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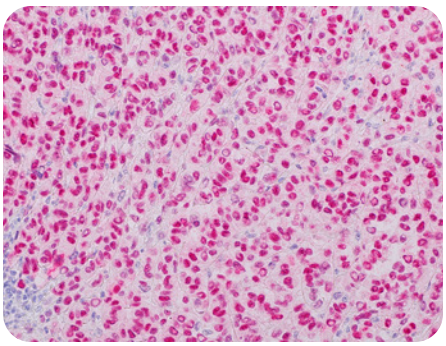
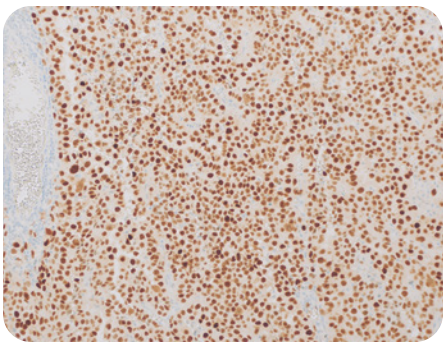
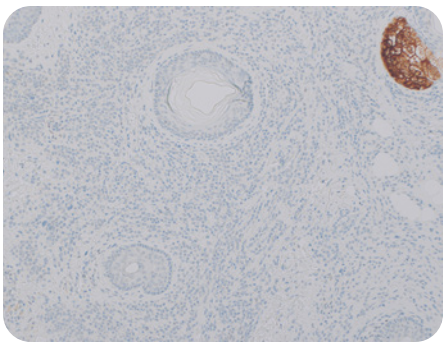
Cell Marque™ Tissue Diagnostics

PRAME (EP461)







Skin cancer is the most diagnosed neoplasm globally, by far. Although the diagnosis of the majority of skin cancer cases (e.g. basal cell carcinoma and squamous cell carcinoma) does not typically require immunostaining, melanoma diagnosis utilizes immunohistochemistry routinely. Existing melanocytic markers, such as S-100, SOX-10, MiTF, and Melan A, differentiate melanocytes from non-melanocytic mimics with varied levels of specificity and sensitivity.[1,2] While such markers aid in establishing melanocytic origin, none are capable of determining malignancy by differentiating melanoma from melanocytic nevi.

PRAME (Preferentially expressed Antigen in Melanoma) is a protein that was isolated from autologous T-cells in a melanoma patient. Nuclear PRAME expression was detected in 83% of primary melanomas and 87% of metastatic melanomas, but only in 13% of cutaneous nevi.[3] PRAME expression also showed a 67% sensitivity and 100% specificity in differentiating malignant from benign melanocytes in nevus-associated melanoma.[4] Additional studies by Gradecki S, et al., found 97.4% sensitivity for metastatic melanoma by PRAME immunohistochemistry[5] as well as very high sensitivity and specificity for lentigo maligna.[6] This data suggests that PRAME is a valuable addition to the skin IHC panel to differentiate melanoma from dysplastic and nodal nevi.

Benefits of PRAME:

- For *in vitro* diagnostic use
- Nuclear visualization to eliminate cytoplasmic melanin interference
- Rabbit Monoclonal technology for robust staining and minimal background
- Differentiates malignant melanocytes from dysplastic and nodal nevi
- May also differentiate malignant peripheral nerve sheath tumors from benign peripheral nerve sheath tumors[7]
- Compatible with standard automation and detection used in diagnostic IHC

Intended Use
The product herein is intended for laboratory use in the detection of PRAME in formalin-fixed, paraffin-embedded tissue stained in qualitative immunohistochemistry (IHC) testing. This product is not a stand-alone diagnostic, and cannot be used for diagnosis, treatment, prevention, or mitigation of disease.

Images (top to bottom)

1. Melanoma, 2. Melanoma, 3. Nevus

Ordering Information

Description	Cat. No.
0.1 mL concentrate	484R-14
0.5 mL concentrate	484R-15
1.0 mL concentrate	484R-16
1.0 mL predilute	484R-17
7.0 mL predilute	484R-18
25.0 mL predilute	484R-10

References

1. Miettinen M, et al. Am J Surg Pathol. 2001; 25(2): 205-11.
2. Jennings C, Kim J. Am J Dermatopathol. 2011; 33(5):474-82.
3. Lezcano C, et al. Am J Surg Pathol. 2018; 42(11): 1456-1465.
4. Lohman ME, et al. J Cutan Pathol. 2021 Jan 12. doi: 10.1111/cup.13958.
5. Gradecki SE, et al. J Cutan Pathol. 2021; 48(4): 479-485.
6. Gradecki SE, et al. Histopathology. 2020 Dec 6. doi: 10.1111/his.14312.
7. Cadwell CR, et al. J Neuropathol Exp Neurol. 2021; 80(4):384-386.

CELL MARQUE™
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USA
Toll Free: **800.665.7284**
Phone: **916.746.8900**
Fax: **916.746.8989**
Email: **service@cellmarque.com**
www.cellmarque.com

CANADA
Phone: **+1 916.746.8900**
Fax: **+1 916.746.8989**
Email: **international@milliporesigma.com**
www.cellmarque.com

MilliporeSigma
400 Summit Drive
Burlington, MA 01803

www.sigmaaldrich.com

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