Beispiel-Firma
Frau Mustermann
Musterstraßenplatz 12
Musterzusatz
23456 Musterstadt
Musterland

Hain Lifescience GmbH
Hardwiesenstraße 1
72147 Nehren
Germany

Date: 20/10/2021

Urgent Safety Information
(FSCA 12102021)

Information for the safe use

of the IVD products:

GenoType MTBDRplus Ver 2.0 / GenoType MTBDRsl 2.0/2,0

Addressee

Users and distributors

Identification of concerned IVD products.

Ref#	Product Name	Lot#		
30496A	GenoType MTBDRplus VER 2.0	OV00253	OV00244	OV00245
		OV00246	OV00248	OV00250
		OV00251	OV00252	-
304A	GenoType MTBDRplus VER 2.0	OU00243	OU00247	OU00249
		OU00254	-	-
317A	GenoType MTBDRsl VER 2.0	AAW00111	-	-
31796A	GenoType MTBDRsl VER 2.0	AAX00112	-	-

30496AGL	GenoType MTBDRplus VER 2,0	VR00126	VR00128	VR00129
		VR00130	VR00131	VR00132
		VR00133	VR00134	-

Product Issue Statement and summary of root cause:

According to our records, you have received at least one kit of the above-mentioned kit lots.

We would like to inform you that the amplification control in the above-mentioned lots may show a weak positive signal in some cases, even if no amplification is performed. This can lead to a false-negative interpretation of the result.
The cause of this behavior is a slight activity of the hot-start polymerase at room temperature.

The amplification control serves to check the correct execution of the test and the functionality of the kit components, as well as an inhibition control for the amplification.

Results already generated are to be regarded as valid if a positive control was included in the PCR run or a positive result was present in the same run. If all the results are exclusively negative and do not match the overall clinical picture, additional diagnostic methods should be used.

What actions are to be taken by the addressee?

To avoid misinterpretation due to false-negative results, it is necessary to carry out a positive control.
In addition, preparation of the PCR should be carried out quickly without any interruptions. The PCR run should be started within one hour after preparing the PCR master mix.

Disclosure of described information:

Please ensure in your organisation that all users of the above Products and other persons are informed of this Urgent Safety Information.

If you have transferred the products to third parties, please forward a copy of this information or inform us via the contact details provided below.

Please retain this Safety Information Document at least until the measure has been completed.

The German Federal Institute for Drugs and Medical Devices has received a copy of

this "Urgent Safety Information".

Contact at Hain Lifescience:

Diagnostics.support@bruker.com

Signature

Kay Scherer

Response to **Urgent Safety Information (** FSCA 1210202) concerning:

Ref#	**Product Name**	**Lot#**		
30496A	GenoType MTBDRplus VER 2.0	OV00253	OV00244	OV00245
		OV00246	OV00248	OV00250
		OV00251	OV00252	-
304A	GenoType MTBDRplus VER 2.0	OU00243	OU00247	OU00249
		OU00254	-	-
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31796A	GenoType MTBDRsl VER 2.0	AAX00112	-	-
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		VR00130	VR00131	VR00132
		VR00133	VR00134	-

By E-Mail to Diagnostics.support@bruker.com

[Address Customer/Trading Partner]

Confirmation of acknowledgment of the urgent safety information by Hain Lifescience GmbH

I / we hereby confirm that I / we have received and acknowledged the urgent safety information regarding the above mentioned IVD Kit lots from Hain Lifescience GmbH and ensure the required procedure.

Place, Date, Name