



URGENT: FIELD SAFETY NOTICE CORRECTION

January 6, 2017

RE: Pak Lx™ Assay

Pak Lx Assay Kit Lot: 3003658

Current Expiration: 2017-03-15

Pak Lx Assay Kit Lot: 3004022

Current Expiration: 2017-05-15

Dear Laboratory or Blood Bank Manager,

Our records show that you received the above product of Immucor GTI Diagnostics, Inc.

We have determined that the Conjugate Diluent included in these kits has an expiration date defined on its labeling which is outside its supported stability. The expiration date for the Conjugate Diluent should be one year shorter than that provided on the labels.

Instructions for correction of the affected product:

1. Do not recognize the Conjugate Diluent expiration date as listed on the vials.
2. Recognize the Pak Lx Assay Kit expiration date as defined by the New Expiration date listed below.

	Current Expiration	New Expiration
Pak Lx Kit Lot: 3003658	2017-03-15	2017-02-15
Pak Lx Conjugate Lot: 3003554	2018-02-15	2017-02-15
Pak Lx Kit Lot: 3004022	2017-05-15	2017-05-15 (unchanged)
Pak Lx Conjugate Lot: 3003881	2018-05-15	2017-05-15

Please note per the Pak Lx Instructions for Use: Reagents contained in the kit are not to be used in conjunction with any other test system.

3. Complete the Response Form and Return by fax to 262.754.1078 OR email to sconran@immucor.com.

We appreciate the trust and confidence you place in our products. Please contact Technical Support should you need additional information at 855.IMMUCOR or waukeshatechsupport@immucor.com.

Acknowledgement is required for this notification. Please complete the Response Form included on page 2 of this communication. Return the response form by fax to 262.754.1078 OR email to sconran@immucor.com.

We regret any inconvenience that this may cause you.



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Sincerely,



Allison Stray
Senior Director, Quality and Regulatory Affairs
Immucor GTI Diagnostics, Inc.

Response Form

I verify that our facility was made aware of the Correction for the Pak Lx Assay		
Lot: 3003658	Current Expiration: 2017-03-15	New Expiration: 2017-02-15
Lot: 3004022	Current Expiration: 2017-05-15	New Expiration: 2017-05-15 (unchanged)
Name: _____		
Position: _____		
Facility/Institution: _____	Customer Number: _____	
City/State: _____		
Telephone: _____		
Fax Number: _____		
Number of Pak Lx kits remaining in stock:		
Lot 3003658:		
Lot 3004022:		