heat fixed at 60°C may lose antibody binding sites. Incubation: 20-60 minutes at room temperature

Application References

1. Fan CY, et al. Expression of androgen receptor and prostatic specific markers in salivary duct

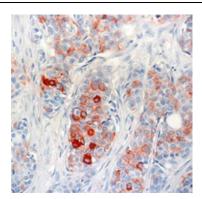
(PubMed link indicates BioLegend citation)

- carcinoma: an immunohistochemical analysis of 13 cases and review of the literature. *Am J Surg Pathol* 24(4):579-586, 2000.
- 2. Wick MR, et al. Gross cystic disease fluid protein-15 as a marker for breast cancer: immunohistochemical analysis of 690 human neoplasms and comparison with alpha-lactalbumin. *Human Path 20(3)*:281-287, 1989.
- Haagensen CD. Disease of the breast. 3rd ed., 250-267. W. B. Saunders Co. Philadelphia, PA, 1986.
- Mazoujian, G, et al. Extramammary paget's disease evidence for an apocrine origin. Am J. Surg. Pathol. 8(1):43-50, 1984.
- Mazoujian G, et al. Immunohistochemistry of a breast gross cystic disease fluid protein (GCDFP-15): a marker of apocrine epthelium and breast carcinomas with apocrine features. Am J Pathol 110:105-111, 1983.

Disclaimer

WARNINGS AND PRECAUTIONS

- 1. Use appropriate personal protective equipment and safety practices per universal precautions when working with this reagent. Refer to the reagent safety data sheet.
- This antibody contains sodium azide. Follow federal, state and local regulations to dispose of this reagent. Sodium azide build-up in metal wastepipes may lead to explosive conditions; if disposing of reagent down wastepipes, flush with water after disposal.
- All specimens, samples and any material coming in contact with them should be considered potentially infectious and should be disposed of with proper precautions and in accordance with federal, state and local regulations.
- 4. Do not use this reagent beyond the expiration date stated on the label.
- 5. Do not use this reagent if it appears cloudy or if there is any change in the appearance of the reagent as these may be indication of possible deterioration.



Staining of BRST-2 (GCDFP-15, clone D6) on formalin fixed paraffin embedded human breast tumor tissue.

C€ FR

IVD



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EC REP

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UK Responsible Person MedEnvoy UK Limited 85, Great Portland Street, First Floor London, W1W 7LT United Kingdom

Symbol	Symbol Title	Description			
ϵ	CE marking	A "CE" mark indicates that a product has been assessed before being placed on the market, and has been found to meet European Union safety, health, and/or environmental protection requirements.			
UK	UKCA marking	A "UKCA" mark indicates that a product has been assessed before being placed in the UK market, and has been found to meet UK safety, health, and/or environmental protection requirements.			

Symbols Glossary*

Symbol	Meaning	Symbol Title	Symbol No.	Symbol	Meaning	Symbol Title	Symbol No.
REF	Catalog number	Catalogue number	5.1.6		Indicates the need for the user to consult the instructions for use.	Consult instructions for use	5.4.3
1	Indicates the temperature limits to which the medical device can be safely exposed.	Temperature limit	5.3.7	*	Indicates a medical device that needs protection from light sources.	Keep away from sunlight	5.3.2
1	Indicates the upper limit of temperature to which the medical device can be safely exposed.	Upper limit of temperature	5.3.6		Indicates the date after which the medical device is not to be used.	Use-by date	5.1.4
	Indicates the medical device manufacturer.	Manufacturer	5.1.1	EC REP	Indicates the authorized representative in the European community.	Authorized representative in the European community.	5.1.2
LOT	Indicates the manufacturer's batch code so that the batch or lot can be identified.	Batch code	5.1.5	IVD	Indicates a medical device that is intended to be used as an in vitro diagnostic medical device.	In vitro diagnostic medical device	5.5.1

^{*} Symbol information is from EN ISO 15223-1:2016 Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied-Part 1: General requirements

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