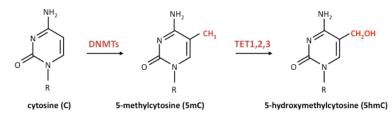
# Intellectual Property (Non-confidential)



# 5hmC as a Biomarker for Cancer in Combination with Ki67

#### 5-hydroxymethylcytosine - the 6th base in DNA



## **DESCRIPTION**

Diagnosis and staging of solid tumors is predominantly accomplished via biopsy, preparation of tissue sample slides, and examination under the microscope. Currently, the predominant diagnostic immunochemical test for cancer involves staining tissue samples with

an antibody that marks proliferating cells (e.g. anti-Ki67 antibody). Rapidly dividing cells would indicate malignancy; however, not all malignant tumors contain large numbers of Ki67-positive cells and may be misdiagnosed.

Using sensitive and quantitative methods, City of Hope has identified a new immunohistological biomarker, 5-hydroxymethylcytosine (5hmC), that can distinguish normal tissue from tumor tissue. 5hmC is a DNA pyrimidine nitrogen base that is formed from cytosine by adding a methyl group and a hydroxyl group. An oxidation product of 5 methylcytosine (5mC) in mammalian DNA, 5hmC is suspected of being an intermediate step in epigenetic gene regulation via DNA methylation. Tumor cells are characterized by low levels of 5hmC and its tumor-associated loss presents a valuable means of improving diagnostic accuracy. By including 5hmC staining in the immunochemical preparation, alongside standard Ki67 staining, pathologists will be able to decrease false negatives and physicians will be able to begin proper cancer treatment for patients sooner.

#### **KEY ASPECTS**

- Immunohistology staining technique to improve accuracy in cancer diagnosis and staging
- Applicable in the following cancers: bone cancer, bladder cancer, brain cancer, breast cancer, cancer of
  the urinary tract, carcinoma, adenocarcinoma, cervical cancer, colon cancer, esophageal cancer, gastric
  cancer, head and neck cancer, hepatocellular cancer, liver cancer, lung cancer, lymphoma and leukemia,
  malignant mesenchymoma, melanoma, neuroblastoma, ovarian cancer, pancreatic cancer, pituitary
  cancer, prostate cancer, rectal cancer, renal cancer, rhabdomyosarcoma, sarcoma, testicular cancer,
  thyroid cancer and uterine cancer.

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	Title	US Patent Application	Filed
	Loss of 5-Hydroxymethlcytosine as a Biomarker for Cancer	61/589,231	1/20/2012

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