

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

Dear Valued Customer,

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Due to the incorrect labeling Automated immuClone Anti-K (Kell) IgM will be withdrawn from the market.

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 The EC certification for the above-mentioned product is no longer valid.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.

Your Actions to Be Taken:

- 1) Please complete the 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.
- 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
01-Aug-2022 | 12:24:45 PM CEST
6158156DCC844B7DAC3E215F60772834

Maria Wilhelmi
Sr. Director RA/QA

FSCA: EU FA #22-01 - FA-IMD-22-001

Customer 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, <hr/> | |
| Printed Name: | |
| Signature: | Date: |
| Position: | |
| Facility / Institution: | |