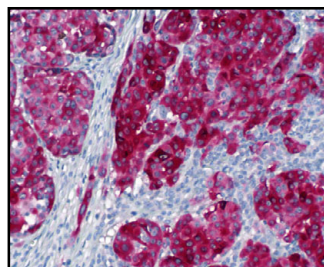


## CONFIRM anti-MART-1/melan A (A103) Mouse Monoclonal Primary Antibody

**REF** 790-2990

05278350001

**IVD**  50



**Figure 1. CONFIRM anti-MART-1/melan A (A103) Mouse Monoclonal Primary Antibody cytoplasmic staining of melanoma.**

### INTENDED USE

This antibody is intended for *in vitro* diagnostic (IVD) use. Ventana Medical Systems, Inc.'s (Ventana) CONFIRM anti-MART-1/melan A (A103) Mouse Monoclonal Primary Antibody is a mouse monoclonal antibody (IgG1) directed against melan A. This antibody is designed to qualitatively detect the presence of melan A by light microscopy in sections of formalin-fixed, paraffin-embedded tissue. Positive staining may aid in the classification of melanoma. The clinical interpretation of any staining, or the absence of staining, must be complemented by morphological studies and evaluation of proper controls.

Evaluation must be made by a qualified pathologist within the context of the patient's clinical history and other diagnostic tests.

### SUMMARY AND EXPLANATION

The anti-MART-1/melan A protein has 118 amino acids with a molecular weight of 13 kDa and is thought to be associated with melanocytes and melanosomes. This histochemical reagent is specific for melanoma tumors and melanoma tumor cell lines.<sup>1,2</sup> This reagent in conjunction with S100 and tyrosinase is expressed in the majority of melanomas, making it a useful marker for those lesions.<sup>1</sup>

### REAGENT PROVIDED

CONFIRM anti-MART-1/melan A (A103) contains sufficient reagent for 50 slides.

One 5 mL dispenser of CONFIRM anti-MART-1/melan A (A103) contains approximately 17 µg of a mouse monoclonal antibody.

The antibody is diluted in 0.05 M Tris-HCl with 2% carrier protein, and 0.10% ProClin 300, a preservative.

Total protein concentration of the reagent is approximately 10 mg/mL. Specific antibody concentration is approximately 3.4 µg/mL. There is no known irrelevant antibody reactivity observed in this product.

Refer to the appropriate VENTANA detection kit package insert for detailed descriptions of: (1) Principles of the Procedure, (2) Materials and Reagents Needed but Not Provided, (3) Specimen Preparation, (4) Quality Control, (5) Troubleshooting, (6) Interpretation of Staining, and (7) General Limitations.

### MATERIALS REQUIRED BUT NOT PROVIDED

Staining reagents such as VENTANA detection kits (for example, *ultraView* Universal Alkaline Phosphatase Red Detection Kit), and ancillary components, including negative and positive tissue control slides, are not provided.

### STORAGE

Store at 2-8°C. Do not freeze.

To ensure proper reagent delivery and stability of the antibody, after every use the cap must be replaced and the dispenser must be immediately placed in the refrigerator in an upright position.

Every antibody dispenser is expiration dated. When properly stored, the reagent is stable to the date indicated on the label. Do not use reagent beyond the expiration date.

### SPECIMEN PREPARATION

Routinely processed, formalin-fixed, paraffin-embedded tissues are suitable for use with this primary antibody when used with VENTANA detection kits and a VENTANA automated slide stainer. The recommended tissue fixative is 10% neutral buffered formalin.<sup>3</sup> Heat induced epitope retrieval with a basic buffer (pH ~8.0) is recommended. Slides should be stained immediately, as antigenicity of cut tissue sections may diminish over time.

It is recommended that positive and negative controls be run simultaneously with unknown specimens.

### WARNINGS AND PRECAUTIONS

1. For *in vitro* diagnostic use.
2. This product contains approximately 2% or less bovine serum which is used in the manufacture of the antibody.
3. Avoid contact of reagents with eyes and mucous membranes. If reagents come in contact with sensitive areas, wash with copious amounts of water.
4. Avoid microbial contamination of reagents.
5. Consult local or state authorities with regard to recommended method of disposal.
6. ProClin 300 is used as a preservative in this solution. It is classified as an irritant and may cause sensitization through skin contact. Take reasonable precautions when handling. Avoid contact of reagents with eyes, skin, and mucous membranes. Use protective clothing and gloves.
7. For supplementary safety information, refer to the product Safety Data Sheet and the Symbol and Risk Phrase Guide located at [www.ventana.com](http://www.ventana.com).

### STAINING PROCEDURE

VENTANA primary antibodies have been developed for use on a VENTANA automated slide stainer in combination with VENTANA detection kits and accessories. A recommended staining protocol for a VENTANA BenchMark XT instrument with *ultraView* Universal Alkaline Phosphatase Red Detection Kit (760-501) is listed below in Table 1. The parameters for the automated procedures can be displayed, printed and edited according to the procedure in the instrument's Operator's Manual. Refer to the appropriate VENTANA detection package insert for more details regarding immunohistochemistry staining procedures.

**Table 1. Recommended Staining Protocol for CONFIRM anti-MART-1/melan A (A103) with *ultraView* Universal Alkaline Phosphatase Red Detection Kit on BenchMark XT Instrument.**

Procedure Type	Method
Deparaffinization	Selected
Cell Conditioning (Antigen Unmasking)	Cell Conditioning 1, Standard
Enzyme (Protease)	None required
Antibody (Primary)	Approximately 16 minutes, 37°C
Counterstain (Hematoxylin)	Hematoxylin II, 4 minutes
Post Counterstain	Bleuing, 4 minutes

Due to variation in tissue fixation and processing, it may be necessary to increase or decrease the primary antibody incubation, cell conditioning or protease pretreatment based on individual specimens and detection used. For further information on fixation variables, refer to "Immunohistochemistry Principles and Advances".<sup>4</sup>

### POSITIVE TISSUE CONTROL

An example of positive control tissue for CONFIRM anti-MART-1/melan A (A103) is melanocyte staining in normal skin or melanoma (as depicted in the above image).

### STAINING INTERPRETATION

The cellular staining pattern for CONFIRM anti-MART-1/melan A (A103) is cytoplasmic.

## SPECIFIC LIMITATIONS

This antibody has been optimized for a 16 minute incubation time on the BenchMark XT automated slide stainer in combination with *ultraView* Universal Alkaline Phosphatase Red Detection Kit (760-501). The user must validate results obtained with this reagent.

## PERFORMANCE CHARACTERISTICS

- Immunoreactivity of CONFIRM anti-MART-1/melan A (A103) was determined by testing formalin fixed, paraffin embedded normal and neoplastic tissues. For normal tissues, results are as follows: Adrenal gland (11/12), bone marrow (0/3), brain cerebrum (0/3), brain cerebellum (0/3), breast (0/3), cervix (0/3), colon (0/3), esophagus (0/3), heart (0/3), hypophysis (0/3), intestine (0/3), kidney (0/3), liver (0/3), lung (0/3), mesothelium (0/3), nerve (0/3), ovary (0/3), pancreas (0/3), parathyroid (0/3), prostate (0/3), salivary gland (0/3), skin (3/3), spleen (0/3), stomach (0/3), striated muscle (0/2), testis (1/3), thymus (0/3), thyroid (0/3), tonsil (0/3), and uterus (0/3). For neoplastic tissues, results are as follows: atypical meningioma (0/1), glioblastoma (0/1), ependymoma (0/1), oligodendroglioma (0/1), ovarian serous papillary adenocarcinoma (0/1), ovarian mucous papillary adenocarcinoma (0/1), islet cell carcinoma (0/1), pancreatic adenocarcinoma (0/1), testicular seminoma and embryonal carcinoma (0/2), medullary thyroid carcinoma (0/1), papillary thyroid carcinoma (0/1), intraductal, lobular, and infiltrating breast carcinoma (0/3), diffuse B-cell lymphoma in spleen (0/1), small cell lung carcinoma (0/1), squamous cell lung carcinoma (0/1), lung adenocarcinoma (0/1), esophageal squamous cell and adenocarcinoma (0/2), adenocarcinoma in stomach (0/1), intestinal adenocarcinoma and mesenchymoma (0/2), colorectal adenocarcinoma and mesenchymoma (0/4), hepatocellular carcinoma (0/1), hepatoblastoma (0/1), clear cell carcinoma (0/1), adenocarcinoma in prostate (0/1), transitional cell carcinoma in prostate and bladder (0/2), uterine leiomyoma (0/1), endometrial carcinoma (0/1), uterine clear cell and squamous carcinomas (0/2), embryonal rhabdomyosarcoma (0/1), rectal melanoma (0/1), basal cell carcinoma in skin (normal melanocytes) (1/1), squamous cell carcinoma in skin (0/1), neurofibroma and neuroblastoma (0/2), mesothelioma (0/1), Hodgkin's lymphoma (0/1), diffuse type lymphoma (0/3), leiomyosarcoma (0/2), osteosarcoma (0/1), and spindle cell rhabdomyosarcoma (0/1).
- Immunoreactivity of CONFIRM anti-MART-1/melan A (A103) was also evaluated by testing a variety of formalin fixed, paraffin embedded target specific neoplastic tissues. Results are as follows: malignant melanoma 121/158 (77%), nevus 20/20 (100%), and adrenal cortical neoplasms 34/46 (74%) stained positively.
- Inter-run reproducibility was determined by staining 5 tissues across 3 days on one each of a BenchMark XT, BenchMark, and NexES instrument. Each respective tissue tested scored equivalently.
- Intra-run reproducibility was determined by staining 19 replicate slides containing the same tissue on a BenchMark XT instrument. 19 of 19 tissues tested scored equivalently.
- Intra-platform reproducibility was determined by staining 10 replicate slides containing the same tissue over 3 BenchMark XT instruments. 30 of 30 tissues tested scored equivalently.
- Inter-platform reproducibility was determined by staining 19 slides containing the same tissue on one each of a BenchMark XT, BenchMark, and NexES instrument. For the BenchMark XT instrument, all 19 slides tested scored equivalently. For the BenchMark instrument, all 19 slides tested scored equivalently. For the NexES instrument, all 19 slides tested scored equivalently.

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