Gesellschaft für Biochemica
und Diagnostica mbH

Max-Planck-Ring 21
65205 Wiesbaden · Germany

Telefon +49 6122 9988-0
Telefax +49 6122 9988-100

Urgent Field Safety Notice

Recall / Replacement

Humatex ASO

06.11.2017

Attention:
Distributors of HUMAN and end users of:

Details on affected devices
Cat. No. 40060, Lot 16008, 17004, 17005

Description of the problem:
During internal evaluations after a customer complaint we noticed that the above mentioned batches led to a agglutination upon reaction of the latex reagent with several negative patient sera, although the negative control material provided with the complete kit (Cat. Nos 40062, 40063) did not show agglutination. Thus the affected lots may provide false positive patient results which are not recognized by the negative control.
HUMAN thus recommends not using the above mentioned product lots anymore.

Advice on action to be taken by:
Distributor:
Please inform the end user of the above product lots about the problem described here, based on this customer information.

Please fill in the attached reply form confirming receipt and send it to customer-support@human.de. Kits still on stock of the distributor or the end user will be replaced as claimed in the Reply form.

User:
End users should stop using the affected lot and confirm receipt of the customer information to the local distributor. Any suspicious positive results (e.g. not in agreement with other information of patient status) should be reconsidered.

Transmission of this Field Safety Notice
This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

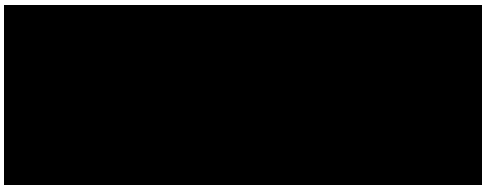
The Federal Institute for Drugs and Medical Devices (BfArM) and other National Competent Authorities of European countries, which are affected by the recall, received a copy of this urgent field safety notice

Contact reference person:
(for distributors only. Distributors should provide their own detailed contact information to their end users):

Sonja, Simonovic
Customer Support & Applications
e-mail: customer-support@human.de
Telephone: +49-6122-9988-383

We regret the inconvenience.

With kind regards,



Sonja Simonovic

Customer Support & Applications

Attachment
Reply Form

Reply Form

Urgent Field Safety Notice

For Humatex ASO
Cat. No. 40060, Lot 16008, 17004, 17005

Please return by e-mail this filled in and signed reply form latest until November 9th, 2017 to
E-mail address: customer-support@human.de

For distributors in the European Union:

- Please attach the Customer Information in your national language, which you have sent out to your end customers, as Human will be approached by your national Competent Authority to provide this.

I confirm receipt of this customer information and have informed all end customers, who have obtained the affected lot, in writing about the problem and the HUMAN recommendations.

I confirm that the affected kits in my stock and those kits, which will be returned from my customers, will be destroyed according to local regulations.

Number of kits of REF 40060, lot 16008 to be replaced: _____

Number of kits of REF 40060, lot 17004 to be replaced: _____

Number of kits of REF 40060, lot 17005 to be replaced: _____

Date: _____

Company: _____

Name: _____ Signature:_____

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Urgent Field Safety Notice

Recall / Replacement

Humatex ASO

06.11.2017

Attention:
Distributors of HUMAN and end users of:

Details on affected devices
Cat. No. 40062 Lots 16004, 16005, 17003

Description of the problem:
During internal evaluations after a customer complaint we noticed that the above mentioned batches led to an agglutination upon reaction of the latex reagent with several negative patient sera, although the negative control material provided with the kit did not show agglutination. Thus the affected lots may provide false positive patient results which are not recognized by the negative control.
HUMAN thus recommends not using the above mentioned product lots anymore.

Advice on action to be taken by:
Distributor:
Please inform the end user of the above product lots about the problem described here, based on this customer information.

Please fill in the attached reply form confirming receipt and send it to support@human.de. Kits still on stock of the distributor or the end user will be replaced as claimed in the Reply form.

User:
End users should stop using the affected lot and confirm receipt of the customer information to the local distributor. Any suspicious positive results (e.g. not in agreement with other information of patient status) should be reconsidered.

Transmission of this Field Safety Notice
This notice needs to be passed on all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Please transfer this notice to other organizations on which this action has an impact.

Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

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(for distributors only. Distributors should provide their own detailed contact information to their end users):

Sonja, Simonovic
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e-mail: support@human.de
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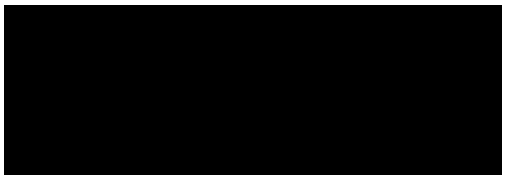
We regret the inconvenience.

With kind regards,



Sonja Simonovic

Customer Support & Applications

Attachment
Reply Form

Reply Form

Urgent Field Safety Notice

For Humatex ASO
Cat. No. 40062 , Lot 16004, 16005, 17003

Please return by e-mail this filled in and signed reply form latest until November 20th, 2017 to
E-mail address: support@human.de

I confirm receipt of this customer information and have informed all end customers, who have obtained the affected lot, in writing about the problem and the HUMAN recommendations.

I confirm that the affected kits in my stock and those kits, which will be returned from my customers, will be destroyed according to local regulations.

Number of kits of REF 40062, lot 16004 to be replaced: _____

Number of kits of REF 40062, lot 16005 to be replaced: _____

Number of kits of REF 40062, lot 17003 to be replaced: _____

Date: _____

Company: _____

Name: _____ Signature:_____

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Urgent Field Safety Notice

Recall / Replacement

Humatex ASO

06.11.2017

Attention:
Distributors of HUMAN and end users of:

Details on affected devices
Cat. No. 40063, Lot. 16009 - 16013, 17005 & 17006

Description of the problem:

During internal evaluations after a customer complaint we noticed that the above mentioned batches led to an agglutination upon reaction of the latex reagent with several negative patient sera, although the negative control material provided with the kit did not show agglutination. Thus the affected lots may provide false positive patient results which are not recognized by the negative control.
HUMAN thus recommends not using the above mentioned product lots anymore.

Advice on action to be taken by:
Distributor:
Please inform the end user of the above product lots about the problem described here, based on this customer information.

Please fill in the attached reply form confirming receipt and send it to support@human.de. Kits still on stock of the distributor or the end user will be replaced as claimed in the Reply form.

User:
End users should stop using the affected lot and confirm receipt of the customer information to the local distributor. Any suspicious positive results (e.g. not in agreement with other information of patient status) should be reconsidered.

Transmission of this Field Safety Notice
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Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

The Federal Institute for Drugs and Medical Devices (BfArM) and other National Competent Authorities of European countries, which are affected by the recall, received a copy of this urgent field safety notice

Contact reference person:
(for distributors only. Distributors should provide their own detailed contact information to their end users):

Sonja, Simonovic
Customer Support & Applications
e-mail: support@human.de
Telephone: +49-6122-9988-383

We regret the inconvenience.

With kind regards,

[redacted]

Sonja Simonovic

Customer Support & Applications

[redacted]

Attachment
Reply Form

Reply Form

Urgent Field Safety Notice

For Humatex ASO
Cat. No. 40063, Lot 16009 - 16013, 17005 & 17006

Please return by e-mail this filled in and signed reply form latest until November 20th, 2017 to E-mail address: support@human.de

For distributors in the European Union:

- Please attach the Customer Information in your national language, which you have sent out to your end customers, as Human will be approached by your national Competent Authority to provide this.

I confirm receipt of this customer information and have informed all end customers, who have obtained the affected lot, in writing about the problem and the HUMAN recommendations.

I confirm that the affected kits in my stock and those kits, which will be returned from my customers, will be destroyed according to local regulations.

Number of kits of REF 40063, lot 16009: _____

Number of kits of REF 40063, lot 16010: _____

Number of kits of REF 40063, lot 16011: _____

Number of kits of REF 40063, lot 16012: _____

Number of kits of REF 40063, lot 16013: _____

Number of kits of REF 40063, lot 17005: _____

Number of kits of REF 40063, lot 17006: _____

Date: _____

Company: _____

Name: _____ Signature:_____