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BREVAGen cleared for sale in California

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Singapore:Ã?Â The Laboratory Field Services Unit of the California Department of Public Health (CDPH) has granted a license to Genetic Technologies' Australia-based laboratory. Following this, BREVAGen, a first-in-class, clinically validated risk assessment test for nonÃ?Â¢Ã¢â??Â¬Ã?Â•familial breast cancer, may now be offered for sale in the state of California.

Based solely on incidence rates, California represents approximately 11 percent of the total breast cancer incidences in the US, with over 25,000 new cases diagnosed annually. (ACS Breast Cancer Facts & Figures 2011-12, ACS Cancer Facts &

Figures 2012)

"We expect California to be a large and significant market for BREVAGen," said Dr Paul MacLeman, chief executive cfficer, Genetic Technologies. "We will be applying sales and marketing resources to drive test adoption and sales in the State in the coming weeks."

US state certification

In April 2011, Genetic Technologies successfully attained CLIA approval, allowing BREVAGen to be sold in 42 US states. Following the company's receipt of a certificate of compliance issued by the Centers for Medicare and Medicaid Services, the company has submitted numerous applications for "Out of State Licensure," which allow BREVAGen to also be sold in Pennsylvania, Rhode Island, Nevada, Tennessee, Maryland, and now in California.

The company has also submitted a licensure application in Florida and expects to receive approval to sell BREVAGen in this key state shortly.

The company has commenced serial submission of an application to the New York State Department of Health, Clinical Laboratory Evaluation Program (CLEP) to offer Out of State Clinical Lab Services to New York State residents.