3130 Gateway Drive,
Norcross, GA 30071 USA

March 28, 2001

IMPORTANT VOLUNTARY RECALL INFORMATION

APPLIES TO THE FOLLOWING LOTS OF IMMUCOR, INC. PRODUCTS:

Capture-R Ready-Screen (Pooled Cells), lots CW021 and N42, expiration 16 Mar 01
(Packaged as part of Test Kits Lots 05559, 05561, 07613, or 07614)
Capture-R Ready-Screen (I and II), lots X2701 and X2801, expiration 16 Mar 01; lot X29, expiration 30 Mar 01
(Packaged as part of Test Kits Lots 05567, 05568, 07607, 07608, 09661, or 09662)
Capture-R Ready-Screen (4), lot G0101, expiration 16 Mar 01; lot G02, expiration 30 Mar 01; lot G03, expiration 13 Apr 01
(Packaged as stand-alone plates or as part of Test Kits 09672, 09673, 09674, 09675, 11732, 11733, 11734, or 11735)
Capture-R Ready-ID, lot ID48, expiration 16 Mar 01; lot ID49, expiration 30 Mar 01
(Packaged as part of Test Kits 05558, 07616, 07622 or 09671)

Dear Distributor of products manufactured by Immucor, Inc.,

Our records indicate that you received for further distribution one or more of the listed lots of Capture-R Ready-Screen and/or Capture-R Ready-ID Solid Phase Test Wells that are manufactured by Immucor, Inc. The purpose of this notification is to inform you that we have initiated a voluntary recall action for the following products: Capture-R Ready-Screen (I and II), Lots X2701, X2801 and X29; Capture-R Ready-Screen (4), Lots G0101, G02, G03; Capture-R Ready-Screen (Pooled Cells), Lots N42 and CW021; and Capture-R Ready-ID, Lots ID48 and ID49. These products have been implicated as missing some examples of anti-Fya. ***Capture-R Ready-Screen Lot X29 has been potentially implicated in a transfusion reaction.***

The following pages are copies of 1) the notification we will be sending within the United States to inform US customer of potential failures that might occur from the use of these lots, and 2) a response questionnaire to document the customer has received notice of and fully understands the purpose of the recall . This notification will also provide you with more information regarding the corrective actions the customer needs to take in the short term. We ask that you forward this notification and response form to your customers, either as we have provided it in English or as a direct translation into the language of your users. THIS NOTICE BE MAY ALSO BE SENT TO YOUR GOVERNMENT BY THE FDA. All information within this notice should be transmitted to the user. We strongly recommend that you have your customers complete and return the response questionnaire that is provided with this correspondence to you. This information should become part of your permanent recall file. Should you receive any indication that any of the products listed above are implicated in a transfusion reaction due to a failure to detect anti-Fy^a, we ask that you forward that information to us immediately.

As mentioned in the customer notification, we will begin shipping replacement product next week. Replacements will be sent as fully packaged Capture-R Ready Test Systems. We ask that you contact our Customer Services department by telephone, facsimile or by e-mail to notify them of the quantity of product you will need to make the replacements. You do not need to collect or return any of the affected lots to us. We will provide you with a status report by next week to inform you of the outcomes of our root cause investigation.

Sincerely,
Susan Rolih
Vice President, Quality and Regulatory Affairs

3130 Gateway Drive,
Norcross, GA 30071 USA

March 28, 2001

IMPORTANT VOLUNTARY RECALL INFORMATION

APPLIES TO THE FOLLOWING LOTS OF IMMUCOR, INC. PRODUCTS:

Capture-R Ready-Screen (Pooled Cells), lots CW021 and N42, expiration 16 Mar 01
(Packaged as part of Test Kits Lots 05559, 05561, 07613, or 07614)
Capture-R Ready-Screen (I and II), lots X2701 and X2801, expiration 16 Mar 01; lot X29, expiration 30 Mar 01
(Packaged as part of Test Kits Lots 05567, 05568, 07607, 07608, 09661, or 09662)
Capture-R Ready-Screen (4), lot G0101, expiration 16 Mar 01; lot G02, expiration 30 Mar 01; lot G03, expiration 13 Apr 01
(Packaged as stand-alone plates or as part of Test Kits 09672, 09673, 09674, 09675, 11732, 11733, 11734, or 11735)
Capture-R Ready-ID, lot ID48, expiration 16 Mar 01; lot ID49, expiration 30 Mar 01
(Packaged as part of Test Kits 05558, 07616, 07622 or 09671)

Dear Blood Bank Supervisor or Regulatory Officer,

Our records indicate that your facility received certain lots of Capture-R Ready-Screen and/or Capture-R Ready-ID Solid Phase Test Wells that are manufactured by Immucor, Inc. The purpose of this notification is to inform you of several actions that are necessary for the continued use of the product lots listed above. These actions are taken in response to complaints we have received since February 2001 regarding the potential for false-negative test results with some examples of anti-Fy^a. Product lots involved in these complaints include Capture-R Ready-Screen (I and II), Lots X2701, X2801 and X29; Capture-R Ready-Screen (4), Lots G0101, G02, G03; Capture-R Ready-Screen (Pooled Cells), Lots N42 and CW021; and Capture-R Ready-ID, Lots ID48 and ID49. ***Capture-R Ready-Screen Lot X29 has been potentially implicated in a transfusion reaction.*** No other blood group system antibodies have been associated with these complaints.

If you are using any of the above lots of Capture-R Ready-Screen in patient testing as your sole means of detecting unexpected antibodies, it is possible you have missed some examples of anti-Fy^a. This IgG antibody is capable of causing a delayed-type transfusion reaction or hemolytic disease of the newborn. Even though the antigen is of relatively high prevalence in the random population, the antibody is common.

New lots of Capture-R Ready-Screen or Ready-ID, manufactured to react with examples of anti-Fy^a provided as part of the complaints, will be available to ship beginning Monday, April 2, 2001. **Until these are available, patient antibody screening that uses any of the lots identified in this notification should also include a second test.**

Once you receive your replacement, we ask you to discontinue the use of, and to destroy the affected lots covered by this notification. You may either notify our Customer Services department at (800) 510-5110 or (770) 441-2051 to notify us of your replacement needs or send us your replacement needs on the return questionnaire that accompanies this notification.

If Capture-R Ready-Screen results have been used in lieu of the antiglobulin crossmatch, we ask that you review the posttransfusion records of patients who developed symptoms of a delayed transfusion reaction (fever, jaundice, drop in hematocrit etc). In those cases, a posttransfusion serum/plasma sample should be tested with another red cell reagent (if not already done) and the red cells of the donor typed with Anti-Fy^a to determine if anti-Fy^a was the cause of the reaction.

In cases where identification tests were performed with Capture-R Ready-ID lots ID48 and ID49, you should take steps to confirm or exclude the presence of anti-Fy^a by testing other Fy(a+) red cells from Immucor or other manufacturers.

If the patient can be shown to be Fy(a+), no further testing is warranted. If the patient is Fy(a-), or if the patient's Fy^a status is unknown, additional testing should include an IgG crossmatch **OR** a second antibody screen using reagent cell lots other than those listed in this notification.

Extended testing on patient samples need only be performed until such time as you receive your replacement product.

Patient screening tests performed with Capture-R Ready-Screen lots not identified in this letter require no additional confirmation.

No further testing is warranted if Capture-R Ready-Screen has been used to screen donor samples for antibodies.

We apologize for any inconvenience this may cause you. If you have questions regarding this recall, please contact Immucor's Technical Support department at (800) 492-2583 or (770) 441-2051.

Sincerely,

Susan Rolih, MS, MT(ASCP)SBB
Vice President, Quality and Regulatory Affairs

Customer Response Form – Voluntary Recall Notification
Capture-R Ready-Screen, Capture- R Ready-ID

APPLIES TO THE FOLLOWING PRODUCTS ONLY:

Capture-R Ready-Screen (Pooled Cells), lots CW021 and N42, expire 16 Mar 01
Capture-R Ready-Screen (I and II), lots X2701 and X2801, expire 16 Mar 01; lot X29, expires 30 Mar 01
Capture-R Ready-Screen (4), lot G0101, expires 16 Mar 01; lot G02 expires 30 Mar 01; lot G03 expires 13 Apr 01
Capture-R Ready-ID, lot ID48, expires 16 Mar 01; lot ID49, expires 30 Mar 01

☐ I verify that our facility is aware of the voluntary recall of Capture-R Ready-Screen and Capture-R Ready-ID.
Status of our inventory: *(Check one.)* ☐ Inspected – no plates of the affected lots remain in our inventory ☐ Inspected – One or more of the affected lots (in date) remain in our inventory. Replace these products. Lot number: _____ Number of plates: _____ Lot number: _____ Number of plates: _____ Lot number: _____ Number of plates: _____ Lot number: _____ Number of plates: _____
☐ We understand that we should verify the results of patient antibody screening tests with an alternative test or method until such time that we receive replacement product.
Patient impact assessment (*Check one*.) ☐ No patient antibody screens were performed with the lots affected by this recall. ☐ Patient antibody screens were performed with one or more of these lots but there is no evidence that any patient manifested a delayed transfusion reaction due to an anti-Fy^a missed by the reagent. ☐ Patient antibody screens were performed with one or more of these lots but there is evidence that a patient manifested a delayed transfusion reaction due to an anti-Fy^a missed by the reagent. Number of patients affected _____
Name: (Print)
Name: (Signature)
Position:
Facility/Institution
City/State
Telephone
Fax number

Please return this form immediately by fax or mail to:

Marlene Jones, Immucor, Inc., 3130 Gateway Drive, Norcross, GA 30071
Tele (770) 441-2051, x 1263
Fax (770) 441-9521