



February 20, 2017

Product: Capture-R® Ready-ID®

LOT ID324 and ID325



2017-05-02

REF 0066204 and 0066214

UDI: 0066204: 10888234001140

0066214: 10888234001188

**Product
Notification**

Issue:

Immucor is issuing this product notification regarding the V antigen typing for donor D1741, Cell #4 on Capture-R Ready-ID, Lots ID324 and ID325. Further DNA testing of donor D1741 has confirmed the donor as V-, instead of V+ as indicated on the Master List.

Impact to Results:

Since donor D1741 is V-, Cell #4 will be nonreactive with specimens that may contain anti-V. V (RH10) is a low prevalence antigen in the RH system. You can evaluate the impact on any previous testing results using these lots per your procedures.

Required Action:

A corrected Master List for Capture-R Ready-ID, lots ID324 and ID325 are attached to this notification; the corrected copies are identified with an "A" in the upper-left corner. Please replace your original Master List(s) with the corrected Master List(s).

Please acknowledge your receipt of this notification by completing the response form below and returning it to us by facsimile +49 (0) 610380566390 or per email: vigilance.eu@immucor.com.

If you have questions or require additional information, please contact Immucor Technical Support at 855-IMMUCOR (855-466-8267).

We apologize for the inconvenience this issue may have caused your laboratory.

Sincerely,

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3130 Gateway Drive
Norcross, GA 30071
855.466.8267
www.immucor.com



RESPONSE FORM

I acknowledge that our facility is aware of the product notification for **Capture-R Ready-ID, lots ID324 and ID325 (FA-17-03)**

Name:

Position:

Facility/Institution

Account number

City/State

Telephone

3130 Gateway Drive
Norcross, GA 30071
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www.immucor.com