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

[Adress customer/distributor]

Managing Directors:

David Hain
Tobias Hain
Dr. Wolfgang Pusch

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

Your reference:	Our reference:	Contact person:	Place, date:
[customer number]	SUB-D_2019-09	Leon Detzell	Nehren, September 19, 2019

Urgent Field Notice

Concerning

Lots G0119 and G0319 of

the **kit constituent Substrate Buffer (SUB-D)**

of the **GenoType Test Systems** from Hain Lifescience GmbH

Identification of the concerned IVDs:

The affected kit constituent is part of the following products/lots:

Brand Name	Cat no.	Kit lot:

Description of the problem:

Our records indicate that you have received at least one unit each of the above listed test kit(s) and respective lot(s).

Internal investigations showed that some bottles of lots G0119 and G0319 of the kit constituent SUB-D contain a small amount of organic foreign substance. Functionality of SUB-D is not impaired by the particles of up to 2 mm in diameter.

What measures need to be taken?

The small amount of the foreign substance does not influence functionality of SUB-D. Affected SUB-D bottles can still be used.

Nevertheless, before using a new SUB-D bottle, please check if it contains any of the foreign particles. In case foreign particles are visible, please decant the SUB-D solution carefully in order to avoid transfer of particles to the mixture of SUB-D and SUB-C. When adhering to SUB-D manipulation in the described way the substrate reaction will not be affected.

In general, the use of appropriate controls will continuously ensure that any issue encountered during hybridization is adequately detected.

In case of any questions regarding the described issue, please do not hesitate to contact Hain Lifescience (see contact person below) or your local distributor.

Circulation of this information:

Please make sure that this **Urgent Field Notice** is forwarded to all end users of the product(s) specified above as well as all persons who have to be informed in your organization. If the respective product(s) has/have 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 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 Notice**.

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

Hain Lifescience GmbH | Hardwiesenstraße 1 | 72147 Nehren | Tel. (0 74 73) 94 51 -0 | Fax -99 | www.hain-lifescience.de

Therefore, please return the attached response letter (page 4) as notice of receipt via fax or e-mail until October 4, 2019.

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

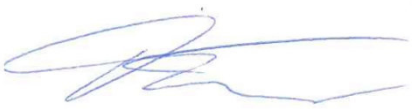
Thank you very much for your cooperation and understanding.

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,



Leon Detzell
Safety Officer (medical devices pursuant to §30(2) Medical Device Act)
Hain Lifescience GmbH

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Reply to **Urgent Field Notice** concerning

Brand name	Cat. no.	Kit lot:

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 September 19, 2019

We herewith confirm receipt of the **Urgent Field Notice** concerning the above-mentioned lot numbers from Hain Lifescience GmbH from September 16, 2019, and assure to take the demanded necessary steps.

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

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