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Urgent: Distributor Field Safety Notice

June 19, 2026

EU FA 26-07 FA-WKS-26-004

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

Dear Valued Customer,

Werfen is issuing this field safety notice for the following products.

Product Name	Product Number	UDI Number	Lot Number	Expiration Date
LIFECODES LSA Class II Kit	265200	10888234400349	3016677	22-Dec-2026
			3016531	22-Oct-2026
			3016316	26-Aug-2026
			3016099	01-Jul-2026

Issue:

Werfen has identified that two beads within the LIFECODES LSA Class II assay will present different DQB1 specificities than previously understood:

- Bead 42 / Antigen ID 242
  Previously associated with DQB1*02:01, this bead instead presents DQB1*02:02
- Bead 44 / Antigen ID 244
  Previously associated with DQB1*02:02, this bead instead presents DQB1*02:01

Note: DQA1*02:01 is present on both beads and therefore not impacted.

Due to this issue, certain reactivity patterns may appear differently than expected:

1. DQB1*02:01 antibodies only (DQB1*02:02 not present)

One DQB1*02:01 bead may be positive (1/2 of relevant beads):

- DQB1*02:01 beads
  - Antigen ID 242 → Negative

- Antigen ID 243 → Positive

2. DQB1*02:02 antibodies only (DQB1*02:01 not present)

Most, but not all, DQB1*02:02 beads may be positive (2/3 of relevant beads):

- DQB1*02:02 beads
  - Antigen ID 244 → Negative
  - Antigen ID 245 → Positive
  - Antigen ID 246 → Positive

When both DQB1*02:01 and DQB1*02:02 antibodies are present, all relevant beads are positive and there is no impact.

- DQB1*02:01 beads
  - Antigen ID 242 → Positive
  - Antigen ID 243 → Positive

- DQB1*02:02 beads
  - Antigen ID 244 → Positive
  - Antigen ID 245 → Positive
  - Antigen ID 246 → Positive

Product Impact:

Patient risk is considered low. The LIFECODES LSA Class II assay is intended for the qualitative detection of IgG antibodies to HLA Class II antigens. Due to built-in redundancy across multiple beads representing DQB1*02:01 and DQB1*02:02 specificities, the assay remains capable of qualitatively detecting IgG antibodies to these specificities.

However, due to the observed bead-specific characteristics associated with this issue, the following considerations apply:

- Partial reactivity observed across relevant beads does not preclude the presence of a DQB1*02 antibody
- For DQB1*02 specificities, interpretation of results should be performed with consideration of:
  - Individual bead-level reactivity patterns
  - The overall assay reactivity profile
  - HLA Typing of the Patient
  - Laboratory expertise, in conjunction with appropriate clinical correlation

Actions taken by the manufacturer:

Werfen conducted a comprehensive evaluation and confirmed that the observed issue is limited to a specific antigen configuration and does not represent a broader product performance concern. The evaluation further verified that the LIFECODES LSA Class II assays continue to perform in accordance with their intended use for the qualitative detection of IgG antibodies to HLA Class II antigens.

An expanded assessment of other DQ beads within the assay was performed, and no similar findings were identified, supporting the integrity of bead antigen assignments across the remainder of the assay panel.

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An assessment of eplets and amino acids distinguishing DQB1*02:01 from DQB1*02:02 was performed. The assessment identified two (2) differentiating eplets (one confirmed, 135D, and one unconfirmed, 135G), compared to twenty-three (23) shared eplets (nine (9) confirmed, thirteen (13) unconfirmed, and one (1) classified as questionable). Only a single amino acid difference distinguishes DQB1*02:01 from DQB1*02:02. These data support that DQB1*02:01 and DQB1*02:02 are commonly assigned together.

For impacted lots, lot-specific worksheets and corresponding software lot-specific EDS files will be updated to support appropriate data interpretation on the Werfen customer center (The impacted EDS files were removed from the customer center on 4:00 PM ET (20:00 UTC) **on Monday, June 15**. The revised files were posted on the customer center by 6:00 PM ET (22:00 UTC) **Monday, June 15**: 301XXXX 301XXXX-C3dSA2v2.eds, 301XXXX 301XXXX-SA2v2.eds, 301XXXX LSA2 LC1689 LSA Class II Worksheet v2, LC1607 301XXXX LSA2 C3d Detection Graph v2). The revised files are labeled with v2 at the end. This customer communication has been issued providing detailed guidance on the review of potentially impacted results.

Distributor Actions to be taken:

Please instruct the customers on the following actions:

Import Revised EDS Files (Required for Future Analysis)

1. Download the revised EDS file for the affected lot(s).
   - 301XXXX 301XXXX-C3dSA2v2.eds
   - 301XXXX 301XXXX-SA2v2.eds
   - 301XXXX LSA2 LC1689 LSA Class II Worksheet v2
   - LC1607 301XXXX LSA2 C3d Detection Graph v2
2. Import the updated EDS file containing corrections for Antigen IDs 242 and 244.
3. Apply this EDS file to ensure all future analyses use the corrected antigen mapping.

Review Impacted Reactivity Patterns

1. Identify samples with reactivity to DQB1*02-related antigens, particularly Antigen IDs 242 and 244
2. Prioritize review where differentiation between DQB1*02:01 and DQB1*02:02 impacts interpretation
3. Confirm whether previously reported results may be affected based on the patterns shown below.

Antigen ID	Specificity	DQB1*02:01 Observed	DQB1*02:01 Correction	DQB1*02:02 Observed	DQB1*02:0 Correction
242	**DQB1*02:01**	**Negative**	**Positive**	**Positive**	**Negative**
243	**DQB1*02:01**	**Positive**	**Positive**	Negative	Negative
244	**DQB1*02:02**	**Positive**	**Negative**	**Negative**	**Positive**

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245	**DQB1*02:02**	Negative	Negative	**Positive**	**Positive**
246	**DQB1*02:02**	Negative	Negative	**Positive**	**Positive**

(Optional) Reanalyze Samples with Updated EDS File

Option A – Reimport Batch Data (Full Reanalysis)

1. Import the updated EDS file.
2. Delete the affected batch(es).
3. Reimport the original CSV/batch files.
4. Allow software to recalculate results with corrected antigen mapping.

Option B – Trigger Reanalysis Within Software (Targeted)

1. Import the updated EDS file.
2. Navigate to specific samples of interest identified during the review of impacted reactivity.
3. Perform a software action (e.g., toggling/reprocessing) to regenerate statistics using the new antigen assignments.

Please acknowledge receipt of this field safety notice by providing us the following documents 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 **July 3, 2026**.

- Signed mandatory distributor response form
- Affected customer list
- Signed mandatory customer response forms from all affected customers

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 to your local Technical Sales Specialist.

Sincerely,

[redacted]-18

Manager Quality Systems
Deputy – Person Responsible for Regulatory Compliance
Immucor Medizinische Diagnostik GmbH

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Mandatory Distributor Response Form

I acknowledge that our facility is aware of this notification **EU FA 26-06 FA-WKS-26-003** for **LIFECODES LifeScreen XP Kit Lot 3016386** and performed the action to be taken.
Distributor:
Country:
Name:
Position:
Address:
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