



20 February 2019

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) No 596/2014 (MAR).

EKF Diagnostics Holdings plc
("EKF", the "Company")

US FDA approval for Quo-Test analyser

EKF Diagnostics Holdings plc (AIM: EKF), the AIM listed point-of-care business, announces that its Quo-Test analyser has received US Food and Drug Administration 510(k) clearance for professional use in a clinical laboratory setting.

The Quo-Test is a fully automated glycosylated haemoglobin (HbA1c) analyser, providing fast, easy and reliable HbA1c measurement for the monitoring and management of diabetes.

The FDA 510(k) clearance allows the Quo-Test to be used in a laboratory setting for *in-vitro* quantitative determination of HbA1c in whole blood samples.

For more information on the Quo-Test see: <https://www.ekfdiagnostics.com/quo-test.html>

Commenting, Julian Baines, CEO of EKF, said:

"We are very pleased with the FDA approval of Quo-Test as this increases the portfolio of products that can now be marketed in the US."

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About EKF Diagnostics Holdings plc (www.ekfdiagnostics.com)

EKF is a leading point-of-care diagnostics and central laboratory assay manufacturer with an estimated 80,000 hemoglobin, hematocrit, HbA1c, glucose and lactate analyzers in regular use across more than 100 countries. EKF specializes in developing tests for use in anemia and diabetes diagnosis and management, as well as providing a portfolio of reagents for use in clinical chemistry analyzers.