

PRIMARY ANTIBODY CARTRIDGE (PAC)

Actin, Smooth Muscle

Monoclonal Mouse, Anti-Actin, Smooth Muscle
 Clone 1A4

REF 014-1135-150

Ready-to-Use ■ 60 Tests

INSTRUCTIONS FOR USE

PAGE 1 of 2

INTENDED USE

IVD For *in vitro* diagnostic use.

Monoclonal mouse anti-Actin, Smooth Muscle, clone 1A4, is intended for laboratory use in identifying smooth muscle cells using light microscopy.

Positive results aid in the classification of normal and abnormal cells/tissues, and serve as an adjunct to conventional histopathology. The clinical interpretation of any positive staining or its absence should be complemented by morphological and histological studies with proper controls. Evaluations should be made by a qualified individual in conjunction with the patient's clinical history and other diagnostic test results.

Refer to the Celerus Wave® RPD Operator's Manual for additional information about Materials Required but Not Provided; Storage; Staining Procedure; Troubleshooting; Interpretation of Staining; and General Limitations.

SUMMARY AND EXPLANATION

Actin, Smooth Muscle, is found in the cytoplasm of smooth muscle cells. The anti-Actin, smooth muscle antibody stains vascular walls, muscularis mucosae and the propria in the gastrointestinal tract, myoepithelial cells of the salivary glands and breast tissue, perifollicular dendritic cells in spleen and Kupffer cells in liver. In neoplastic tissues, anti-Actin, Smooth Muscle is useful in identifying leiomyomas and leiomyosarcomas. The antibody is also a marker for myogenic soft tissue tumors and smooth muscle differentiation.

PRINCIPLE OF PROCEDURE

Immunohistochemistry is a multi-step process to identify specific cell markers within tissue biopsies or tumor specimens. The sequential steps include antigen retrieval (optional), antibody application, and antibody visualization followed by optional counter-staining. Specimens are then coverslipped and observed under light microscopy by trained personnel. Normally, multiple antibodies are tested to determine lineage and cell cycle markers. The Celerus Wave® RPD is an automated IHC system that produces stained tissue.

Refer to the Celerus Wave® RPD Operator's Manual for additional information about the staining procedure.

MATERIALS AND METHODS

Reagent Provided

CLONE	Ig CLASS	IMMUNOGEN
1A4	IgG _{2a} , kappa	N-terminal decapeptide of smooth muscle alpha-Actin of human origin

READY-TO-USE IN PRIMARY ANTIBODY CARTRIDGE

Anti-Actin, Smooth Muscle is provided with sodium azide as a preservative, in a Primary Antibody Cartridge (PAC), a self-contained dispenser of reagents. Each PAC contains sufficient reagent to complete 60 stained slides. PACs must remain upright to avoid spilling. PAC must be primed before first use.

Refer to the Celerus Wave® RPD Operator's Manual for additional information about the Primary Antibody Cartridge.

SPECIFICITY

Human alpha Actin, Smooth Muscle.

PRECAUTIONS

For professional users.

Minimize microbial contamination of reagents or an increase in nonspecific staining may occur.

Proper handling procedures should be used.

A Material Safety Data Sheet is available upon request.

Sodium azide deposits in drainage pipes made of lead or copper can result in the formation of highly explosive metallic azides. To avoid such deposits in drainage pipes, sodium azide should be discarded in a large volume of running water.

Sodium azide in the concentration used is not classified as hazardous. The following are the appropriate Risk (R) and Safety (S) phrases.

R36	Irritating to eyes.
R43	May cause sensitization by skin contact.
S24	Avoid contact with skin.
S26	In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
S35	This material and its container must be disposed of in a safe way.
S37/39	Wear suitable gloves and eye/face protection.
S46	If swallowed, seek medical advice immediately and show the product container or label.

WASTE DISPOSAL

Adhere to all local laws when disposing of the PAC.

PACKAGING DAMAGE

DO NOT USE this product if it is leaking, has leaked, has spilled, cannot be primed, or has visually apparent physical damage.



PRIMARY ANTIBODY CARTRIDGE (PAC)

Actin, Smooth Muscle

Monoclonal Mouse, Anti-Actin, Smooth Muscle
Clone 1A4

REF 014-1135-150

Ready-to-Use ■ 60 Tests

INSTRUCTIONS FOR USE

PAGE 2 of 2

MATERIALS REQUIRED BUT NOT PROVIDED

Celerus Wave® RPD Instrument.

Refer to the Celerus Wave® RPD Operator's Manual for additional information about Materials Required but Not Provided.

STORAGE AND HANDLING

Store at the temperature indicated on the product label. Do not freeze. This product is stable up to the expiration date on the product label. Do not use this product after the expiration date.

To ensure a valid staining assay, the use of positive and negative tissue controls is recommended.

SPECIMEN COLLECTION AND HANDLING

Formalin-fixed paraffin embedded (FFPE) tissues, frozen tissues, or smears are suitable for use. Wave RPD detection kits have been optimized for tissues fixed with 10% formalin.

Slides should be baked overnight at 37 °C, or at 60 °C for one hour.

Use standard histochemical techniques to deparaffinize processed slides. Place slides in the Wave RPD Slide Rack according to the staining grid provided by the instrument software. Avoid drying tissue specimen during this process. After all slides to be stained have been inserted and reagents mounted on the instrument, start the staining run.

When the staining run is complete, remove the slide rack, then slides. Coverslip slides and view under light microscopy.

PRODUCT-SPECIFIC LIMITATIONS

Actin, Smooth Muscle antibody, when used on the Wave RPD instrument, detects antigens that survive routine formalin fixation, tissue processing, and sectioning. Staining from poorly fixed tissue specimens, decalcified specimens treated with proteolytic digestion, or specimens handled without regard to tissue preservation may yield nonspecific staining.

RESULTS EXPECTED / PERFORMANCE CHARACTERISTICS

Positive staining with Actin, Smooth Muscle (1A4) antibody occurs in the cytoplasm of smooth muscle cells.

Normal Tissues

Normal adult tissues that exhibit positive staining with Actin, Smooth Muscle include: vascular walls, muscularis mucosae and the propria in the gastrointestinal tract, myoepithelial cells of the salivary glands and breast tissue, perfollicular dendritic cells in spleen and Kupffer cells in liver.









Abnormal Tissues

Anti-Actin, Smooth Muscle is useful in identifying leiomyomas and leiomyosarcomas. The antibody is also a marker for myogenic soft tissue tumors and smooth muscle differentiation.

REFERENCES

- Hiruta N, Kameda N, Tokudome T, Tsuchiya K, Nonaka H, Hatori T, Akima M, Miura M. Malignant glomus tumor: a case report and review of the literature. *Am J Surg Pathol.* 1997 Sep;21(9):1096-103. Review.
- Kutzner H, Mentzel T, Kaddu S, Soares LM, Sanguenza OP, Requena L. Cutaneous myoepithelioma: an under-recognized cutaneous neoplasm composed of myoepithelial cells. *Am J Surg Pathol.* 2001 Mar;25(3):348-55.
- Lukinmaa PL, Hietanen J, Warfvinge G, Sane J, Tuominen S, Henriksson V, Larsson A. Solitary fibrous tumour of the oral cavity: clinicopathologic and immunohistochemical characterization of three cases. *J Oral Pathol Med.* 2000 Apr;29(4):186-92.
- Meis-Kindblom JM, Kindblom LG. Angiosarcoma of soft tissue: a study of 80 cases. *Am J Surg Pathol.* 1998 Jun;22(6):683-97.
- Miettinen M, Sarlomo-Rikala M, Sobin LH, Lasota J. Gastrointestinal stromal tumors and leiomyosarcomas in the colon: a clinicopathologic, immunohistochemical, and molecular genetic study of 44 cases. *Am J Surg Pathol.* 2000 Oct;24(10):1339-52.
- Oda Y, Miyajima K, Kawaguchi K, Tamiya S, Oshiro Y, Hachitanda Y, Oya M, Iwamoto Y, Tsuneyoshi M. Pleomorphic leiomyosarcoma: clinicopathologic and immunohistochemical study with special emphasis on its distinction from ordinary leiomyosarcoma and malignant fibrous histiocytoma. *Am J Surg Pathol.* 2001 Aug;25(8):1030-8.
- Ordenez NG. Desmoplastic small round cell tumor: II: an ultrastructural and immunohistochemical study with emphasis on new immunohistochemical markers. *Am J Surg Pathol.* 1998 Nov;22(11):1314-27. Review.
- Shidham VB, Chivukula M, Gupta D, Rao RN, Komorowski R. Immunohistochemical comparison of gastrointestinal stromal tumor and solitary fibrous tumor. *Arch Pathol Lab Med.* 2002 Oct;126(10):1189-92.

EXPLANATION OF SYMBOLS

REF Catalog Number	 Temperature Limitations	LOT Batch Code	 Sufficient for <n> Tests	 Harmful, Irritant	 Warning
IVD In Vitro Diagnostic Medical Device	 Use By	 European Conformity	EC REP EC Representative	 Manufacturer	 Refer to Instructions for Use

