

## GlobalData

LONDON, UK (GlobalData), 20 May 2014 - As one of the fastest emerging areas of in vitro diagnostic devices, the **companion diagnostics testing market value** will increase from \$421 million in 2013 to \$669.7 million by 2020, at a Compound Annual Growth Rate (CAGR) of 6.85%, says research and consulting firm GlobalData.

According to the company's latest report\*, the major feature of the companion diagnostic testing market is the current domination of tests for mutations, which are important in the prognosis and diagnosis of non-small cell lung cancer (NSCLC). Currently, NSCLC companion diagnostic tests account for 55% of the market, followed by breast and colorectal cancer tests.

Andrew Thompson, Ph.D., GlobalData's Senior Analyst covering In Vitro Diagnostics, says: "A key driver behind this growth, at least in the US, is that the development of a companion diagnostic test is now an essential part of the Food and Drug Administration's (FDA) approval of any new therapeutic drug.

"While integrating FDA-level quality and efficacy requirements into a companion diagnostic program during drug development can seem onerous, improved patient stratification will emerge by adopting these standards."

Despite support from the FDA, GlobalData believes that reimbursement is a significant barrier to further market growth.

"Approval of new companion diagnostic tests does not signify adoption, which is highly dependent upon reimbursement policies. If molecular tests and new therapies cannot be reimbursed, then there will be no need for the uptake of companion diagnostic tests, unless a secondary use can be found for physicians to employ in managing a patient's condition," Thompson concludes.

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\* [MediPoint: Companion Diagnostic Tests in Oncology - Global Analysis and Market Forecasts](#)