werfen

Urgent: Field Safety Notice for Distributor

February 17, 2025

EU FA 25-01 FA-WKS-25-001

Product: PF4 Enhanced® and PF4 IgG

Manufacturer:	Authorized Representative:
werfen Immucor GTI Diagnostic, Inc., 20925 Crossroads Circle Waukesha, WI 53186 USA 855.466.8267 werfen.com	**werfen** Immucor Medizinische Diagnostik GmbH Robert-Bosch-Str. 32 63303, Dreieich Germany werfen.com

Dear Valued Distributor,

Werfen is issuing this field safety notice regarding lower mean OD values of following lots of PF4 Enhanced® and PF4 IgG:

Product Name	Product Number	UDI Number	Lot Number	Expiration Date
PF4 Enhanced	303287 / X-HAT13	10888234500025	3015307	MAR 26 2026
			3015141	AUG 01 2025
			3014732	JUL 06 2025
			3014209	JUN 08 2025

Product Name	Product Number	UDI Number	Lot Number	Expiration Date
PF4 Enhanced	303288 / X-HAT45	10888234500032	3015055	MAR 26 2026
			3014832	FEB 16 2026
			3014626	JUN 29 2025
			3014427	JUN 29 2025
			3014121	MAY 15 2025
			3014027	MAY 10 2025

Product Name	Product Number	UDI Number	Lot Number	Expiration Date
PF4 IgG	303289 / HAT13G	10888234500049	3015429	APR 11 2026
			3015288	MAR 21 2026
			3014729	DEC 12 2025
			3014403	JUL 20 2025
			3013937	APR 19 2025

Product Name	Product Number	UDI Number	Lot Number	Expiration Date
PF4 IgG	303290 / HAT45G	10888234500056	3015230	APR 04 2026
			3015037	MAR 25 2026
			3014992	NOV 15 2025
			3014935	MAR 07 2026
			3014831	JAN 22 2026

			3014813	DEC 21 2025
			3014625	NOV 08 2025
			3014499	OCT 04 2025
			3014404	SEP 26 2025
			3014270	JUL 20 2025
			3014184	JUN 20 2025
			3014033	MAY 15 2025
			3014013	MAY 10 2025
			3013916	APR 19 2025
			3013825	MAR 23 2025

Issue Details:

As a result of a complaint investigation, we have determined the lot-matched Anti-Human IgG Conjugate (HAG) included with PF4 IgG kits and the lot-matched Anti-Human IgG/A/M (HAH) Conjugate included with the PF4 Enhanced kits have the potential to generate Positive Control Serum (HPC) mean OD values lower than the validity criteria of ≥ 1.800. These lower mean OD values would result in an invalid assay. Impacted lots are listed in the tables above.

Product Impact:

The risk to patients is low as results from invalid assays are not reportable. Results from valid assays are not impacted and have been determined to be accurate.

Actions Taken by the manufacturer:

Immucor GTI Diagnostics, Inc. has stopped distribution of the affected PF4 IgG ad PF4 Enhanced kits.

Customer Actions to be taken:

Please take the following actions:

1) Notify customers who have received any of the impacted lots and instruct them that they may continue to use the affected kit lot numbers using the acceptance criteria as labeled in the IFU for PF4 IgG and PF4 Enhanced kits. Assay results generating passing control values are considered valid.

2) Inform them to evaluate and monitor your rate of invalid assays. Contact Werfen Customer Support at the number listed if they observe an increased rate of invalid tests.

3) It is important to remind customers that assay results generated with passing controls are considered valid. There is no requirement to re-test samples from these runs.

4) There is no requirement to return any kits.

5) Please acknowledge receipt of this notification by completing and returning the response form by e-mail to **vigilance.eu@werfen.com** or mail to: Immucor Medizinische Diagnostik GmbH, RA/QA, Robert-Bosch-Strasse 32, 63303 Dreieich, Germany, by **March 07, 2025**, so that we may complete our records.

We apologize for any inconvenience this issue has caused. We appreciate the trust and confidence you place in our products. If you need additional information, please reach out via email at tech.support.int.transplant@werfen.com, or contact your local Technical Sales Specialist.

Sincerely,

[redacted]

17-Feb-2025

[redacted]
Director RA/QA – Site Director
Immucor Medizinische Diagnostik GmbH

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Mandatory Distributor Response Form

I acknowledge that our facility is aware of this notification **EU FA 25-01 FA-WKS-25-001** for above-listed **PF4 IgG and PF4 Enhanced lots.**
Distributor:
Country:
Name:
Position:
Contact:
Regulatory Authority Notification required?
If yes, Name of Authority and Date Notified?
Date/Signature:

Email to vigilance.eu@werfen.com or

Mail to:

Immucor Medizinische Diagnostik GmbH
RA/QA
Robert-Bosch-Strasse 32
63303 Dreieich
Germany

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February 17, 2025

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Actions Taken by the manufacturer:

Immucor GTI Diagnostics, Inc. has stopped distribution of the affected PF4 IgG ad PF4 Enhanced kits.

Customer Actions to be taken:

Please take the following actions:

1) You may continue to use the affected kit lot numbers using the acceptance criteria as labeled in the IFU for PF4 IgG and PF4 Enhanced kits. Assay results generating passing control values are considered valid.

2) Evaluate and monitor your rate of invalid assays. Contact Werfen Customer Support at the number listed below if you observe an increased rate of invalid tests.

3) Assay results generated with passing controls are considered valid. There is no requirement to re-test samples from these runs.

4) There is no requirement to return any kits.

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If you have questions or for additional information, please contact your local Werfen representative.

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Sincerely,

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17-Feb-2025

[redacted]

Director RA/QA – Site Director
Immucor Medizinische Diagnostik GmbH

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Mandatory Customer Response Form

I acknowledge that our facility is aware of this notification **EU FA 25-01 FA-WKS-25-001** for above-listed **PF4 IgG and PF4 Enhanced lots.**
CUSTOMER NUMBER:
Facility:
Name:
Position:
Address:
Telephone:
Affected lot number:
Quantity of affected lot number:
Date/Signature:

Email to vigilance.eu@werfen.com or

Mail to:
Immucor Medizinische Diagnostik GmbH
RA/QA
Robert-Bosch-Strasse 32
63303 Dreieich
Germany