

EC DECLARATION OF CONFORMITY

We,

Thermo Fisher Scientific Oy, Clinical Diagnostics Finland

hereby declare that the reagent kit with

Trade name: **α -HBDH**
Code: **981380**

comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC.

This Declaration is valid for all batches which are placed on the market by ourselves on or after December 22, 2003 and which bear the CE marking.

Vantaa, July 28, 2009

Thermo Fisher Scientific Oy



Silja Halme
Quality Manager
Quality, Regulatory and Compliance
Clinical Diagnostics Finland