

TEST TITLE CHANGE

NOTIFICATION DATE: September 7, 2012 **EFFECTIVE DATE:** September 25, 2012

HER2 (HERCEPTEST), BREAST, QUANTITATIVE IMMUNOHISTOCHEMISTRY, AUTOMATED Test ID: 81504

EXPLANATION: This test will have a method change from the FDA-approved HercepTest Immunoperoxidase Stain to the FDA-approved Ventana Pathway Immunoperoxidase Stain.

CURRENT PUBLISHED NAME: HER2 (HercepTest), Breast, Quantitative Immunohistochemistry, Automated

NEW PUBLISHED NAME: HER2, Breast, Quantitative Immunohistochemistry, Automated

CURRENT REFERENCE VALUE: Reported as negative (0, 1+), equivocal (2+), and strongly positive (3+) according to the interpretation guidelines in the FDA-approved HercepTest.

NEW REFERENCE VALUE: Reported as negative (0, 1+), equivocal (2+), and strongly positive (3+) according to the interpretation guidelines for the FDA-approved Ventana Pathway HER2 (4B5) antibody.