

Recall -- Firm Press Release

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Roche Diagnostics Announces Nationwide Recall on Medical Device Used to Determine Blood Clotting Time

Contact:

Roche Diagnostics' Point-of-Care Technical Service Center
1-800-820-0995

FOR IMMEDIATE RELEASE

-- October 19, 2006 -- Roche Diagnostics is notifying users of an important recall of all CoaguChek® PT test strips currently in the market, due to a potential for a test strip defect that may cause falsely elevated test results. The company has identified the root cause and is instituting corrective action with highest priority. To date, the company has confirmed one incident and its internal investigation suggests that a small percentage of strips may be affected. To date, no deaths, illnesses or injuries have been reported due to this issue.

CoaguChek PT test strips are used by patients in the home and by professionals in medical settings to determine blood clotting time of patients taking anti-coagulants, also known as blood thinners. Blood thinners are used to treat patients with a potential for blood clots, for example, patients with heart valve replacements, certain types of heart disease or blood clots in their legs. Incorrect results may have serious or life threatening consequences because patients may be improperly treated.

Roche Diagnostics has determined the potential for a test strip defect when insufficient active ingredient (thromboplastin) is applied to the test strip, possibly causing falsely elevated results. As a result of the unpredictable positive bias, patient test results may be falsely elevated. This can result in an incorrect dose of anti-coagulant or unnecessary corrective measures to reduce the effect of circulating anti-coagulants. Both incorrect treatment choices could put patients at risk for blood clots.

Roche Diagnostics is notifying all home users of the CoaguChek PT test strip to immediately discontinue use of and discard the product as well as to consult with their health care provider to determine alternate testing methodologies and clinical implications. U.S. customers with questions or concerns should call Roche Diagnostics' Point-of-Care Technical Service at 1-800-820-0995.

Roche Diagnostics is notifying all health care professionals who use the CoaguChek PT test strip to institute 'duplicate testing' - or two strips on each patient - using different lot numbers to reduce the risk of bias. If health care professionals require another lot to enable duplicate testing, they are encouraged to call their medical supply distributor. For general questions, health care professionals should call the company's Point-of-Care Technical Service Center at 1-800-820-0995. These actions must remain in place until the issue has been resolved and health care professionals are supplied with unaffected replacement product.

Letters are being sent to customers, providers and physicians – including additional information regarding this voluntary action. Roche Diagnostics is working with its affiliates worldwide to coordinate appropriate activities. Any adverse reactions experienced with the use of this product, and/or quality problems should also be reported to the FDA's MedWatch Adverse Event Reporting program online [at www.fda.gov/MedWatch/report.htm], by phone [1-800-FDA-1088], or by returning the postage-paid FDA form 3500 [which may be downloaded from www.fda.gov/MedWatch/getforms.htm] by mail to [MedWatch, 5600 Fishers Lane, Rockville, MD 20852-9787] or fax [1-800-FDA-0178]. This action is being taken by Roche Diagnostics with the knowledge of the U.S. Food and Drug Administration.

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