URGENT FIELD SAFETY NOTICE

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Important Information Regarding Donor N3512

This communication is to inform you of reports that Immucor has received concerning unexpected positive reactivity when testing donor N3512 with anti-V. Our initial investigation into these reports has confirmed that donor N3512 is V+ when tested with additional sources of anti-V. Donor N3512 will be labelled as V+ going forward.

Red blood cells from donor N3512 were used in the manufacturing of the following Reagent Red Blood Cells (Product) and donor N3512 was listed as V- on the Master List:

Product	Lot#	Cell#	Expiration Date
Capture-R® Ready-ID®	ID286	11	2016-03-22
Capture-R® Ready-ID®	ID287	12	2016-03-22
Panocell-20®	47436	18	2016-01-29
Panocell-16®	39330	16	2015-12-04
Panocell-20®	23160	16	2015-08-14
Panocell-20®	14052	18	2015-06-12
Capture-R® Ready-ID® Extend II	DN074	13	2014-07-29

These products are intended for use in the identification of unexpected antibodies to red blood cells. These products met release specifications. We are notifying you so that you can evaluate the impact this may have on results generated with these product lots per your procedures.

For lots that are still in date we have included a revised Master List with this notification. If you are currently using one of these lots we ask that you discard the Master List that shipped with your product and replace it with the corresponding updated version.

We apologise for any confusion this may have caused. Please contact Technical Support on 0330 3338741 should you have any questions about the information contained in this communication.

Please verify your receipt of this notification by completing the Customer Response Form and returning it to us by faxing to 0330 333 8749 or by mail to questsales@immucor.com.

Sincerely,

Yves Ohandja, PhD
Manager Quality and Regulatory Affairs Europe