

Press Release

Novodiox 10-Minute ihcDirect® Calponin, Podoplanin, CK7 and GFAP Assays Available for IVD Use

Hayward, CA, April 20, 2018– Novodiox Inc., a leader in intraoperative immunohistochemistry (IHC) technology, announces the availability of four new ihcDirect staining kits for *in vitro* diagnostic (IVD) use: Calponin, Podoplanin, CK7 and GFAP Assays. “These are the first products available on the market to achieve the milestone of completing an IHC test on frozen tissues in 10-minutes,” explained Jianfu Wang, PhD, CEO of Novodiox. The Oncology assays reduce the time a surgeon must wait from hours to minutes for clinical interpretation of the tissue staining pattern often eliminating subsequent follow up visits and surgery.

The ihcDirect Calponin assay interacts with Calponin antigen. Calponin is involved in smooth muscle contraction mechanisms and is expressed in smooth muscle tissue. It can also be observed in myoepithelial cells. The calponin antibody may be used as a marker of the differentiated contractile phenotype of developing smooth muscle and may help to differentiate benign sclerosing lesions of the breast from carcinoma. The assay may be performed using either frozen or formalin-fixed paraffin-embedded tissues.

The ihcDirect CK7 assay reacts with cytokeratin 7 antigens which may be found in simple glandular epithelium, and in transitional epithelium. Cytokeratin 7 is expressed in the majority of cases of carcinoma, with exception of those carcinoma arising from the colon, prostate, and thymus; carcinoid tumors of the lung and gastrointestinal tract origin; Merkel cell tumors of the skin in frozen or formalin-fixed paraffin-embedded tissues.

The ihcDirect Podoplanin assay is used in the detection of Podoplanin antigen. This marker is selectively expressed in lymphatic endothelium as well as lymphangiomas, Kaposi sarcomas and in a subset of angiosarcomas with probable lymphatic differentiation. Podoplanin has also been shown to be expressed in epithelioid mesotheliomas, hemangioblastomas, seminomas and some oral squamous cell carcinomas. The assay is for use in frozen or formalin-fixed paraffin-embedded tissues.

The ihcDirect GFAP assay is intended for several types of central nervous system cells including astrocytes and ependymal cells. In neoplastic tissues, the antibody may be useful for the identification of astrocytomas and ependymomas using either frozen or formalin-fixed paraffin-embedded tissues.

Using our patent pending technology, antibody incubation time is only 3-minutes for frozen tissues. The technology also reduces the number of test steps when compared to traditional IHC test methods by eliminating the need for secondary antibodies and 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. These ready-for-use immunohistochemistry test kits arrive complete with antibody, blocker and DAB chromogen. The test results for this product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. These products are intended for *in vitro* diagnostic (IVD) use.

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 allowing rapid determination of tissue during intraoperative procedures and is exploring applications for companion diagnostics. For further information visit our website at www.novodiox.com.

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