URGENT: FIELD SAFETY NOTIFICATION

Datum: 2 August 2022 **EU FA #22-01 - FA-IMD-22-001**

Cijenjeni korisniče,

Naši zapisi ukazuju na to da ste dobili jedan ili više sljedećih proizvoda:

Naziv proizvoda	Broj proizvoda	Broj serije	Datum isteka valjanosti
Automatizirani immuClone Anti-K (Kell) IgM	0066088	922040	30. 11. 2022.
Automatizirani immuClone Anti-K (Kell) IgM	0066088	922041	30. 4. 2023.
Automatizirani immuClone Anti-K (Kell) IgM	0066088	922042	31. 10. 2023.
Automatizirani immuClone Anti-K (Kell) IgM	0066088	922043	30. 4. 2024.

Proizvođač
Immucor Medizinische Diagnostik GmbH
Robert-Bosch-Str. 32
63303 Dreieich
Njemačka
+49 (0) 6103 80560
www.immucor.com

Pojedinosti izdanja:

Tijekom prijenosa gore navedenih proizvoda u Propis o IVD medicinskim uređajima (EU) 2017/746, naš dobavljač naveden u oznaci proizvoda Automatizirani immuClone Anti-K (Kell) IgM je obavijestio tvrtku Immucor Medizinische Diagnostik GmbH kako je klon K1.1.21.HM.EF zapravo klon MS-56.

Klon identificiran u uputama za korištenje, K1.1.21.HM.EF, temeljen je na dokumentaciji koju je dao dobavljač. Tvrtka Immucor Medizinische Diagnostik GmbH nema saznanja o tome da je stvarni klon drugačiji, kao ni o neispravnom brendiranju.
Kako nema utjecaja na razinu djelotvornosti ustanovljenu za proizvod, vjerojatnost pojave škodljivosti za pacijenta ostaje niska.

Utjecaj na proizvod:

Nema utjecaja na djelotvornost i rezultate proizvoda.
Zbog neispravnog označavanja će se proizvod Automatizirani immuClone Anti-K (Kell) IgM povući s tržišta.

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Radnje koje smo poduzeli:

Tvrtka Immucor Medizinische Diagnostik GmbH će pružiti informacije nadležnim tijelima i pokrenuti opoziv proizvoda. EC certifikat za gore navedeni proizvod više ne vrijedi.
Osim toga, procijenit ćemo utjecaj na rezultate glede nacionalnih propisa, poput zahtjeva za korištenjem različitih klonova.

Radnje koje vi trebate poduzeti:

1) Popunite Obrazac odgovora koji se nalazi na stranici 3 ove poruke. Vratite obrazac odgovora putem faksa na broj +49 6103 8056 6393, e-pošte na vigilance.eu@immucor.com ili poštom na adresu: Immucor Medizinische Diagnostik GmbH, RA/QA, Robert-Bosch-Strasse 32, 63303 Dreieich, Njemačka.
2) Potvrdite da je preostali inventar uništen.

Cijenimo vaše povjerenje u naše proizvode. Kontaktirajte svoju lokalnu tehničku podršku na broj +49 (0) 6103 8056-100 ili na tech.support.eu@immucor.com za pomoć ili za dodatne upute ako trebate daljnju podršku.

Ispričavamo se zbog neugodnosti koje je ovaj problem možda prouzročio.

Srdačan pozdrav,

DocuSigned by Maria Wilhelmi
Maria Wilhelmi | I approve this document
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Maria Wilhelmi
Sr. Director RA/QA

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Obrazac odgovora klijenta

Potvrđujem kako je naša ustanova obaviještena o korektivnim radnjama za terensku sigurnost proizvoda Automatizirani immuClone Anti-K (Kell) IgM i kako je preostali inventar uništen, _____	
Ime tiskanim slovima:	
Potpis:	**Datum:**
Položaj:	
Ustanova / Institucija:	

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URGENT: FIELD SAFETY NOTIFICATION

Date: 1 August 2022 **EU FA #22-01 - FA-IMD-22-001**

Dear Valued Distributor,

Our records indicate that you have received one or more of the following products:

Product Name	Product Number	Lot Number	Expiry Date
Automated immuClone Anti-K (Kell) IgM	0066088	922040	2022-11-30
Automated immuClone Anti-K (Kell) IgM	0066088	922041	2023-04-30
Automated immuClone Anti-K (Kell) IgM	0066088	922042	2023-10-31
Automated immuClone Anti-K (Kell) IgM	0066088	922043	2024-04-30

Manufacturer
Immucor Medizinische Diagnostik GmbH
Robert-Bosch-Str. 32
63303 Dreieich
Germany
+49 (0) 6103 80560
www.immucor.com

Issue details:

During the transfer of the above-mentioned product to the Regulation on IVD Medical Devices (EU) 2017/746, our supplier listed in the product labeling of Automated immuClone Anti-K (Kell) IgM informed Immucor Medizinische Diagnostik GmbH, that the clone K1.1.21.HM.EF is indeed clone MS-56.

The clone identified in the instructions for use, K1.1.21.HM.EF, was based on the documentation provided by the supplier. Immucor Medizinische Diagnostik GmbH had no knowledge that actual clone was different and of the incorrect branding.
As the performance level established for the product is not affected, the probability for occurrence for patient harm remains low.

Product Impact:

The performance of the product and the results are not affected.
Due to the incorrect labeling Automated immuClone Anti-K (Kell) IgM will be withdrawn from the market.

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Our Actions Taken:

Immucor Medizinische Diagnostik GmbH will provide the information to the competent authorities and initiate the recall of the product. The EC certification for the above-mentioned product is no longer valid.
In addition, we will evaluate the impact on the results with regards to national regulations, such as the requirement to use different clones.

Distributor Actions to Be Taken:

1) The customer notice contains a response verification form on page 3 that we have prepared for customers. As a field correction to our action, we ask that you distribute the attached customer notice to your customers or provide them with a reasonable translation. The response verification is intended to assist you and us in determining if the customer received and understood this notification.
2) Please complete the Distributor Response Form included on page 3 of this communication. Return the response form by fax to +49 6103 8056 6393, email to vigilance.eu@immucor.com or mail to: Immucor Medizinische Diagnostik GmbH, RA/QA, Robert-Bosch-Strasse 32, 63303 Dreieich, Germany.
3) Confirm that the remaining inventory has been destroyed.

Customer Actions to Be Taken:

1) Please complete the Response Form included on page 3 of the customer communication. Return the response form by fax to +49 6103 8056 6393, email to vigilance.eu@immucor.com or mail to: Immucor Medizinische Diagnostik GmbH, RA/QA, Robert-Bosch-Strasse 32, 63303 Dreieich, Germany.
2) Confirm that the remaining inventory has been destroyed.

We appreciate the trust and confidence you place in our products. Please contact your local Technical Support under +49 (0) 6103 8056-100 or at tech.support.eu@immucor.com for assistance or additional instructions should you need further support.

We apologize for inconveniences this issue may have caused.

Sincerely,

DocuSigned by Maria Wilhelmi
Maria Wilhelmi | I approve this document
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Maria Wilhelmi
Sr. Director RA/QA

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Distributor Response Form

I verify that our facility was made aware of the Field Safety Corrective Action for Automated immuClone Anti-K (Kell) IgM and that any remaining inventory has been destroyed, _____	
Printed Name:	
Signature:	**Date:**
Position:	
Facility / Institution:	
Other Countries, where the product has been distributed:	

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