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**EKF Diagnostics Holdings PLC** 

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

## PointMan™ successfully enriches low-level mutations in DNA extracted from blood

EKF Diagnostics Holdings plc (AIM: EKF), the AIM listed point-of-care diagnostics business, announces a major breakthrough for its Pointman technology for potential use in future cancer testing and treatment.

The first successful results of a collaboration between EKF Molecular Diagnostics and the Institute of Life Sciences at Swansea University have demonstrated the detection of gene mutations in blood from samples archived in the Wales Cancer Bank. The Company's PointMan™ technology was used to analyse the whole blood of cancer patients diagnosed with metastatic melanoma (skin cancer that has spread) enabling the identification of gene mutations associated with response to drug treatment.

Very importantly, the results observed for mutations in the gene BRAF were consistent with the formalin fixed paraffin embedded (FFPE) tissue samples. FFPE being the laboratory standard method to prepare all biopsy samples for pathology review in order to diagnose the cancer. These results have been confirmed by DNA sequencing which had failed to identify the mutations prior to sample enrichment through our PointMan $^{\text{TM}}$  technology.

**Dr Ricardo Del Sol, Senior Lecturer, ILS Swansea University, commented:** "These results are a clear indication of the potential for PointMan to enable the use of a blood sample to assess the mutation status of cancer patients. We look forward to continuing this important work with EKF Molecular to validate our findings."

Julian Baines, CEO of EKF, commented: "This is a major step forward not just for the Company but also for the future testing of cancer patients where we hope that less-invasive testing will become routine using our Pointman technology. We are looking forward to continuing to work with ILS Swansea to continue to build the evidence base. Further evidence will be generated from other collaborations and I look forward to providing you more updates during 2014."

EKF Molecular's portfolio of PointMan™ DNA enrichment products include; BRAF, KRAS, EGFR, NRAS and JAK2. This achievement is in line with the

Company's vision to change current DNA extraction and detection practices and address the fast growing companion diagnostics market. Current collaborations focus on the unmet requirements for patient monitoring from a peripheral sample thereby negating the requirement for a surgical procedure to obtain a tissue biopsy and screening for early cancer diagnosis.

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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: <a href="https://www.ekfdiagnostics.com">www.ekfdiagnostics.com</a>

## About PointMan™

PointMan $^{\text{m}}$  provides a reliable and highly sensitive determination of the presence or absence of a mutation in the DNA sequence. Mutations are associated with diseases such as cancer and importantly the patient's response to treatment, known as personalised healthcare.

PointMan<sup>TM</sup> works by targeting the PCR (polymerase chain reaction) towards the mutant sequence whilst suppressing the amplification of the non-mutated (wild type) sequence and this means that these enriched samples contain artificially high levels of mutated DNA, significantly enhancing detection. This drives the sensitivity of the PointMan<sup>TM</sup> technology far beyond existing PCR technology (PointMan<sup>TM</sup> can detect 1 mutant gene in 100,000 normal gene copies against the nearest technology that detects 1 in 100).

The efficiency of PointMan™ therefore maximises the use of smaller biopsy samples as well as allowing multiplexing of mutations in a single test rather than many individual tests as current competing technologies do.

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