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FDA accepts The NGAL Test for review

The US Food and Drug Administration (FDA) has initiated review of BioPorto's application for approval of The NGAL Test™ for the diagnosis of acute kidney injury. FDA approval would mean that the test can be sold for diagnostic use in hospitals and laboratories throughout the USA, which today makes up about 40% of the global diagnostic market. The NGAL Test™ is already approved for diagnostic use in Europe and Canada, where the test is currently undergoing a series of clinical studies and evaluations in different hospitals.

As early as 2006 BioPorto launched the world's first commercial NGAL ELISA kit for the diagnosis of acute kidney injury. In 2010 this test was implemented by the US Mayo Medical Laboratories, one of the world's most highly acknowledged health institutions, where the laboratory evaluated the test itself and is hence allowed to use it for diagnostic purposes. At present this is the only NGAL test on the American market for the diagnosis of acute kidney injury.

At the end of 2010 BioPorto launched the NGAL test in a new user-friendly format that enables it to be carried out on the vast majority of automated clinical chemistry analyzers. With the new test, which is simply named The NGAL Test™, the clinician can obtain vital information about the patient's status within a very short time, and as the test is designed for use on existing laboratory equipment, the hospital does not need to invest in new apparatus to perform the test. The existing availability of diagnostic NGAL measurements is expected to favor a more rapid acceptance of The NGAL Test™ by the important American market, once FDA approval has been obtained.

The NGAL Test™ and acute kidney injury
Acute kidney injury affects up to 13 million people a year, of whom about 4 million die. Nevertheless, there has been no real progress in methods of diagnosing kidney injury over the last half century. The NGAL Test™ now provides physicians with the tool they need to diagnose kidney injury much earlier than ever before. Existing methods, e.g. measuring serum creatinine, only indicate kidney failure 24-72 hours after kidney injury has taken place. In contrast, NGAL determination can demonstrate kidney injury within a few hours and thus allow physicians to take measures before the damage progresses to potentially fatal kidney failure. In addition to benefitting the patient, cost-benefit analyses shows that implementation of NGAL testing will contribute to saving hospital expenditure on treating patients with kidney damage.

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