

November 22, 2018

Urgent Field Safety Notice

Product removal from the market

Product: Lactose intolerance quick test (Cat.Nos. 602010, 602012)

Lot number: 12LA1802

Dear Partner,

Biohit Oyj has made a decision to recall the following kit lot from the market:

Product: Lactose intolerance quick test (Cat.Nos. 602010, 602012)

Kit lot: **12LA1802 (exp. 03-2019)**

We have recently noticed some anomalies with the kit lot mentioned above. More specifically, the colour of the reaction does not change as specified. Therefore, the functionality of the kits has been compromised so that misdiagnosis is possible (risk of false lactose intolerance negative results). At the time of writing, the root cause still needs to be confirmed.

Due to this incident, we kindly ask you to take the following measures:

Phase I - Immediate Customer Information

- Please immediately discontinue shipping the above mentioned kit lot to your customers.
- In addition, please inform your customers about possible false negative results and ask them to stop the use of these kit lots.
- Please confirm that you have received this information and have informed your customers by signing the *Immediate Customer Information Form* attached.

Phase II – Inventories

- Please inform us about the number of kits you have in your own and/or customer's stock by filling in the attached *Distributor Inventory Form*.
- All remaining kits should be disposed of.

We apologize for any inconvenience this causes to you and your customers.

With best regards,



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Product removal from the market

Product: Lactose intolerance quick test (Cat.Nos. 602010, 602012)

Lot numbers: 31LA1806, 31LA1807, 38LA1809

Dear Partner,

Related to the previous Field Safety Notice (dated 14.11.2018, concerning kit lots 16LA1803, 21LA1804 and 30LA1805), as a precautionary measure, Biohit Oyj has made a decision to recall also the following kit lots from the market:

Product: Lactose intolerance quick test (Cat.Nos. 602010, 602012)

Kit lots: **31LA1806 (exp. 07-2019), 31LA1807 (exp. 07-2019), 38LA1809 (exp. 09-2019)**

We have data from previous lots, which shows that the reagents might not retain their specified performance until the expiry date (07-2019, 09-2019) as indicated on the label. However, internal investigations confirm that until this day, the results obtained with the concerned kit lots (31LA1806, 31LA1807, 38LA1809) have not been compromised.

At the time of writing, the root cause of the issue is considered to be related to packaging, but this still needs to be confirmed with additional testing.

Please inform your customers that the above mentioned kit lots should not be used anymore and should be disposed of.

Please send information on how many of the above mentioned kit lots you or your customers still have in inventory to the e-mail address: cs@biohit.fi. Biohit will replace those kits.

We apologize for any inconvenience this causes to you and your customers.

With best regards,



November 22, 2018

Distributor Inventory Form

Please complete and send by e-mail to cs@biohit.fi

Product name: Lactose intolerance quick test

Cat.Nos: 602010, 602012

Kit lots: **12LA1802 (exp. 03-2019)**

Please, fill in the following information:

The following number of products have been handled as instructed by Biohit Oyj:

Cat.No: 602010, Lot number: 12LA1802

Number of kits in your own / customer's inventory: _____/_____

Cat.No: 602012, Lot number: 12LA1802

Number of kits in your own / customer's inventory: _____/_____

Name:

Title:

Distributor Name:

Country:

Signature:

Date:

November 22, 2018

Immediate Customer Information Form

Please complete and send by e-mail to cs@biohit.fi immediately after informing your customers on the removal from the market of

Product name: Lactose intolerance quick test
Cat.Nos: 602010, 602012
Kit lot: **12LA1802 (exp. 03-2019)**

We understand that we should immediately:

1. discontinue distribution of the above mentioned kit lot
2. inform the customers
3. dispose of remaining kits

Name:

Title:

Distributor Name:

Country:

Signature:

Date: