

April 9, 2020

URGENT FIELD SAFETY NOTICE and CORRECTIVE ACTION

for

In-vitro-Diagnostic Medical Device (IVDD) Mentype® MycoDerm^{QS} Lateral Flow PCR3

Affected are the kit lots: DERM01357 und DERM01361

Field Safety Corrective Action (FSCA): Recall

Sender:

Biotype GmbH
Moritzburger Weg 67
01109 Dresden

Adresse:

Laboratory Manager and end-user of IVDD Mentype® MycoDerm^{QS} Lateral Flow PCR3

Product Identification:

Name: Mentype® MycoDerm^{QS} Lateral Flow PCR3

Reference Number: 45-17613-050

Kit Lot: DERM01357 und DERM01361

Description of the problem and the ascertained reason:

Dear Customer,

We would like to inform you as a user of our in vitro diagnostic medical device Mentype® MycoDerm^{QS} Lateral Flow PCR3 that the specific components LF Primermix, LF Control DNA, LF Hybrid Mix were incorrectly declared as PCR2 when the kitbox (shipping on dry ice) was externally labelled. However, the reference/item number (REF) 45-17613-050 of the outer stickers is correct. Similarly, the affected kit boxes also contain the correct kit components for performing the PCR3 and are also labelled correctly.

Detailed description of the issue

It is an incorrect marking of the kit boxes (repackaging of the individual components) which you have received on dry ice. However, the contents of the kit boxes (individual components and their marking) are correct.

Since correct labelling is a safety-relevant information of an in vitro diagnostic medical device, the affected batches should not be used.

Circulation of the information:

Please destroy the affected kit batches immediately.

Please make sure that the information of this Field Safety Notice (FSN) will be passed to all users within your organization and all other persons who should be informed. Please forward a copy of this information if you have delivered the product to third parties or inform a representative of our company, as named below. Please keep this information until the closure of this corrective action.

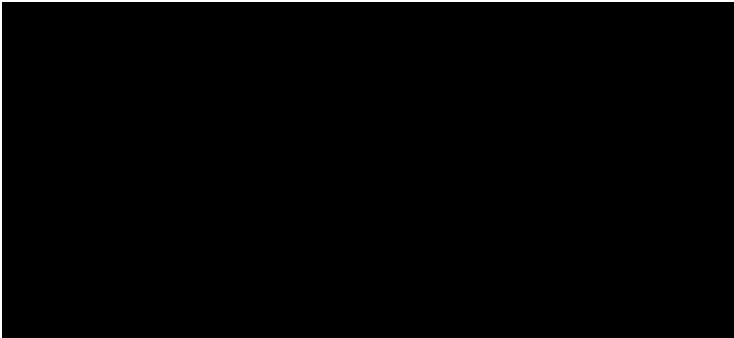
A copy of this Urgent Field Safety Notice was sent to The German Federal Institute for Drugs and Medical Devices (BfArM - Bundesinstitut für Arzneimittel und Medizinprodukte).

Contact Person:

Dr. Anja Seiler
Tel.: 0351-88 38 411
a.seiler@biotype.de

To ensure that all affected users are notified and that according to applicable national statutory provisions, we are obliged to provide the proof of notification in the market to the National Competent Authorities (NCA). Therefore, please complete and sign the included acknowledgement (attachment A) of the receipt form by April 24, 2020 and either email it to Biotype GmbH at support@biotype.de or fax it to ++49 (0)351 8838 403.

Yours sincerely,



Attachment AConformation of receipt and proof of disposal**Please return to:**

Biotype GmbH
Moritzburger Weg 67
01109 Dresden

Fax: +49 (0)351-8838 403

E-Mail: support@biotype.de

Sender:

Name of Institution _____
Contact Person: _____
Address: _____
Phone or E-Mail _____
Customer Number _____

Please check:

() I confirm the receipt of this letter and declare that I destroyed the Mentype® MycoDerm^{QS} Lateral Flow PCR3 kit (50 Reactions).

The following kit lots are affected: DERM01357 and DERM01361

Kit lot: _____

Number of kits: _____

Title, first name, family name: _____

Place, Date, Signature: _____