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Date: 07 June 2022  
Subject: MabTrack level infliximab kit (M2920)

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## URGENT FIELD SAFETY NOTICE

Ref: 188282

Dear Customer,

We regret to have to inform you that we have identified a potential production error of Control 1 and Control 2 of the following product:

Name	Product number	Kit lot Number	Expiry date
MabTrack level infliximab	M2920	8000455783	16.02.2023

According to our information, your lab has received one or more kits with the above-mentioned lot number. Based on our risk-analysis, there is a minor chance that your kit contains a control that generates an out of specification result.

This notice needs to be passed on to all those who need to be aware within your organisation or to all organisations the potentially affected devices have been sent to.

### Impact

If your kit contains a control that generates an out of specification result, observed results will not be valid for interpretation, as described in the Instructions For Use (IFU). Since the infliximab drug level is one of the main decisive parameters in the treatment of children with severe Inflammatory Bowel Disease<sup>1</sup>, a delay in measurement result could have serious consequences.

### Action

We request you to do the following:

1. Stop using the Mabtrack level infliximab kit with lot number 8000455783. If there is urgent need for measuring infliximab concentrations in patient samples before the replacement kit has arrived, please contact us via email [reagents@sanquin.nl](mailto:reagents@sanquin.nl) or phone our product manager Mr. Bram de Jong mobile: + 31 6 15 43 73 64.

2. Please complete the attached 'Declaration Document' within 10 days and send it to reagents@sanquin.nl. We will replace all kits you declared to have received free of charge. Please note that the replacement kits contain standards and controls calibrated against the NIBSC-standards. Also see the customer notification REF133757 sent on the 15<sup>th</sup> of April 2022.
3. Please **complete and return** the attached 'Declaration of Destruction' form of all not used Mabtrack level inflixmab kits with lot number 8000455783 and return it to reagents@sanquin.nl.

Should you have any questions, please contact our product manager Bram de Jong (mobile: + 31 6 15437364) or email: [reagents@sanquin.nl](mailto:reagents@sanquin.nl).

Our sincere apologies for any inconvenience caused and we thank you in advance for your full cooperation.

[Redacted signature block]

- 1) **The Medical Management of Paediatric Crohn's Disease: an ECCO-ESPGHAN Guideline Update**  
Patrick F van Rheenen, Marina Aloj, Amit Assa, Jiri Bronsky, Johanna C Escher, Ulrika L Fagerberg, Marco Gasparetto, Konstantinos Gerasimidis, Anne Griffiths, Paul Henderson, Sibylle Koletzko, Kaija-Leena Kolho, Arie Levine, Johan van Limbergen, Francisco Javier Martin de Carpi, Víctor Manuel Navas-López, Salvatore Oliva, Lissy de Ridder, Richard K Russell, Dror Shouval, Antonino Spinelli, Dan Turner, David Wilson, Eytan Wine, Frank M Ruemmele ; *Journal of Crohn's and Colitis*, Volume 15, Issue 2, February 2021, Pages 171–194, <https://doi.org/10.1093/ecco-jcc/jjaa161>

**DECLARATION DOCUMENT**  
**REF188282**

**Institute**

Name

Department

Address

Country

**Contact person**

Name

Job title

Telephone

Email

**Product information**

A. Total number of kits with following lot number at institute (lot 8000455783)

Number of kits used

Number of kits in stock

A. Patient population (please tick all that applies)

Children

Adults

B. Did you encounter any problems with the aforementioned lots? No  / yes

If yes, please specify:

Signature

Date

Please complete this Declaration Document and return it to [reagents@sanquin.nl](mailto:reagents@sanquin.nl).

**DECLARATION OF DESTRUCTION  
REF188282**

**Institute**

Name

Department

Address

Country

**Contact person**

Name

Job title

Telephone

Email

**Information**

A. We have **discarded/destroyed** our in stock MabTrack level infliximab kit(s) with lot number: **8000455783**.

No  / yes

B. Specify the number of kits and lot number(s) you have discarded/destroyed:

Signature

Date

Please complete this document and return it to [reagents@sanquin.nl](mailto:reagents@sanquin.nl).