

RDNZ Customer Bulletin

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REFERENCE: CB 08/07

AmpliChip® CYP450 Package Insert Change

Product: AmpliChip CYP450 CE-IVD Test Kit – P/N 04381866-190

Purpose: Beginning March 15, 2008, CE-IVD AmpliChip CYP450 kits will be manufactured with a new package insert containing a forward notification about CYP2D6 genotypes which have an impaired ability to metabolize tamoxifen into the active metabolite, endoxifen.

What is the change?

The notification in the new package insert is as follows:



NOTE: The AmpliChip CYP450 Test is intended to identify CYP2D6 genotypes which have an impaired ability to metabolize tamoxifen into the active metabolite, endoxifen. Such poor metabolizer 2D6 genotypes have been shown to be associated with worse recurrence-free and disease-free survival in post-menopausal women with estrogen receptor-positive breast cancer treated with Tamoxifen²⁷⁻³⁰. As such, the AmpliChip CYP450 Test may be used as an aid to clinicians in determining the therapeutic strategy for women receiving tamoxifen, who either carry genetic variants associated with low or absent CYP2D6 activity or who receive concomitant medications known to inhibit CYP2D6 activity.^{28,31-33}

Why is this important? The previous package insert referenced tamoxifen in Table 9 (Clinically relevant drug substrates for metabolism by CYP2C19 and CYP2D6 enzymes). The change contained in this revision emphasizes the tamoxifen utility. The information provided in the package insert is derived from recently published clinical studies and from the outcome of a US-FDA advisory panel committee meeting on this subject.

How to use this information?

Please use this information to update the clinicians using this test service. Additionally, the new labelling provides an opportunity to educate and raise awareness of the clinical utility of 2D6 genotyping.

For more information contact Jennifer Barnes on Techline