

Press Release

Novodiox introduces ihcDirect® Pan-CK 4Abs, AE1/AE3, CEA, and CD45 reagents to growing list of 10-Minute IHC Assays for *in-vitro* diagnostic use.

Hayward, CA, August 16, 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: Pan-CK 4Abs, AE1/AE3, CEA and CD45 Assays. “These products demonstrate our continued drive to deliver meaningful 10-minute IHC test results on frozen tissues to improve patient care for hospitals and clinicians,” said Jianfu Wang, PhD, CEO of Novodiox. The Oncology assays can reduce surgeon wait times for histology results from hours to minutes, thus speeding the clinical interpretation of tissue staining patterns while often eliminating subsequent follow up visits and surgeries.

The ihcDirect Pan-CK 4Abs (pan-cytokeratin 4 antibodies) assay detects cytokeratins 1-8, 10, 14-16, 18, and 19. Pan-cytokeratin tests have been used for evaluating micrometastases in sentinel lymph nodes from patients with breast carcinomas. The cocktail also overcomes the poor reactivity of AE1/AE3 in frozen epithelial tissues, such as skin and lung.

The ihcDirect CEA assay detects Carcinoembryonic Antigen, (CEA, also known as CD66e) that is expressed in colorectal cancers (CRC) and is a biomarker commonly used in a colorectal cancer IHC antibody panel. CEA expression can be seen in adenocarcinomas from the lung, colon, stomach, liver, and breast. The marker is often used with other markers to help distinguish between adenocarcinoma and epithelioid malignant mesotheliomas.

The ihcDirect CD45 (Cluster of Differentiation 45) assay is intended for the identification of a broad range of leucocytes. CD45, also named Leucocyte Common Antigen (LCA), is expressed in all leucocytes including both B and T lymphocytes as well as other hematopoietic cells, such as basophils, granulocytes, macrophages / histiocytes, mast cells, and monocytes. This test may be applied to individuals suspected of having related forms of lymphomas or other hematopoietic tumors.

The ihcDirect AE1/AE3 assay is intended for the identification of a broad range of cytokeratin proteins which are expressed in tissues of epithelial origin, including squamous and glandular epithelial cells.

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 reagents and test kits use 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 reagents and antibody test kits can be purchased as individual reagents or as a complete test kit including: 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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