



Hain Lifescience GmbH | Hardwiesenstr. 1 | 72147 Nehren (Germany)

[Address customer/distributor]

Managing Directors:

David Hain
Tobias Hain
John Daniel Carr
Dr. Wolfgang Pusch

Registered Office: Nehren
HRB 381410
AG Stuttgart
Tax number: 86/113/6100/8

Your reference:

[customer number]

Our reference:

GXT_NA_2019-02

Contact person:

Dr. Steffen Schlag

Place, date:

Nehren, February 20, 2019

Urgent Field Safety Notice

Concerning

Kit Lot TD00046 of

GXT NA Extraction Kit VER 1.0 from Hain Lifescience GmbH

Identification of the concerned IVD:

GXT NA Extraction Kit VER 1.0, order no. 12.08.02 (96 samples), **kit lot TD00046**

Description of the problem and determined cause:

Our records indicate that you have received kit lot TD00046 of **GXT NA Extraction Kit VER 1.0**.

Due to a malfunction during the filling process some of the reagent cartridges (lot number 71801-112018) included in kit lot TD00046 may not contain Magnetic Beads (see figures 1 to 3).

Using a reagent cartridge that does not contain Magnetic Beads in conjunction with an internal extraction control will likely lead to an invalid result in downstream applications (e. g. PCR).

Fig. 1:

The lot number of the reagent cartridges included in kit lot TD00046 of **GXT NA Extraction Kit VER 1.0** is imprinted on the top side of the cartridges: **LOT** 71801-112018.



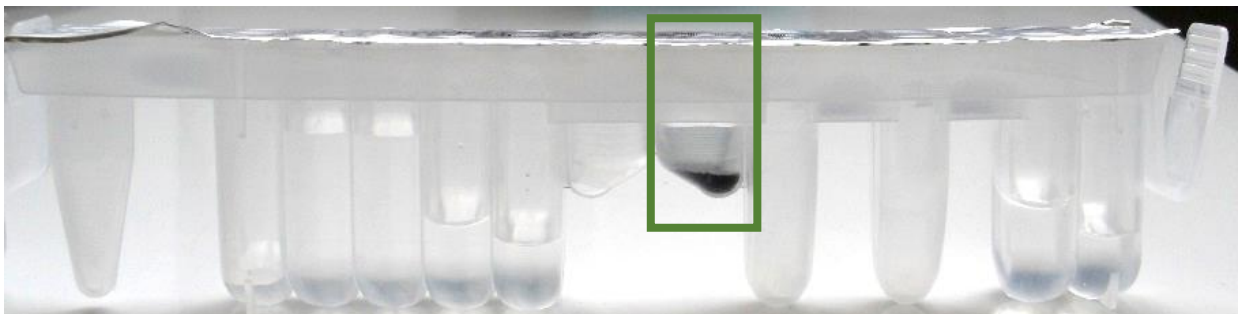
Fig. 2:

Example of a reagent cartridge that does not contain Magnetic Beads in well 8



Fig. 3:

Example of a reagent cartridge with correct filling of Magnetic Beads in well 8 (500 µl of Magnetic Bead Solution; depicted are sedimented beads)



What measures need to be taken?

Before using kit lot TD00046 of **GXT NA Extraction Kit** VER 1.0, please verify that the reagent cartridge contains Magnetic Beads in well 8 (see Fig. 1 to 3; lot number of the cartridges: 71801-112018). Please only use the cartridge if it contains Magnetic Beads in well 8.

If you identify a reagent cartridge included in kit lot TD00046 that does not contain Magnetic Beads, please do not use it and discard it according to your local regulations. In this case, please contact your local distributor. You will be provided with new kits at no charge.

If you have used the affected kit lot TD00046 we recommend reviewing the corresponding results of downstream applications (e. g. PCR) and checking for irregularities, e. g. for an increased occurrence of invalid results. In case you have noticed any irregularities, please contact your local distributor.

In general, the use of internal extraction controls will continuously ensure that any issue encountered during nucleic acid extraction is adequately detected.

Commercial partners/distributors:

Distribution of kit lot TD00046 of **GXT NA Extraction Kit** VER 1.0 must be stopped. If you have kit lot TD00046 in stock please contact our support team (see below).

Circulation of this information:

Please make sure that this **Urgent Field Safety Notice** is forwarded to all end users of the product specified above as well as all persons who have to be informed in your organization. If the respective product has been passed on to a third party, please forward this message to them and inform us accordingly (see contact person below).

Commercial partners/distributors:

Please forward this **Urgent Field Safety Notice** to your customers and follow up on the acknowledgement of receipt with your customers.

Please preserve this letter at least until all described measures have been taken and the issues are resolved.

The German *Federal Institute for Drugs and Medical Devices* received a copy of this **Urgent Field Safety Notice**.

According to applicable regulations we are obliged to report all corrective actions to the competent authorities.

Therefore, please return the attached response letter (page 5) as notice of receipt via fax or e-mail until March 08, 2019.

We are deeply sorry for our mistake and would like to apologize for any inconvenience this may have caused.

Thank you very much for your cooperation and understanding.

Please do not hesitate to contact us directly with any further questions and concerns via:

Contact person:

Andrea Kühn (Support)

Phone: +49 - 74 73 - 94 51 - 744

Fax: +49 - 74 73 - 94 51 - 31

E-Mail: Support.mdx.de@bruker.com

Yours sincerely,

A handwritten signature in blue ink, appearing to read "Steffen Schlag".

Dr. Steffen Schlag

Safety Officer (medical devices pursuant to §30(2) Medical Device Act)

Hain Lifescience GmbH

Reply to **Urgent Field Safety Notice**

concerning **Kit Lot TD00046** of **GXT NA Extraction Kit** VER 1.0 from Hain Lifescience GmbH

Please send by fax to +49 - 74 73 - 94 51 - 31 or
via e-mail to Support.mdx.de@bruker.com.

[Address customer/distributor]

Confirmation of receipt of Hain Lifescience notice from February 20, 2019

We herewith confirm receipt of the **Urgent Field Safety Notice**

concerning **Kit Lot TD00046** of **GXT NA Extraction Kit** VER 1.0 from Hain Lifescience GmbH
from February 20, 2019, and assure to take the demanded necessary steps.

City, date, name in block letters, legally binding signature