

## Instructions For Use A00046-IFU-IVD

Rev. Date: July 10, 2008

**Revision: 1** 

Page 1 of 3

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

### Cathepsin D

Availability/Contents: <u>Item #</u> <u>Volume</u>

A20046 2 ml A00046 6 ml A00046.25 25 ml

### **Description:**

Species: Mouse

Immunogen: BALB/C mice were injected with purified cathepsin D from human spleen.

Clone: C5 Isotype: IgG2b

Specificity:

Format: This antibody has been pretitered and quality controlled to work on formalin-fixed paraffin-

embedded as well as acetone fixed cryostat tissue sections. No further titration is required. Synthesized as a 54kDa precursor which is proteolytically processed to an intermediate

48kDa single chain which matures into more stable 34kDa and 14kDa two chain form. It is an estrogen-regulated lysosomal protease that has been suggested to facilitate cancer cell migration and invasion by digesting the basement membrane, extracellular matrix, and connective tissue. Because of its mitogenic and proteolytic activities, it has been implicated as a prognostic marker in many tumor types, especially breast cancer. Cathepsin D is expressed in epithelial cells as well as in macrophages. Immunoreactivity of cancer cells

and tissue infiltrating macrophages must be recorded separately.

Species Reactivity: Human. Others-not known.

Positive Control: Macrophages in breast carcinoma.

Cellular Localization: Fine granular cytoplasmic, indicating lysosomal localization.

Titer/Working Dilution: No further dilution is required. Microbiological State: This product is not sterile.

**Uses/Limitations:** For In Vitro Diagnostic Use.

This product is intended for qualitative immunohistochemistry with normal and neoplastic formalin-

fixed, paraffin-embedded tissue sections, to be viewed by light microscopy.

Do not use past expiration date.

Storage and Stability: 2-8° Centigrade.

Product is stable for 24 months from date of manufacture.

If reagent is not stored as recommended, performance must be validated by the user.

### **Procedure:**

- Tissue Section Pretreatment: Staining of formalin fixed, paraffin embedded tissue sections is enhanced by pretreatment with Citrate Plus (ScyTek catalog# CPL500) or 10mM citrate buffer, pH 6.0 (ScyTek Catalog# CBB500, see IFU for instructions). Enzymatic predigestion with Pepsin (ScyTek catalog# PSS060, see IFU for instructions) is recommended prior to staining.
- 2. Primary Antibody Incubation Time: We suggest an incubation period of 30-60 minutes at room temperature.



ScyTek Laboratories, Inc. 205 South 600 West Logan, UT 84321 U.S.A.

C E IVD

EmergoEurope (31)(0) 70 345-8570 Molsnstraat 15

Molsnstraat 15 2513 BH Hague The Netherlands



# Instructions For Use A00046-IFU-IVD

Rev. Date: July 10, 2008

**Revision: 1** Page 2 of 3

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

However, depending upon the fixation conditions and the staining system employed, optimal incubation should be determined by the user.

 Visualization: For maximum staining intensity we recommend the "Retrieval HRP Anti-Polyvalent Lab Pack" (ScyTek catalog# RPL125, see IFU for instructions) combined with the "DAB Chromogen/Substrate Bulk Pack (High Contrast)" (ScyTek catalog# ACV500, see IFU for instructions).

#### **Precautions:**

Contains Sodium Azide as a preservative (0.09% w/v).

Do not pipette by mouth.

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

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

This product contains no hazardous material at a reportable concentration according to U.S. 29 CFR

1910.1200, OSHA Hazardous Communication Standard and EC Directive 91/155/EC.

#### References:

- Gohring UJ; Scharl A; Thelen U; Ahr A; Crombach G. Comparative prognostic value of CathepsinD and urokinase plasminogen activator, detected by immunohistochemistry, in primary breast arcinoma. Anticancer Research, 1996 Mar-Apr. 16(2):1011-8.
- 2. Gohring UJ; Scharl A; Thelen U; Ahr A; Crombach G; Titius BR. Prognostic value of cathepsin D in breast cancer: comparison of immunohistochemical and immunoradiometric detection methods. Journal of Clinical Pathology, 1996 Jan, 49(1):57-64.
- 3. Holm R; Tanum G. Evaluation of the prognostic significance of nm23/NDP kinase and cathepsin D in anal carcinomas. An immunohistochemical study. Virchows Archiv, 1996 May, 428(2):85-9.
- Kristensen GB; Holm R; Abeler VM; Trope CG. Evaluation of the prognostic significance of cathepsin D, epidermal growth factor receptor, and c-erbB-2 in early cervical squamous cell carcinoma. An immunohistochemical study. Cancer 1996 Aug 1, 78(3):433-40.
- Lipponen PK. Expression of cathepsin D in transitional cell bladder tumours. Journal of Pathology, 1996 Jan, 178(1):59-64.
- Losch A; Kohlberger P; Gitsch G; Kaider A; Breitenecker G; Kainz C. Lysosomal protease cathepsin D is a prognostic marker in endometrial cancer. British Journal of Cancer. 1996 Jun. 73(12):1525-8.
- Sloman A; D'Amico F; Yousem SA. Immunohistochemical markers of prolonged survival in small cell carcinoma of the lung. An immunohistochemical study. Archives of Pathology and Laboratory Medicine, 1996 May, 120(5):465-72.
- 8. Valentini AM; Pirrelli M; Armentano R; Caruso ML. The immunohistochemical expression of cathepsin D in colorectal cancer. Anticancer Research, 1996 Jan-Feb, 16(1):77-80.
- Aaltonen M; Lipponen P; Kosma VM; Aaltomaa S; Syrjanen K. Prognostic value of cathepsin-D expression in female breast cancer. Anticancer Research, 1995 May-Jun, 15(3):1033-7.
- 10. Adenis A; Huet G; Zerimech F; Hecquet B; Balduyck M; Peyrat JP. Cathepsin B, L, and D activities in colorectal carcinomas: relationship with clinico-pathological parameters. Cancer Letters, 1995 Sep 25, 96(2):267-75.
- 11. Dickinson AJ; Fox SB; Newcomb PN; Persad RA; Sibley GN; Harris AL. An immunohistochemical and prognostic evaluation of cathepsin D expression in 105 bladder carcinomas. Journal of Urology, 1995 Jul, 154(1):237-41.
- 12. Gion M; Mione R; Dittadi R; Romanelli M; Pappagallo L; Capitanio G; Friede U; Barbazza R; Visona Á; Dante S. Relationship between cathepsin D and other pathological and biological parameters in 1752 patients with primary breast cancer. European Journal of Cancer, 1995, 31A(5):671-7.
- Holm R; Hole J; Kaalhus O; Nesland JM. Immunohistochemical detection of nm23/NDP kinase and cathepsin D in medullary carcinomas of the thyroid gland. Virchows Archiv, 1995, 427:289-94.
- 14. Joensuu H; Toikkanen S; Isola J. Stromal cell cathepsin D expression and long-term survival in breast cancer. British Journal of Cancer, 1995 Jan, 71(1):155-9.
- 15. Moul JW; Maygarden SJ; Ware JL; Mohler JL; Maher PD; Schenkman NS; Ho CK. Cathepsin D and epidermal growth factor receptor immunohistochemistry does not predict recurrence of prostate cancer in patients undergoing radical prostatectomy. Journal of Urology, 1996 Mar, 155(3):982-5.
- Nielsen AL; Nyholm HC. Endometrial adenocarcinoma of endometrioid subtype with squamous differentiation: an immunohistochemical study of MIB-1 (ki-67 paraffin), cathepsin D, and C-erbB-2 protein (p185). International Journal of Gynecological Pathology, 1995 Jul, 14(3):230-4.
- 17. O'Donoghue AE; Poller DN; Bell JA; Galea MH; Elston CW; Blamey RW; Ellis IO. Cathepsin D in primary breast carcinoma: adverse prognosis is associated with expression of cathepsin D in stromal cells. Breast Cancer Research and

Storage: 2°C 1 8°C

ScyTek Laboratories, Inc. 205 South 600 West Logan, UT 84321 U.S.A.

<u>(</u> (

IVD

EmergoEurope (31)(0) 70 345-8570

Molsnstraat 15 2513 BH Hague The Netherlands



### Instructions For Use A00046-IFU-IVD

Rev. Date: July 10, 2008

**Revision: 1** 

Page 3 of 3

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

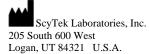
Treatment, 1995, 33(2):137-45.

- Podhajcer OL; Bover L; Bravo Al; Ledda MF; Kairiyama C; Calb I; Guerra L; Capony F; Mordoh J. Expression of cathepsin D in primary and metastatic human melanoma and dysplastic nevi. Journal of Investigative Dermatology, 1995 Mar, 104(3):340-4.
- Ross JS; Nazeer T; Figge HL; Fisher HA; Rifkin MD. Quantitative immunohistochemical determination of cathepsin D levels in prostatic carcinoma biopsies. Correlation with tumor grade, stage, PSA level, and DNA ploidy status. American Journal of Clinical Pathology, 1995, 104(1):36-41.
- 20. Theodoropoulos GE; Lazaris AC; Panoussopoulos D; Davaris P; Golematis BC. Significance of estrogen receptors and cathepsin D tissue detection in gastric adenocarcinoma. Journal of Surgical Oncology, 1995 Mar, 58(3):176-83.
- 21. Armas OA; Gerald WL; Lesser ML; Arroyo CD; Norton L; Rosen PP. Immunohistochemical detection of cathepsin D in T2N0M0 breast carcinoma. American Journal of Surgical Pathology, 1994 Feb, 18(2):158-66.
- 22. Castiglioni T; Merino MJ; Elsner B; Lab TT; Sloane BF; Emmert-Buck MR. Immunohistochemical analysis of cathepsins D, B, and L in human breast cancer [see comments]. Human Pathology, 1994 Sep, 25(9):857-62.
- Diez-Itza I; Vizoso F; Merino AM; Sanchez LM; Tolivia J; Fernandez J; Ruibal A; Lopez-Otin C. Expression and prognostic significance of apolipoprotein D in breast cancer. American Journal of Pathology, 1994 Feb, 144(2):310-20.
   Eng Tan P; Benz CC; Dollbaum C; Moore DH 2<sup>nd</sup>; Edgerton SM; Zava DT; Thor AD. Prognostic value of Cathepsin D
- Eng Tan P; Benz CC; Dollbaum C; Moore DH 2<sup>nd</sup>; Edgerton SM; Zava DT; Thor AD. Prognostic value of Cathepsin E expression in breast cancer: immunohistochemical assessment and correlation with radiometric assay. Annals of Oncology, 1994 Apr, 5(4):329-36.
- 25. Nazeer T; Church K; Amato C; Ambros RA; Rosano TG; Malfetano JH; Ross JS. Comparative quantitative immunohistochemical and immunoradiometric determinations of cathepsin D in endometrial adenocarcinoma: predictors of tumor aggressiveness. Modern Pathology, 1994, 7:469-74.
- 26. Ravdin PM; Tandon AK; Allred DC; Clark GM; Fuqua SA; Hilsenbeck SH; Chamness GC; Osborne CK. Cathepsin D by western blotting and immunohistochemistry: failure to confirm correlations with prognosis in node-negative breast cancer. Journal of Clinical Oncology, 1994 Mar, 12⊗3):467-74.
- Vignexwaran N; Muller S; DeRose P; Cohen C. Cathepsin- D and tumor associated antigen DF3 in salivary gland neoplasia. Differential diagnostic and prognostic applications. Pathology, Research and Practice, 1994 Dec, 190(12):1174-84.

### 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. 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 or pseudoperoxidase activity in erythrocytes and endogenous biotin may cause non-specific staining depending on detection system used.





<u>(</u>

IVD

EmergoEurope (31)(0) 70 345-8570 Molsnstraat 15

2513 BH Hague The Netherlands