

Press Release

Novodiox 10-Minute ihcDirect[®] CK5 and Mart-1 (Melan A) Assays Available for IVD Use

Hayward, CA, September 19, 2017– Novodiox Inc announces the availability of the company’s first two ihcDirect staining kits for *in vitro* diagnostic (IVD) use, ihcDirect CK5 (Cytokeratin 5) and ihcDirect Mart-1. These ready-for-use immunohistochemistry test kits arrive complete with antibody, blocker and DAB chromogen and can be performed using frozen tissues in 10-minutes. “These products are the first IHC tests available on the market to achieve the milestone of completing an IHC test on frozen tissues in just 10-minute,” explained Jianfu Wang, PhD, CEO of Novodiox.

According to the National Cancer Institute (<https://seer.cancer.gov/statfacts/html/melan.html>) there will be an estimated 87,110 new cases of melanoma in the US in 2017 and approximately 9,700 people will die from the disease. The Novodiox Mart-1 antibody recognizes Melan A, a protein which is a melanocyte differential antigen and present in melanocytes of normal skin, retina, nevi, and in more than 85% of melanomas (1,2). The CK5 test kit may be used to help distinguish the origin of tumors such as those found in individuals that have or are suspected of having invasive ductile carcinoma and cancers of the breast, ovary, skin, kidney, prostate and lung organs. The CK5 test kit may also help distinguish the poorly differentiated or infiltrating non-melanoma skin cancers from inflammation, stromal reaction or processing artifacts during a Mohs surgery.

The key component of all ihcDirect test kits is the patent pending polymerized horseradish peroxidase (pHRP) enzyme labeled anti-human antibody that facilitates the direct conjugation of antibodies onto pHRP. Using this technology, antibody incubation times are just 3-minutes for frozen tissues. The technology also reduces the number of test steps when compared to other IHC test methods by eliminating the need for secondary antibodies and the subsequent wash steps. All Novodiox ihcDirect test kits operate using the same 10-minute test turnaround protocol for frozen tissues. Most of the tests can also be performed using formalin-fixed paraffin-embedded (FFPE) tissues.

1. Orchard GE. Melan A (Mart-1): a new monoclonal antibody for malignant melanoma diagnosis. *Br J Bioed Sci* 1998 Mar; 55(1): 9-9
2. Kageshita T et al. Differential expression of Mart-1 in primary and metastatic melanoma lesions. *J Immunother.* 1997; 20:460-5

About Novodiox:

Novodiox, Inc. is a privately held company founded in 2009 and dedicated to advancing tissue-based and cell-based diagnostics and immunoassays. The company developed the innovative ihcDirect platform and is working to fully commercialize this and other technologies. For further information visit our website at www.novodiox.com.



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Advancing immunoassays through innovation

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