A/C gets US nod to sell "cheapest" homocysteine test

A/C Diagnostics believes it is poised to capture a “significant” share of the homocysteine test sector, after gaining US clearance to sell what it claims will be the least expensive assay for the marker.

The Enzymatic Homocysteine Assay is based on a genetically engineered enzyme specific for homocysteine, a risk factor for cardiovascular and other diseases. It is the only homocysteine test that uses just a single enzyme and that avoids the need for an immunochemical step, a spokeswoman for the company told Clinica. These features, she says, translate into a test that is simple, very cheap to manufacture and that provides the highest throughput. They are also expected to cut homocysteine testing costs, by allowing A/C to sell its product at a “significantly” lower price than rival tests.

Designed for use in a laboratory, A/C’s test can be run on the Hitachi 912 analyser or an equivalent platform. A/C is currently in discussions with a number of manufacturers regarding the use of the test on other systems.

With regard to a launch date, the company is finalising manufacturing and distribution plans for the US. International markets will be targeted thereafter. In the future, A/C plans to offer as a package, three tests related to cardiac disease and other risks. An upcoming B6 Enzymatic Assay and a Cysteine Enzymatic Assay will be used on the same platform as the homocysteine test. In addition, developments are underway to adapt the homocysteine assay for point-of-care use.

A/C, a unit of San Diego, California firm AntiCancer is now one of a number of firms to have gained US approval for a homocysteine test. As for its position regarding patent rights, the company said it held seven issued patents covering the Homocysteine Enzymatic Assay and that no valid claim from any other issued patent covered the product.