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**Announcement no. 07**

**BioPorto's NGAL test approved for use by leading U.S. reference laboratory**

Mayo Medical Laboratories (Rochester, Minnesota, U.S.A.) are now offering BioPorto's NGAL test for the diagnosis of acute renal injury.

Mayo's implementation of NGAL testing is a decisive step in BioPorto's entry onto the considerable routine diagnostic market in the U.S.A. At present there is no FDA (Food and Drug Administration) approved NGAL test on the market. That Mayo Medical Laboratories can nevertheless offer BioPorto's test is due to the process of so-called *home-brew* approval, whereby the laboratory itself validates the test and takes responsibility for its diagnostic use.

Mayo Medical Laboratories is part of the famed Mayo Clinic, one of the world's most highly recognized health care institutions. The Mayo Clinic is well known for being first movers in many diagnostic and therapeutic areas, and this year U.S. News and World Report named the Mayo Clinic as U.S.A.'s best hospital, also in the area of kidney diseases.

Mayo has recently concluded a large clinical study, a major aspect of which was the determination of NGAL levels on emergency admission and relating them to the presence or absence of renal injury. The results, which also indicate which cutoff levels give the best diagnostic performance, are seen as highly favorable. Mayo Medical Laboratories have consequently chosen to implement precisely BioPorto's NGAL Rapid ELISA Kit (KIT 037) for the diagnosis of acute renal injury.

In 2005 BioPorto launched, as the first in the world, a commercial test for measuring human NGAL. Since then the test has been accepted by many physicians around the world, which has put NGAL measurement well on the way to international recognition as an aid to the diagnosis of acute renal injury. A large proportion of the clinical evidence that has continuously been published about NGAL has been obtained by means of BioPorto's NGAL products, and as a result BioPorto's NGAL tests have obtained the status of gold standard in the area.

BioPorto expects that access to the NGAL test through Mayo will help prepare the market for the new fully automated NGAL laboratory test, called *The NGAL test*, which the Company plans to launch early in 2011. Mayo's implementation is not expected to have any significant effect on BioPorto's sales of ELISA kits during the current year.

On August 9, 2010, BioPorto issued an announcement concerning the objections that have been presented against the Company's European patent in the NGAL area. The Company's patent advisers, Høiberg A/S, have reviewed the objections and do not expect them significantly to affect BioPorto's rights, so that the overall patent situation remains unchanged. It is still necessary for others to acquire a license to BioPorto's rights on marketing an NGAL test for the diagnosis of acute renal injury.

The objections principally concern the cutoff value of 250 ng/mL or higher which is described in the patent. It is expected that as NGAL gradually achieves real use as a diagnostic marker and is no longer merely used in studies on selected patient groups, the patented cutoff value will be consolidated. This expectation is just what has been supported by the Mayo Clinic's validation and use of the NGAL test, about which they state: "Neutrophil gelatinase-associated lipocalin (NGAL) concentrations in urine above approximately 300 ng/mL are highly predictive of renal injury".

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