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**EKF Diagnostics Holdings PLC** 

29 November 2011

# EKF Diagnostics Holdings plc ("EKF" or "the Company")

# **Update on US market expansion**

EKF Diagnostics Holdings plc (AIM: EKF), a growing business within the in-vitro diagnostic devices market, provides an update on developments as the Company grows its market share in the US haemoglobin testing market.

## **Waiver Granted Notification**

EKF has now received notification from the US Food and Drug Administration that the application for CLIA waived status in relation to the Stanbio HemoPoint H2 Hemoglobin Measurement System has been accepted, having modified the name to the Alere HemoPoint H2 Hemoglobin Measurement System. This will allow Alere Inc., the exclusive distributor of EKF's HemoPoint H2 product, to begin sales into the US market.

#### **US Patent**

EKF has also received a notice of allowance from the US Patent and Trademark Office in relation to patent rights for the cuvettes that are used with the HemoPoint H2 product. It is expected that a Grant of Patent Rights will be issued shortly following the payment of due fees.

Commenting, Julian Baines, CEO of EKF Diagnostics Holdings plc, said: "Whilst the granting of the CLIA waived notification might be seen as a formality it is a necessary step to allow Alere to sell our HemoPoint H2 product into the US market. With Alere's strong customer relationships and clear expertise in this market, we are confident that we will gain considerable market share in the US one of the largest haemoglobin markets in the world."

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## **About EKF Diagnostics Holdings plc**

EKF Diagnostics Holdings plc was formed in July 2010 following the acquisition of EKF-diagnostic GmbH for €14.32m and refocused its strategy to one of building a substantial point of care diagnostics business. As part of this strategy, the Group has integrated three further acquisitions, Quotient Diagnostics Limited (acquired in October 2010 for a maximum of £5.41m), Argutus Medical Limited (acquired in December 2010 for £2.18m) and Stanbio Laboratory L.P. (acquired in June 2011 for a maximum of US\$25.5m).

The Company, with its head office in Cardiff and operations in London, Germany, Poland, Russia, Ireland and the US, is a leading diagnostics business, focused on the development, production and distribution of chemical reagents and analysers for the testing of Glucose, Lactate, Haemoglobin, Haematocrit and HbA1c.

In May 2011 EKF entered into a distribution agreement with Alere Inc ("Alere"), a global diagnostics company, under which Alere was appointed the exclusive distributor of EKF's CLIA waived Hemo\_Control device and cuvettes in the US, Canada and United Kingdom. The device is distributed in the US under the name HemoPoint H2.

For more information please visit the website: www.ekfdiagnostics.co.uk

This information is provided by RNS
The company news service from the London Stock Exchange

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