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Roche receives FDA clearance for CoaguChek XS Pro system with bar code reader for PT/INR testing at the point of care

Built-in scanner automatically captures bar-coded operator and patient ID information to help save time, prevent errors due to manual entry of information

INDIANAPOLIS – Roche Diagnostics announced today it has received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the CoaguChek® XS Pro system, a new point-of-care anticoagulation monitor with a built-in bar code reader that can automatically scan and capture operator and patient identification information. The bar code reader works in conjunction with the RALS®-Plus information management system to help healthcare professionals save time and prevent errors that could occur from manually entering the information for PT/INR (blood clotting time) testing with patients on warfarin therapy.

“The addition of the CoaguChek XS Pro system to the CoaguChek family of products expands the options that healthcare providers have for PT/INR testing at the point of care,” said Tim Huston, director of marketing, professional diagnostics at Roche Diagnostics Corporation. “The bar code reader functionality, in particular, can help them ensure patient safety and simplify regulatory compliance, making it easier to manage an anticoagulation clinic.”

The newest member of the CoaguChek XS family of meters, the CoaguChek XS Pro system requires a small sample of blood – only 8 microliters – and provides test results in about one minute. It uses built-in quality controls and offers the option to run two levels of additional liquid controls. The meter can store up to 1000 patient results and 500 optional liquid quality control results, and the operator has the option to enter comments related to either type of result.

The CoaguChek XS Pro system also offers extensive connectivity and data management

capabilities by communicating via its optional handheld base unit with the RALS-Plus information management system. The connectivity enables several reporting and device management features, including operator and QC lockout, operator and patient list management and PT/INR and QC test comment management. These features can help hospital staff streamline the regulatory compliance documentation process, capture reimbursable costs and improve their organizational efficiency.

About the CoaguChek family of products

Clinicians have been using CoaguChek systems for PT/INR (Prothrombin Time/International Normalized Ratio) testing since 1994. The CoaguChek XS Pro system represents the fifth generation of point-of-care anticoagulation monitoring devices from Roche Diagnostics. Today, in the U.S., more CoaguChek test strips are sold for point-of-care anticoagulation testing than all other brands combined.

About Roche

Headquartered in Basel, Switzerland, Roche is a leader in research-focused healthcare with combined strengths in pharmaceuticals and diagnostics. Roche is the world's largest biotech company with truly differentiated medicines in oncology, virology, inflammation, metabolism and CNS. Roche is also the world leader in in-vitro diagnostics, tissue-based cancer diagnostics and a pioneer in diabetes management. Roche's personalized healthcare strategy aims at providing medicines and diagnostic tools that enable tangible improvements in the health, quality of life and survival of patients. In 2009, Roche had over 80,000 employees worldwide and invested almost 10 billion Swiss francs in R&D. The Group posted sales of 49.1 billion Swiss francs. Genentech, United States, is a wholly owned member of the Roche Group. Roche has a majority stake in Chugai Pharmaceutical, Japan. For more information: www.roche.com or www.roche-diagnostics.us.

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