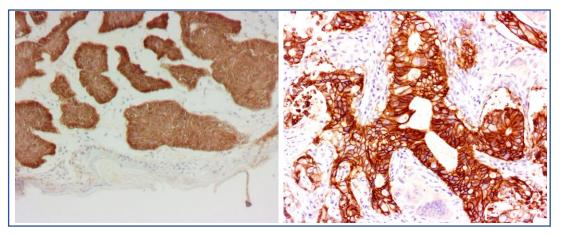


Novodiax ihcDirect® EpCAM Rapid IHC test, similar to BerEP4 clone

As of October 13th, 2020 Novodiax Inc. in Hayward, CA is very pleased to announce the introduction of our rapid ihcDirect EpCAM (epithelial cell adhesion molecule) antibody (Ab) assay for *in vitro* diagnostic (IVD) immunoassay test. The ihcDirect EpCAM clone R1007 shows similar staining results to the well-known BerEP4 clone. This novel EpCAM marker is an important addition to the Novodiax menu of IHC tests and has broad uses for cancers such as basal cell carcinoma.

Novodiax continues to pioneer the areas of rapid histology and rapid cytology testing bylaunching 21 IVD assays for frozen tissue and FFPE histology tissue sections to date. These assays are especially useful for Mohs/dermatology applications, surgical pathology and the tests can be performed in nearly any medical setting including physician offices and potentially applicable to remote laboratory testing sites like radiology where image-guided biopsies are being managed. ihcDirect EpCAM can be completed in approximately 10 minutes on frozen sections and clearly supports clinical decision making where the desired test turnaround times are limited to 20 minutes or less.

The ihcDirect EpCAM assay utilizes the proprietary Novodiax polymerized HRP chemistry which helps to improve staining sensitivity and increase test speed.



EpCAM Ab in frozen tissue sections: Left) Basal Cell in Skin, Right) Colon Cancer

ihcDirect EpCAM is a polymerized horseradish peroxidase (pHRP) conjugated rabbit monoclonal antibody. EpCAM, is a molecule, is a cell membrane glycoprotein with a molecular weight of approximately 35 kDa. EpCAM is expressed on healthy epithelia and in a variety of carcinomas such as breast, colon and in dermal basal cell carcinoma.

The ihcDirect EpCAM assay does not require any special handling such as heat-induced epitope retrieval (HIER) pretreatment or antigen retrieval of the tissue prior to running frozen tissue sections. This assay is convenient manually but can be easily adapted to open automated IHC systems. This means that EpCAM testing can fit neatly into dermatology practices, hospitals, clinics and other settings within close proximity to the patient.

NOVODIAX

Advancing immunoassays through innovation

Novodiax oncology assays can help drive efficiencies within medical institutions by providing rapid turnaround of histology results on frozen or formalin-fixed paraffin-embedded (FFPE) tissues. Rapid histology tests can help improve patient care in a number of ways:

- By providing increased sensitivity and specificity over H&E tests.
- By improving practitioner and patient workflows via vastly shortened histology test turnaround times.
- Improved workflows help physicians make earlier and more informed decisions, reducing surgeon waiting times for vital results.
- Clearer detection of malignant cells may translate into preservation of vital tissues, e.g. on face during Mohs procedure so fewer tissues are extracted and the use of these antibodies may also help to eliminate the need for subsequent follow-up visits and surgeries.

ihcDirect EpCAM is a ready-to-use Ab and is conveniently packaged in 5mL, 10mL, 15mL, and 30mL configurations. For comparison information showing images of our ihcDirect EpCAM vs. the BER EP4 clone, or to learn about our other assays in development such as; Chromogranin A, Napsin A, p40, TTF1 and Synaptophysin, please contact us to learn more!

About Novodiax:

Novodiax, 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 cytology and companion diagnostics. For further information visit our website at <u>www.novodiax.com</u>.

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