

Press Release

Novodix 10-Minute ihcDirect® CK8/18 Assays Available for IVD Use

Hayward, CA, November 7, 2017– Novodix Inc., a leader in intraoperative immunohistochemistry (IHC) technology, announces the availability of the company’s third ihcDirect staining kit for *in vitro* diagnostic (IVD) use, ihcDirect CK8/18. “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-minutes,” explained Jianfu Wang, PhD, CEO of Novodix. The 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 CK8/18 is intended for laboratory use in the detection of the Cytokeratin 8 & 18 protein in frozen or formalin-fixed paraffin-embedded neoplastic tissues. The assay kit utilizes labeled mouse anti-human cytokeratin 8/18 antibody (clone C94) and contains sufficient reagent components to test approximately 50 or 100 tissues.

Using our patent pending technology, antibody incubation times are just 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 Novodix 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. This product should be interpreted by a qualified pathologist in conjunction with histological examination, relevant clinical information, and proper controls. This antibody is intended for *in vitro* diagnostic (IVD) use.

About Novodix:

Novodix, 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.novodix.com.

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