

December 15, 2014

RE: PF4 Enhanced, PF4 IgG or PF4 Concentrated Wash

Dear Laboratory Manager:

Our records show that you received the above product of Immucor GTI Diagnostics, Inc. Specific kit and reagent lot numbers are provided on page 2 of this communication.

We have determined that the PF4 Concentrated Wash (10X) lots indicated in this letter were manufactured at a slightly more dilute concentration. As a result, this may lead to slightly increased Optical Density (OD) values with results generated using these buffer lots.

The increased OD values are not expected to cause invalid results. Samples demonstrating a higher background reactivity may demonstrate false positive result (borderline reactivity) at or near the cutoff for the assay, but otherwise with no specific anti-PF4: polyanion reactivity.

To date, Immucor has not received any complaints that can be correlated to the OD increase and resulting in any false positive results.

Previous results generated using this lot of product (PF4 Concentrated Wash) may be considered valid provided that:

1. testing was performed according to the package insert instructions,
2. quality control testing gave acceptable results,
3. consideration was given to the LIMITATIONS section of the package insert, and
4. borderline positive results were reviewed in relation to additional clinical and testing information that may be available.

Instructions for correction of the affected product:

1. Stop using the affected PF4 Concentrated Wash.
2. Do not destroy the other components of the Kits.

Concurrent to this letter we are sending you replacement PF4 Concentrated Wash based on the total number of kits you have previously ordered. If there is an urgent need for additional wash buffer, please contact Technical Support at 262.754.1000 or waukeshatechsupport@immucor.com

3. Log the number of bottles and Lot number of the PF4 Concentrated Wash on the Customer Response Form.
4. Determine additional number of bottles of PF4 Concentrated Wash you require besides those already provided as part of this action. Log this number on the Customer Response Form.
5. Destroy the affected PF4 Concentrated Wash.



6. Complete the included Customer Response Form and Return to waukeshatechsupport@immucor.com.
7. All orders shipped after December 9, 2014, will contain non-affected PF4 Concentrated Wash.

PF4 Enhanced/PF4 IgG affected Kit Lots and Reagent Lots

Product Name	Item Code	Lot#/Serial#	Reagent Lot#	Expiration Date
PF4 IgG	HAT45G	3001956	3001620	2015-08-15
PF4 Enhanced	X-HAT45	3001974	3001620	2015-11-15
PF4 IgG	HAT45G	3001992	3001620	2015-08-15
PF4 Enhanced	X-HAT45	3001994	3001620	2015-11-15
PF4 Enhanced	X-HAT45	3002007	3001620	2015-11-15
PF4 Enhanced	X-HAT45	3002013	3001620	2015-11-15
PF4 IgG	HAT45G	3002026	3001620	2015-12-15
PF4 IgG	HAT45G	3002074	3001620	2016-02-15
PF4 Enhanced	X-HAT45	3002049	3001987	2016-06-15
PF4 Enhanced	X-HAT45	3002076	3001987	2016-06-15
PF4 Enhanced	X-HAT45	3002089	3001987	2015-07-15
PF4 Enhanced	X-HAT13	3002090	3001987	2016-06-15
PF4 IgG	HAT13G	3002099	3001987	2016-06-15
PF4 Enhanced	X-HAT45	3002121	3001987	2016-03-15
PF4 Enhanced	X-HAT45	3002131	3001987	2016-06-15
PF4 Enhanced	X-HAT45	3002139	3001987	2016-06-15
PF4 Enhanced	X-HAT13	3002151	3002083	2016-06-15
PF4 Enhanced	X-HAT45	3002176	3002083	2016-06-15
PF4 IgG	HAT45G	3002179	3002083	2016-08-15
PF4 Enhanced	X-HAT45	3002190	3002083	2016-08-15
PF4 IgG	HAT45G	3002211	3002083	2016-06-15
PF4 Enhanced	X-HAT45	3002212	3002083	2016-08-15
PF4 IgG	HAT45G	3002227	3002153	2016-08-15
PF4 Enhanced	X-HAT13	3002236	3002153	2016-08-15
PF4 IgG	HAT13G	3002240	3002153	2016-08-15
PF4 Enhanced	X-HAT45	3002262	3002153	2016-08-15



We have implemented corrective actions in our procedures to prevent recurrence of this issue. All PF4 Concentrated Wash solution distributed after December 9th has been manufactured under the corrected procedures.

Please contact Technical Support should you need additional information at 262.754.1000 or waukeshatechsupport@immucor.com

Acknowledgement is required for this notification. Please Complete the Customer Response Form and return it to Immucor GTI Diagnostics Technical Support at waukeshatechsupport@immucor.com

We regret the inconvenience that this may cause you.

Sincerely,



Director Regulatory Affairs and Quality Assurance, Immucor GTI Diagnostics, Inc.



Customer Response Form

Technical Support Phone: 800.233.1843 or 262.754.1000
Technical Support Fax: 262.754.9831
Technical Support E-mail: waukeshatechsupport@immucor.com

PF4 Concentrated Wash Replacement Confirmation

Instructions

Please follow all instructions detailed in the accompanying letter and then complete, sign, and return this Customer Response Form to Immucor GTI Diagnostics Technical Support. Forms can be returned by fax to 262.754.9831 or by scanning the completed form and emailing to waukeshatechsupport@immucor.com. Notify us if there are any changes to your contact information so we can update our database.

Please remember to review and sign this form.

Please check all applicable boxes below:

- We have no remaining inventory of the product(s) listed below on hand.
- We have documented our remaining inventory for the affected lot in the "Quantity On Hand" column in the table listed below.
- I have followed the enclosed instructions.

I verify that our facility was made aware of the voluntary (field action) of PF4 Concentrated Wash.

Comments:

Name: _____

Position: _____

Facility/Institution: _____

Address: _____

City/State: _____

Telephone: _____ Fax Number: _____

Product Description / Reagent Lot Number	List impacted kit lot(s)	Reagent Qty Delivered	Reagent Qty On-Hand	Reagent Qty Destroyed	Additional Reagent Qty Needed (in addition to replacement reagent)
PF4 Concentrated Wash /					
PF4 Concentrated Wash /					
PF4 Concentrated Wash /					