

## Instructions For Use A00078-IFU-IVD

Rev. Date: Jan. 8, 2024

Revision: 3

Page 1 of 2

P.O. Box 3286 - Logan, Utah 84323, U.S.A. - Tel. (800) 729-8350 - Tel. (435) 755-9848 - Fax (435) 755-0015 - www.ScyTek.com

### CA 15-3; Clone GP1.4

Catalog Number	Format	Volume
A00078-0002	(Ready-To-Use)	2 ml
A00078-0007	(Ready-To-Use)	7 ml
A00078-0025	(Ready-To-Use)	25 ml
A00078-C.1	(Concentrate)	0.1 ml
A00078-C	(Concentrate)	1 ml

#### Intended Use

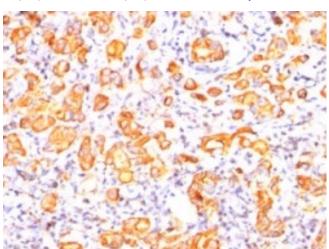
For In-Vitro Diagnostic Use. This antibody is intended for the qualitative visualization of the anatomical elements listed in the Specificity section. It is intended to be used within an Immunohistochemistry (IHC) procedure on formalin-fixed paraffin-embedded (FFPE) human tissue followed by visualization by light microscopy.

#### Description

Titer/Working Dilution: Ready-to-Use: No further dilution required. Concentrate: Suggested dilution is 1:100-200 Species: Mouse Immunogen: Human milk fat globule membranes Clone: GP1.4 lgG1, kappa Isotype: Entrez Gene ID: 4852 Hu Chromosome Loc.: 1g22 Synonyms: Breast carcinoma-associated antigen DF3, CA15-3, Carcinomaassociated mucin Episialin, Epithelial Membrane Antigen, H23AG, KL-6, MAM6, MUC-1, MUC-1/SEC, MUC-1/X, CA 15-3alpha, CA 15-3-beta, CA 15-3-CT, CA 15-3-NT, CA 15-3/ZD, Mucin 1 cell surface associated, Mucin-1 subunit beta, Peanutreactive urinary mucin, PEM, PEMT, Polymorphic epithelial mucin, PUM, Tumor-associated epithelial membrane antigen, Tumor-associated mucin. Mol. Wt. of Antigen: 265-400 kDa Format: Ready-To-Use antibody has been pre-titered and quality controlled to work on formalin-fixed paraffin-embedded as well as acetone fixed cryostat tissue sections. No further titration is required. Concentrate antibody is provided at 200µg/ml of Ab purified from Bioreactor Concentrate by Protein A/G. Prepared in 10mM PBS with 0.05% BSA & 0.05% Sodium Azide. In Western blotting, this antibody recognizes proteins in a MW Specificity: range of 265-400kDa, identified as different glycoforms of CA 15-3. This antibody reacts with the DTRP epitope within the tandem repeats. In immunohistochemical assays, it superbly stains routine formalin/paraffin carcinoma tissues. An antibody to CA 15-3 is useful as a pan-epithelial marker for detecting early metastatic loci of carcinoma in bone marrow or liver. Background: CA 15-3 is proteolytically cleaved into alpha and beta subunits that form a heterodimeric complex consisting of the N-terminal alpha subunit and the C-terminal beta subunit. The alpha subunit of CA 15-3 has cell adhesive properties. It can act both as an adhesion and an anti-adhesion protein. CA 15-3 may provide a protective layer on epithelial cells against bacterial and enzymatic attack. The beta subunit contains a C-terminal domain, which is involved in cell signaling through phosphorylation and proteinprotein interactions **Species Reactivity:** Human, Others-not known. **Positive Control:** MCF-7 or MDA-231 cells. Breast or colon carcinomas.







Formalin-fixed, paraffin-embedded human breast cancer stained with MUC1; Clone GP1.4. Note cytoplasmic and membrane staining.

Cellular Localization: Cytoplasmic and Cell surface Microbiological State: Nonsterile

#### Materials and Reagents Required but not Provided

- 1. Control tissue and reagents
- 2. Xylene, graded alcohols, and deionized/distilled water
- 3. Antibody Diluent.

4. IHC detection system. Suggested: ScyTek Cat# ABZ125 "CRF Anti-Polyvalent HRP Polymer" and ScyTek Cat# ACV500 "DAB Chromogen/Substrate Kit (High Contrast)".

- 5. Wash buffer for rinses (ScyTek Cat# TBT500)
- 6. HIER Retrieval Solution
- 7. Hematoxylin counterstain and bluing reagent (ScyTek Cat# HMM500 and BRT500) 8. Mounting medium and coverslips

Note: ScyTek Laboratories has a wide range of IHC reagents and ancillaries that can be found at scytek.com.

#### **Procedure**

1. Tissue Section Pretreatment (Highly Recommended): Staining of formalin fixed paraffin embedded tissue sections is significantly enhanced by pretreatment with Tis-EDTA HIER Solution (10x) pH 9.0 (ScyTek catalog# TES500) or Citrate Plus (10x) HIER Solution (ScyTek catalog# CPL500)

2. **Primary Antibody Incubation Time:** We suggest an incubation period of 30 minutes at room temperature. However, depending upon the fixation conditions and the staining system employed, optimal incubation should be determined by the user.

3. Visualization: For maximum staining intensity we recommend the "CRF Anti-Polyvalent HRP Polymer" (ScyTek catalog# ABZ125, see IFU for instructions) combined with the "DAB Chromogen/Substrate Bulk Pack (High Contrast)" (ScyTek catalog# ACV500, see IFU for instructions).

#### Storage and Stability

Do not Freeze. Store at 2-8°C. Return to 2-8° immediately after use. Do not use after expiration date printed on label. Verify visually that antibody has not been contaminated before use. Do not use if reagent becomes cloudy or precipitates.

CE IVD

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Page 2 of 2

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#### **Limitations**

Immunohistochemistry is a complex technique involving both histological and immunological detection methods. Tissue processing and handling prior to immunostaining can cause inconsistent results. Variations in fixation and embedding or the inherent nature of the tissue specimen may cause variations in results. Endogenous peroxidase activity in erythrocytes and endogenous biotin may cause non-specific staining depending on detection system used. This data sheet's recommendations and procedures were validated using ScyTek IHC reagents and may not be suitable for other detection systems.

#### **Precautions**

 Contains Sodium Azide as a preservative (0.09% w/v), do not ingest. Sodium Azide may react with lead and copper plumbing to form highly explosive metal azides. Upon disposal, flush with large volumes of water to prevent azide build-up in plumbing. This product contains no hazardous material at a <u>reportable concentration</u> according to U.S. 29 CFR 1910.1200, OSHA Hazardous Communication Standard and EC Directive 91/155/EC.
Do not pipette by mouth.

3. Avoid contact of reagents and specimens with skin and mucous membranes.

4. Avoid microbial contamination of reagents or increased nonspecific staining may occur.

5. The user must validate any procedures and recommendations that differ from this data sheet

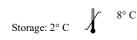
6. The SDS may be found at scytek.com

#### References

1. Stanley CM, Phillips TE. Am J Physiol. 1999 Jul;277(1 Pt 1):G191-200.

#### Warranty

No products or "Instructions For Use (IFU)" are to be construed as a recommendation for use in violation of any patents. We make no representations, warranties or assurances as to the accuracy or completeness of information provided on our IFU or website. Our warranty is limited to the actual price paid for the product. ScyTek Laboratories, Inc. is not liable for any property damage, personal injury, time or effort or economic loss caused by our products.







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