

February 11, 2019

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**URGENT FIELD SAFETY NOTICE and CORRECTIVE ACTION**  
**for**  
**In-vitro Diagnostic Medical Device (IVDD) Mentype® MycoDerm<sup>QS</sup> Lateral Flow**

**Field Safety Corrective Action (FSCA)**

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**Sender:**

Biotype Diagnostic GmbH  
Moritzburger Weg 67  
01109 Dresden  
Germany

**Addressee:**

Laboratory Manager and End-user of IVDD Mentype® MycoDerm<sup>QS</sup> Lateral Flow

**Product Identification:**

**Name:** Mentype® MycoDerm<sup>QS</sup> Lateral Flow

Catalogue Numbers:      PCR1: 45-17611-050

   PCR1: 45-17611-010

## Description of the problem and the reason:

Dear Valued Customer,

We would like to inform you as a user of the IVDD Mentype® MycoDerm<sup>QS</sup> Lateral Flow that we have identified a weak and non-homogenous color precipitate at the first detection line (*T. rubrum* band) which is close to the conjugate pad of the lateral-flow strip.

## Detailed description of the issue:

When using the IVDD Mentype® MycoDerm<sup>QS</sup> Lateral Flow PCR 1, a weak non-homogeneous color precipitate may be observed at the first detection line after the conjugate pad at PCR 1.

Hence, depending on the expression, a weak band at the level of the pathogen *T. rubrum* (PCR 1) can be observed in the process control (negative control) and in the samples.

The following notes or visual representations of the lateral flow strips should be considered in the evaluation of the lateral flow test.

## Note on process control (negative control):



1. The process control contains only the visible bands of the quality sensor (QS). This band also serves as a DNA extraction control, amplification, and inhibition control for the PCR, as well as as a running control, to demonstrate the functionality of the lateral flow test strip.

When evaluating the lateral flow strips, a non-homogenous color precipitate, which may appear in a weak form at the level of the *T. rubrum* band, is negligible. It is not a contamination because the TMEN band is missing. The representation of the process control with the visible bands of the quality sensor (QS) and the weak color precipitation is shown in Figure 1.

The occurrence of a TMEN band without or with a *T. rubrum* band in case of process control is a contamination. It is also a contamination if you detect a band at position 2 or 3 after the conjugate pad. The reagents are contaminated. Please initiate the appropriate measures.

**Figure 1:** Lateral flow test strips with the QS band and the weak non-specific color precipitate.

## Note on evaluation of a *T. rubrum*- or TMEN-positive PCR 1



1. PCR 1 comprises, at position 4 after the conjugate pad, an additional line for the group-specific detection of dermatophytes in sensu stricto *Trichophyllum*, *Microsporum*, *Epidermophyton*, and *Nannizzia* (TMEN-Zone). Within the sensitivity range of the observed non-specific *T. rubrum* zone, a positive TMEN zone must also be detected in the presence of the pathogen *T. rubrum*.

The TMEN signal serves as a confirmation test for *T. rubrum* so that a false positive result for this pathogen can be excluded.

When evaluating the lateral flow strips, please note that the detection of the pathogen *T. rubrum* is only positive in conjunction with the TMEN band. The intensities of the TMEN band and the *T. rubrum* band must be similar. Figure 2 shows the corresponding visual representation of the positive detection of the pathogen *T. rubrum*.

**Figure 2:** Lateral flow test strips with the typical positive control band pattern from PCR1 (original stripes)



2. PCR 1 comprises, at Position 4 after the conjugate pad, an additional line for the group-specific detection of dermatophytes in sensu stricto *Trichophyllum*, *Microsporum*, *Epidermophyton*, and *Nannizzia* (TMEN-Zone). The TMEN signal serves as a confirmatory test for the group-specific detection of dermatophytes.

The detection of a weak non-homogeneous color precipitate in the *T. rubrum* zone, together with the TMEN band, is a negative result for the pathogen *T. rubrum*.

Owing to the positive TMEN band, please perform the Mentype® **MycoDerm**<sup>QS</sup> Lateral Flow PCR 2 and 3 tests.

**Figure 3:** Lateral flow test strips with the quality sensor, the TMEN band, and a weak non-homogeneous color precipitate at the first detection line *T. rubrum* (marked in blue) (original strip).

### Actions which should be undertaken by the customer and/or the end-user:

- Please pay special attention to the changes in the instructions for use which are listed in the appendix to this letter.
- Please consider this in your medical findings and inform the matter to your customers (doctors).
- For questions or uncertainties regarding the evaluation, always read the chapter "Troubleshooting" (instruction for use).
- You will find the current version of the user manual on our homepage ([www.biotype.de](http://www.biotype.de)) or sent by email together with the field safety notice
- Forward this information to all individuals within your organization using the affected product lots.
- Please complete the acknowledgement of the receipt form attached to this letter and send it to us.
- Please contact us if you have any further questions.

**Actions performed by the manufacturer:**

- All technical documentation (instructions for use, homepage) have been adapted by the Biotype Diagnostic GmbH. A new user manual will be sent to you with this letter or is available for download on the homepage ([www.biotype.de](http://www.biotype.de)).

**Circulation of the information:**

Please make sure that the information of this field safety notice (FSN) is passed to all users in your organization and all other persons who should be informed. Please forward a copy of this information if you have already 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.

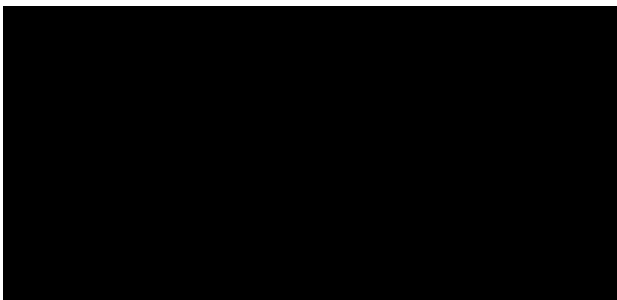
A copy of this urgent field safety notice was sent to The German Federal Institute for Drugs and Medical Devices (BfArM - Bundesinstitut für Arzneimittel und Medizinprodukte).

**Contact Person:**

Dr. Anja Seiler  
Tel.: 0351-88 38 411  
[a.seiler@biotype.de](mailto:a.seiler@biotype.de)

To ensure that all affected users are notified, as well as according to the 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 of the receipt form by February 28, 2019, and either email it to the Biotype Diagnostic GmbH at [service@biotype.de](mailto:service@biotype.de) or fax it to +49 (0)351 8838 403.

Yours sincerely,



1. Attachment A: Excerpts from the new instructions for use (pp. 25–27)
2. Attachment B: Acknowledgement of the receipt form
3. Instructions for use

Attachment A: Excerpts from the new instructions for use (pp. 25–27)

**7. Troubleshooting**

**7.1 PCR amplification**

Usage of a thermocycler with an uncoated aluminum block:

If the PCR band and/or the band of the QS is missing, please check the block of your thermocycler. Please use the following PCR parameter when your thermocycler is equipped with an uncoated aluminum block:

Temperature	Time
96 °C	4 min ( <b>hot start</b> for activation of the Multi Taq2 DNA Polymerase)
96 °C	30 s
60 °C	120 s
72 °C	75 s
10 °C	∞ until the end

For carrying out the PCR amplification, a **heating rate** (ramping) of the thermocycler at **3 °C/s** should be used.

PCR product present, QS band suppressed or missing entirely:

In an unfavorable concentration ratio of the QS and the pathogen DNA, the Quality Sensor's band can be suppressed because of a too-high concentration of pathogen DNA in the PCR. To ensure the validity of the reaction, please repeat the PCR with diluted sample DNA (e.g. 1:4). The QS band should be always present.

Note on process control (negative control):



The process control contains only the visible bands of the Quality Sensor (QS). This band also serves as a DNA extraction control, amplification, and inhibition control for the PCR and as a running control to demonstrate the functionality of the lateral flow test strip.

When evaluating the lateral flow stripes, there is a negligible non-homogenous color precipitate, which may appear in a weak form at the level of the *T. rubrum* band. It is not a contamination because the TMEN band is missing. The representation of the process control with the visible bands of the QS and the weak color precipitation is shown in Illustration 4.

The occurrence of a TMEN band without or with a *T. rubrum* band in the case of process control is a contamination. It is also a contamination if you detect a band at Position 2 or 3 after the conjugate pad. The reagents are contaminated. Please initiate the appropriate measures.

**Illustration 4:** Lateral flow test strips with QS band and weak nonspecific color precipitate.

Reagents are contaminated:

- Always use freshly pipetted reaction mixtures.
- Make sure that the pipettes are not contaminated; they should be regularly cleaned/sterilized.
- Use filter-tips to avoid contamination.
- Use a separate pipette set for the pre- and post-PCR processing.
- Seal each individual reaction mixture after processing.
- Change your gloves regularly.

#### **Note on evaluation of a *T. rubrum*- or TMEN-positive PCR 1**



1. PCR 1 comprises, at Position 4 after the conjugate pad, an additional line for the group-specific detection of dermatophytes in sensu stricto *Trichophyton*, *Microsporum*, *Epidermophyton*, and *Nannizzia* (TMEN-Zone).

In the sensitivity range of the observed non-specific *T. rubrum* zone, a positive TMEN zone must also be detected in the presence of the pathogen *T. rubrum*. The TMEN signal serves as a confirmatory test for *T. rubrum*, meaning that the likelihood of a false positive result for this pathogen can be excluded.

When evaluating the lateral flow stripes, please note that the detection of the pathogen *T. rubrum* is **only** positive in conjunction with the TMEN band. The intensity of the TMEN band and the *T. rubrum* band must be similar. Illustration 5 shows the corresponding visual representation of the positive detection of the pathogen *T. rubrum*.

**Illustration 5:** Lateral flow test strips with the typical positive control band pattern from PCR1 (original stripes)



2. PCR 1 comprises, at Position 4 after the conjugate pad, an additional line for the group-specific detection of dermatophytes in sensu stricto *Trichophyton*, *Microsporum*, *Epidermophyton*, and *Nannizzia* (TMEN-Zone).

The TMEN signal serves as a confirmatory test for the group-specific detection of dermatophytes.

The detection of a weak, non-homogeneous color precipitate in the *T. rubrum* zone together with the TMEN band is a negative result for the pathogen *T. rubrum*.

Due to the positive TMEN band, please perform the Mentype® **MycoDerm**<sup>QS</sup> Lateral Flow PCR2 and three tests.

**Illustration 6:** Lateral Flow test strips with the Quality Sensor, the TMEN band, and a weak, non-homogeneous color precipitate at the first detection line *T. rubrum* (marked in blue) (original strip).

Attachment B: Acknowledgment of Receipt

**Please return to:**

**Biotype Diagnostic GmbH**

Moritzburger Weg 67  
01109 Dresden

Fax: +49 (0)351-8838 403

Email: [support@biotype.de](mailto:support@biotype.de)

**Sender:**

Name of the Organization / Company \_\_\_\_\_

Contact Person: \_\_\_\_\_

Address: \_\_\_\_\_

Phone or email: \_\_\_\_\_

Customer Number, if available: \_\_\_\_\_

**Please check**

( ) I confirm the receipt of this letter and declare that I am only using the newly sent version of the instructions for the use of " Mentype-MycoDerm-Lateral-Flow-Instructions-for-use-CEVD-MDLFGAv4en."

**Title, first name, family name readable:** \_\_\_\_\_

**Place, Date, Signature:** \_\_\_\_\_