

## Hitno: Obavijest o sigurnosti na terenu za kupca

19. lipnja 2026.

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

<p><u>Proizvođač:</u> <b>werfen</b></p> <p>Immucor GTI Diagnostics, Inc. 20925 Crossroads Circle Waukesha, WI 53186 SAD <a href="http://werfen.com">werfen.com</a></p>	<p><u>Ovlašteni predstavnik u EU:</u> <b>werfen</b></p> <p>Immucor Medizinische Diagnostik GmbH Robert-Bosch-Str. 32 63303, Dreieich Njemačka <a href="http://werfen.com">werfen.com</a></p>
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Cijenjeni korisniče,

Werfen izdaje ovu obavijest o sigurnosti na terenu za sljedeće proizvode:

Naziv proizvoda	Šifra proizvoda	Jedinstvena identifikacija proizvoda (UDI)	Broj serije	Datum isteka
LIFECODES LSA Class II Kit	265200	10888234400349	3016677	22. prosinca 2026.
			3016531	22. listopada 2026.
			3016316	26. kolovoza 2026.
			3016099	1. srpnja 2026.

### **Problem:**

Werfen je utvrdio da će dvije kuglice unutar LIFECODES LSA Class II testa pokazati različite DQB1 specifičnosti a ne ono što se prije mislilo:

- Kuglica 42 / Antigen ID 242  
Prethodno povezana s DQB1\*02:01, ova kuglica umjesto toga predstavlja DQB1\*02:02
- Kuglica 44 / Antigen ID 244  
Prethodno povezana s DQB1\*02:02, ova kuglica umjesto toga predstavlja DQB1\*02:01

Napomena: DQA1\*02:01 je prisutan na obje kuglice i stoga nije pogođen.

Zbog ovog problema, određeni obrasci reaktivnosti mogu se pojaviti kao drugačiji od očekivanih:

# werfen

## 1. Samo DQB1\*02:01 antitijela (DQB1\*02:02 nisu prisutna)

Jedna DQB1\*02:01 kuglica može biti pozitivna (1/2 relevantnih kuglica):

- DQB1\*02:01 kuglice
  - Antigen ID 242 → Negativno
  - Antigen ID 243 → Pozitivno

## 2. Samo DQB1\*02:02 antitijela (DQB1\*02:01 nije prisutno)

Većina, ali ne sve, DQB1\*02:02 kuglice mogu biti pozitivne (2/3 relevantnih kuglica):

- DQB1\*02:02 kuglice
  - Antigen ID 244 → Negativno
  - Antigen ID 245 → Pozitivno
  - Antigen ID 246 → Pozitivno

Kada su prisutna i DQB1\*02:01 i DQB1\*02:02 antitijela, sve relevantne kuglice su pozitivne i nema utjecaja.

- DQB1\*02:01 kuglice
  - Antigen ID 242 → Pozitivno
  - Antigen ID 243 → Pozitivno
- DQB1\*02:02 kuglice
  - Antigen ID 244 → Pozitivno
  - Antigen ID 245 → Pozitivno
  - Antigen ID 246 → Pozitivno

### **Utjecaj na proizvod:**

Rizik za pacijenta smatra se niskim. LIFECODES LSA Class II test namijenjen je kvalitativnom otkrivanju IgG antitijela na antigene HLA klase II. Zbog ugrađene redundancije na više kuglica koje predstavljaju DQB1\*02:01 i DQB1\*02:02 specifičnosti, test i dalje može kvalitativno detektirati IgG antitijela na te specifičnosti.

Međutim, zbog uočenih svojstava specifičnih za kuglice povezanih s ovim problemom, primjenjuju se sljedeća razmatranja:

- Djelomična reaktivnost uočena na relevantnim kuglicama ne isključuje prisutnost DQB1\*02 antitijela
- Za specifičnosti DQB1\*02, interpretaciju rezultata treba provesti uzimajući u obzir:
  - Pojedinačne obrasce reaktivnosti na razini kuglica
  - Ukupni profil reaktivnosti testa
  - HLA tipizaciju pacijenta
  - Laboratorijsku stručnost, u kombinaciji s odgovarajućom kliničkom korelacijom

### **Radnje koje poduzima proizvođač:**

Werfen je proveo sveobuhvatnu procjenu i potvrdio da je uočeni problem ograničen na specifičnu konfiguraciju antigena i ne predstavlja širu zabrinutost u vezi s učinkovitošću proizvoda. Procjena je dodatno potvrdila da LIFECODES LSA Class II testovi i dalje funkcioniraju u skladu s njihovom namjenom za kvalitativno otkrivanje IgG antitijela na antigene HLA klase II.

Provedena je proširena procjena drugih DQ kuglica unutar testa i nisu pronađeni slični nalazi, što podržava integritet dodjele antigena kuglicama u ostatku panela testa.

Izvršena je procjena epleta i aminokiselina koje razlikuju DQB1\*02:01 od DQB1\*02:02. Procjena je identificirala dva (2) različita epleta (jedan potvrđen, 135D, i jedan nepotvrđen, 135G), u usporedbi s dvadeset tri (23) zajednička epleta (devet (9) potvrđenih, trinaest (13) nepotvrđenih i jedan (1) klasificiran kao upitan). Samo jedna razlika u aminokiselini razlikuje DQB1\*02:01 od DQB1\*02:02. Ovi podaci podupiru tvrdnju da se DQB1\*02:01 i DQB1\*02:02 obično dodjeljuju zajedno.

Za pogođene serije, radni listovi specifični za serije i odgovarajuće softverske EDS datoteke specifične za serije bit će ažurirane kako bi podržale odgovarajuću interpretaciju podataka u korisničkom centru Werfen (Pogođene EDS datoteke uklonjene su iz korisničkog centra u 16:00 ET (20:00 UTC) **u ponedjeljak, 15. lipnja**. Revidirane datoteke objavljene su u korisničkom centru do 18:00 ET (22:00 UTC) **u ponedjeljak, 15. lipnja**: 301XXXX 301XXXX-C3dSA2v2.eds, 301XXXX 301XXXX-SA2v2.eds, 301XXXX LSA2 LC1689 LSA Class II Worksheet v2, LC1607 301XXXX LSA2 C3d Detection Graph v2). Revidirane datoteke su na kraju označene s v2. Ova komunikacija s klijentima izdana je s detaljnim smjernicama o pregledu potencijalno pogođenih rezultata.

## **Radnje koje moraju poduzeti kupci:**

Poduzmite sljedeće radnje:

### Uvezite revidirane EDS datoteke (potrebno za buduću analizu)

1. Preuzmite revidiranu EDS datoteku za pogođenu/e seriju/e.
  - 301XXXX 301XXXX-C3dSA2v2.eds
  - 301XXXX 301XXXX-SA2v2.eds
  - 301XXXX LSA2 LC1689 LSA Class II Worksheet v2
  - LC1607 301XXXX LSA2 C3d Detection Graph v2
2. Uvezite ažuriranu EDS datoteku koja sadrži ispravke za Antigen ID-ove 242 i 244.
3. Primijenite ovu EDS datoteku kako biste osigurali da sve buduće analize koriste ispravljeno mapiranje antigena.

### Pregledajte pogođene obrasce reaktivnosti

1. Identificirajte uzorke s reaktivnošću na antigene povezane s DQB1\*02, posebno Antigen s ID-ovima 242 i 244
2. Dati prioritet pregledu slučajeva gdje razlika između DQB1\*02:01 i DQB1\*02:02 utječe na tumačenje
3. Potvrdite mogu li prethodno prijavljeni rezultati biti pogođeni na temelju dolje prikazanih obrazaca.

ID Antigena	Specifičnost	DQB1*02:01	DQB1*02:01	DQB1*02:02	DQB1*02:0
		Opaženo	Ispravka	Opaženo	Ispravka
242	DQB1*02:01	Negativno	Pozitivno	Pozitivno	Negativno
243	DQB1*02:01	Pozitivno	Pozitivno	Negativno	Negativno
244	DQB1*02:02	Pozitivno	Negativno	Negativno	Pozitivno
245	DQB1*02:02	Negativno	Negativno	Pozitivno	Pozitivno
246	DQB1*02:02	Negativno	Negativno	Pozitivno	Pozitivno

(Neobavezno) Ponovno analizirajte uzorke s ažuriranom EDS datotekom

Opcija A – Ponovni uvoz podataka serije (potpuna ponovna analiza)

1. Uvezite ažuriranu EDS datoteku.
2. Izbrišite pogodoenu/e seriju/e.
3. Ponovno uvezite izvorne CSV datoteke/datoteke serije.
4. Dopustite softveru da ponovno izračuna rezultate s ispravljenim mapiranjem antigena.

Opcija B – Pokretanje ponovne analize unutar softvera (Ciljano)

1. Uvezite ažuriranu EDS datoteku.
2. Idite na specifične uzorke od interesa identificirane tijekom pregleda pogodne reaktivnosti.
3. Izvršite softversku radnju (npr. prebacivanje/ponovnu obradu) za regeneriranje statistike pomoću novih dodjela antigena.

Potvrdite primitak ove obavijesti slanjem ispunjenog obrasca za odgovor putem e-pošte na [vigilance.eu@werfen.com](mailto:vigilance.eu@werfen.com) ili poštom na adresu: Immucor Medizinische Diagnostik GmbH, RA/QA, Robert-Bosch-Strasse 32, 63303 Dreieich, Njemačka, by **3. srpnja 2026.**, kako bismo kompletirali evidenciju.

Ispričavamo se zbog neugodnosti koje je ovaj problem prouzročio. Cijenimo povjerenje koje imate u naše proizvode. Ako su vam potrebne dodatne informacije, obratite se lokalnom stručnjaku za tehničku prodaju.

S poštovanjem,

Signed by Jimyung Moon



Jimyung Moon

I approve this document  
2026-06-18 | 11:52:57 PM PDT

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2026-06-18

Dr. Jimyung Moon  
Manager Quality Systems  
Deputy – Person Responsible for Regulatory Compliance  
Immucor Medizinische Diagnostik GmbH

**Obvezni obrazac za odgovor kupca**

Potvrđujem da je naša ustanova upoznata s ovom obavijesti <b>EU FA 26-07 FA-WKS-26-004</b> za gore navedene <b>LIFECODES LSA Class II Kit serije</b> i poduzela potrebne radnje.
<b>ŠIFRA KUPCA</b>
Ustanova:
Ime i prezime:
Radno mjesto:
Adresa:
Telefon:
Količina primljenih kompleta:  3016677:                      3016531: 3016316:                      3016099:
Datum/Potpis:

**Pošaljite e-poštom na [vigilance.eu@werfen.com](mailto:vigilance.eu@werfen.com) ili**

**poštom na adresu:  
Immucor Medizinische Diagnostik GmbH  
RA/QA  
Robert-Bosch-Strasse 32  
63303 Dreieich  
Njemačka**

## Urgent: Distributor Field Safety Notice

June 19, 2026

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

<b>Manufacturer:</b> <b>werfen</b>  Immucor GTI Diagnostics, Inc. 20925 Crossroads Circle Waukesha, WI 53186 USA <a href="http://werfen.com">werfen.com</a>	<b>Authorized Representative in EU:</b> <b>werfen</b>  Immucor Medizinische Diagnostik GmbH Robert-Bosch-Str. 32 63303, Dreieich Germany <a href="http://werfen.com">werfen.com</a>
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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.

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	DQB1*02:01	DQB1*02:02	DQB1*02:0
		Observed	Correction	Observed	Correction
<b>242</b>	<b>DQB1*02:01</b>	<b>Negative</b>	<b>Positive</b>	<b>Positive</b>	<b>Negative</b>
<b>243</b>	<b>DQB1*02:01</b>	<b>Positive</b>	<b>Positive</b>	Negative	Negative
<b>244</b>	<b>DQB1*02:02</b>	<b>Positive</b>	<b>Negative</b>	<b>Negative</b>	<b>Positive</b>

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](mailto: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,

Signed by Jimyung Moon



Jimyung Moon

I approve this document  
2026-06-18 | 11:51:55 PM PDT

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2026-06-18

Dr. Jimyung Moon  
Manager Quality Systems  
Deputy – Person Responsible for Regulatory Compliance  
Immucor Medizinische Diagnostik GmbH

**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](mailto:vigilance.eu@werfen.com) or**

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