Curetis GmbH · Max-Eyth-Straße 42 · 71088 Holzgerlingen · Germany

Holzgerlingen, 13. Feb 2017

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URGENT SAFETY INFORMATION

Instruction for dealing with false positive results from

Propionibacterium acnes

concerning

Unyvero BCU BLOOD CULTURE Application

Contact person: [redacted]
Department: Marketing
Phone.: +49(0)7031 49195-[redacted]
Fax: +49(0)7031 49195-[redacted]
e-mail: support@curetis.com

Dear Customer

According to our recording, the following products were delivered to you:

Product description:

Art.# 10051 Unyvero BCU Cartridge Set

- Lot Number 02057 (includes BCU Cartridge Lot 02055)
- Lot Number 02112 (includes BCU Cartridge Lot 02096).

Description of the problem:

Background corrective action:

As a part of our ongoing quality controls was ascertained that in the application of the BCU Cartridge false positive results of the *Propionibacterium acnes* can occur.

Description of the product problems:

The control measurement shows that a signal above the threshold for *Propionibacterium acnes* even this pathogen was not present in the sample. A false positive signal was displayed on the overview and the detailed results screen.

- Possible false positive results above the threshold can lead to a false diagnosis of an infection with *Propionibacterium acnes* if the clarification is missing or delayed by the microbiological culture.
- In case of an infection with a microorganism not covered by the specific analyte of the BCU system, a false positive *P.acnes* signal could be erroneously interpreted as the cause of infection. Further studies on the microorganism identification may not be initiated.

This failure only concerned the measurement of *Propionibacterium acnes* in the BCU application. All further applications are not affected (e.g. ITI Cartridge)

Malfunction and cause:

The described failure is caused by defective or contaminated PCR chambers.

Impact to the patients:

Risk to patients, who have already been treated

The samples used for the Unyvero BCU cartridge are positive blood culture bottles in which microorganisms grew. These can be pathogens, which are detected by the Unyvero Cartridge, but also those that are not shown on the panel. In the first case, the risk is falsely detecting a *P.acnes* co-infection. In the second scenario, the clinical picture of a *P.acnes* infection would be assigned and possibly further investigations on the causative pathogen identification would not be initiated. Since the panel covers over 90% of the clinical relevant pathogens, this situation should only occur in a few cases.

The detection of *P.acnes* must be carefully weighed and interpreted in the context of the clinical picture since *P. acnes* is often found as a contaminant in blood culture bottles inoculated with native blood or other body fluids. These are described in the literature with regard to bacteremia in more than 90% of cases, with endocarditis up to 75% and for infections as a result of the use of medical products depending on the type of the implant with approximately 20%.

Depending on the suspicious diagnosis and being tested sample material there are different risks for the patients:

A *P. acnes* bacteremia is rarely clinically relevant (approximately 3% of the cases) and the assessment of the *P. acnes* result would be interpreted as contamination in most cases.

In the case of endocarditis, but also in the case of infections resulting from the use of medical products (e.g. implants, shunts), the false-positive result in blood culture or inoculated blood culture samples can result in inadequate therapies in both cases.

Rating of the risk

In general, the risk of pathogen infections is considered negligible.

Necessary actions:

Handling instruction what should be done with the affected product

The affected batches must be destroyed.

Recommendations for the follow-up of patients who have been treated

For all patients who were treated for *P. acnes* due to a result, the current therapy and, if necessary, the planning of upcoming surgeries should be re-examined using microbiological data.

Description of a safe application of the product until implementation of the measure

- Possible false-positive results can lead to a false diagnosis of infection with *P. acnes* if microbiological cultivation is not carried out or delayed. A corresponding finding is therefore absolutely necessary with an independent method, e.g. microbiological culture and to evaluate it in a clinical context.
- The described error only occurs with the BCU application, other Unyvero applications are not affected and can be used without restriction.
- Please dispose of the above affected batches immediately.

Please ensure in your organization that all users of the aforementioned products and other persons to be informed are aware of this urgent safety information. If you have distributed the products to any third party, please forward a copy of this information and inform the contact person listed below.

Please retain this information at least until the action has been completed.

The German Federal Institute for Drugs and Medical Devices or the competent authority has received a copy of this **urgent safety** information.

We regret this incident and apologize for any inconvenience this may have caused you.

For further questions please do not hesitate to contact us +49(0)7031 49195-[redacted]

Yours sincerely,

curetis

[redacted]

[redacted]

Appendix A: Acknowledgement t of receipt

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Please send it to Curetis GmbH:
Fax: +49(0)7031 49195-19

Name of the Hospital: _____

Customer number: _____

Contact person: _____

Postcode/ Place: _____

Questions:

	Yes	No
1. Have you read the instructions on using the BCU cartridge in the enclosed urgent safety information?	☐	☐
2. Have you followed the instructions and implemented the actions specified in this urgent safety information?	☐	☐
3. Have you received reports regarding a patient's injury, unnecessary medical treatment or a delay in the necessary medical treatment in connection with the *false positive results of Propionibacterium acnes?*	☐	☐
Comment:		

Date: _____

Signature: _____