Ki-67 (MKI67) proliferation marker testing in ductal carcinoma in situ (DCIS) and breast cancer

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Authors' conclusions
Breast cancer is one of the most commonly diagnosed cancers with an estimated 226,870 women expected to be diagnosed in the United States in 2012. As a result of effective screening programs, 93% of breast cancer is identified in its early stages as a localized tumor or with spread limited to nearby lymph nodes. The 5-year survival is 98% for localized and 84% for regional breast cancer. Ductal carcinoma in situ (DCIS) is a noninvasive disorder that may progress to invasive breast cancer. In breast cancer, the choice of whether to use neoadjuvant treatments of chemotherapy and/or hormonal therapy is complex, with many factors that may be prognostic or predictive of success with a specific neoadjuvant therapy. Some of the factors that are commonly used are stage, which includes primary tumor size, nodal status, metastatic status, and the results of pathological analysis if available; and immunohistochemical (IHC) analysis of tumor specimens for the estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor 2 receptor (HER2, ERBB2). Ki-67, also called MKI67, is a nuclear protein that has variable expression during the life cycle of cells. Although expression of Ki-67 is tightly related to cell proliferation, the actual role of Ki-67 remains unclear. The Ki-67 protein is coded by the MKI67 gene, which has 15 exons, and is located on the long arm of chromosome 10 at band q26.2 (10q26.2). In the clinical management of breast cancer, Ki-67 has been investigated as a biomarker for: the general prognosis of patient outcome; as a replacement for the Oncotype DX® assay (Genomic Health Inc.) to provide prognosis of patient outcomes; as a predictor of patient outcome with various neoadjuvant treatments, including endocrine therapy and chemotherapies; as a measure of proliferation and as an early surrogate marker of response to treatment with endocrine therapy and various chemotherapies; and in combination with other biomarkers such as ER, PR, and HER2 to allow subtyping of breast cancer for both prognosis and prediction of patient outcomes.

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