

Date : 03 February 2022
Subject : MabTrack level infliximab kit (M2920)

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FIELD SAFETY NOTICE

Ref: 181410

Dear Customer,

We regret to inform you that we have identified a production issue involving the following product:

Name	Product number	Kit Lot Number	Exp. date
MabTrack level infliximab	M2920	8000453601 8000454131 8000455051 8000455209 8000455211	16.02.2023

According to our information, your lab has received one or more of these affected kit lots. There is a small chance that your kit contains a defective microtiter plate.

Impact

If your kit contains a defective microtiter plate, no results will be generated and wells of the plate will remain transparent. As a consequence, you may encounter a delay in infliximab drug level measurement. Since the infliximab drug level is one of the main decisive parameters in the treatment of children with severe Inflammatory Bowel Disease¹, a delay in measurement result could have serious consequences.

Action

We request you to do the following:

1. Do **not** assemble plates with strips from different kits. Even if kits/plates contain the same lot number. Only use strips from the same package.
2. When the above precaution is followed, aforementioned kits can still be used and reliability of results is not affected. Please note that if calibrators and controls do not generate a result, the plate must be considered erroneous and cannot be used for further testing. Please inform Sanquin Reagents in this case via reagents@sanquin.nl.

3. Please complete the attached 'Declaration Document' within 10 days and send it to reagents@sanquin.nl. We will replace the kits you have in stock free of charge. Extra tests will be performed to ensure these replacement kits do not contain defective plates.

Should you have any questions, please contact our product manager Mr. Bram de Jong (mobile: + 31 6 15 43 73 64 or email: reagents@sanquin.nl).

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

Yours sincerely,



H.J. Bos
Manager QA/QC

- 1) **The Medical Management of Paediatric Crohn's Disease: an ECCO-ESPGHAN Guideline Update**
Patrick F van Rheenen, Marina Aloï, 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

Institute

Name

Department

Address

Country

Contact person

Name

Job title

Telephone

Email

Product information

A. Total number of kits with following lot numbers at institute (lot 8000453601, 8000454131, 8000455051, 8000455209, 8000455211)

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.