Ortho Clinical Diagnostics	**Follow-up to URGENT PRODUCT CORRECTION NOTIFICATION Increased Haemolysis Reported for Reagent Red Blood Cell Products**

Date Issued April 2017 (Updated with product code 6902319)

Issue

Previously, Ortho Clinical Diagnostics (Ortho) issued an Urgent Product Correction Notification due to the intermittent presence of marked haemolysis caused by microbial contamination in some Ortho Reagent Red Blood Cell (RRBC) products as well as Quality Control products containing red blood cells. The notification and its follow-up included lists of affected products that were identified to be potentially affected by contamination.

Product List Discrepancy

The updated product code listing in the body of the follow-up letter did not list product code 6902319 although this code was indicated in the revised List of Affected Products. The List of Affected Products was not enclosed with the follow-up letter, and it has been stated in that letter that the customer may request Ortho for the listing if required.

Product code 6902319 is not registered in Singapore and is not supplied to customers in Singapore.

Product Code	Product Name from Instructions for Use (IFU)
6902319	Reagent Red Blood Cells 0.8% Resolve® Panel C System

Sincerely,

[redacted]

Jon Wong, 7 April 2017
QA Manager