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Ortho-Clinical Diagnostics Issues Voluntary Recall for Cardiac Marker

Raritan, N.J., July 8, 2004 — Ortho-Clinical Diagnostics, Inc., a Johnson & Johnson company, initiated a voluntary nationwide recall of 4 lots of the VITROS® Immunodiagnostic Products Troponin I Reagent Pack. VITROS® Immunodiagnostic Products Troponin I Reagent Pack is distributed to clinical laboratories. Troponin tests are used to aid doctors in the diagnosis of a heart attack.

The company has received complaints of random occurrences of false-positive results, which could lead to unnecessary medical procedures. An investigation by Ortho-Clinical Diagnostics determined that the occurrences were limited to an interaction between a component in the affected lots and specific patient plasma samples. All current and future lots are undergoing enhanced testing designed to screen for this potential interaction.

The recall includes the following products:

VITROS® Immunodiagnostic Products Troponin I Reagent Pack (1949882) lots 1110, 1130 (distributed worldwide)

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VITROS® Immunodiagnostic Products Troponin I Reagent Pack (6801857) lots 2510, 2530 (distributed in the US)

Ortho-Clinical Diagnostics initiated a voluntary recall by notifying all customers with affected lot numbers. The U.S. Food and Drug Administration has been apprised of this action. No injuries have been reported to date.

Clinical laboratories were instructed to stop using the product, discard any remaining material, and notify the health care provider who ordered the test. Replacement product was provided.

A troponin test is usually ordered, along with other cardiac tests, as an aid in the diagnosis of myocardial infarction. The results of troponin tests should be used in conjunction with other diagnostic information including other cardiac markers, ECG, clinical observations, and symptoms.

Clinical laboratories with questions may contact the company at 1-800-421-3311.

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