

Indication for Use

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The Aperio ePathology eIHC IVD System is an automated digital slide creation, management, viewing and analysis system. It is intended for in vitro diagnostic use as an aid to the pathologist in the display, detection, counting and classification of tissues and cells of clinical interest based on particular color, intensity, size, pattern and shape.

The IHC HER2 Image Analysis application is intended for use as an aid to the pathologist in the detection and semi-quantitative measurement of HER2/neu (c-erbB-2) in formalin-fixed, paraffin-embedded neoplastic tissue.

The IHC HER2 Image Analysis application is intended for use as an accessory to the Dako HercepTest™ to aid in the detection and semi-quantitative measurement of Her2/neu (c-erbB-2) in formalin-fixed, paraffin-embedded neoplastic tissue. When used with the Dako HercepTest™, it is indicated for use as an aid in the assessment of breast cancer patients for whom HERCEPTIN®(Trastuzumab) treatment is being considered.

Note: The IHC HER2 Image Analysis application is an adjunctive computer-assisted methodology to assist the reproducibility of a qualified pathologist in the acquisition and measurement of images from microscope slides of breast cancer specimens stained for the presence of HER-2 receptor protein. The IHC HER2 Image Analysis application is intended to be used on images viewed on a computer monitor. The accuracy of the test result depends upon the quality of the immunohistochemical staining. It is the responsibility of a qualified pathologist to employ appropriate morphological studies and controls as specified in the instructions for the Dako HercepTest™ to assure the validity of the IHC HER2 Image Analysis application assisted HER-2/neu score. The actual correlation of the Dako HercepTest™ to Herceptin® clinical outcome has not been established.

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The IHC ER Image Analysis application is intended for use as an aid to the pathologist in the detection and quantitative measurement of ER (Estrogen Receptor) in formalin-fixed paraffin-embedded neoplastic tissue.

The IHC PR Image Analysis application is intended for use as an aid to the pathologist in the detection and quantitation measurement of PR (Progesterone Receptor) in formalin-fixed, paraffin-embedded neoplastic tissue.

It is indicated for use as an aid in the management, prognosis, and prediction of therapy outcomes of breast cancer.

Note: The IHC ER and PR Image Analysis applications are an adjunctive computer-assisted methodology to assist the reproducibility of a qualified pathologist in the acquisition and measurement of images from microscope slides of breast cancer specimens stained for the presence of estrogen and progesterone receptor proteins. The IHC ER and PR Image Analysis applications are intended to be used on images viewed on a computer monitor. The accuracy of the test result depends upon the quality of the immunohistochemical staining. It is the responsibility of a qualified pathologist to employ appropriate morphological studies and controls as specified in the instructions for the ER and PR reagent/kit used to assure the validity of the IHC ER and PR Image Analysis application assisted scores.