

November 14, 2018

Field Safety Notice

Product removal from the market

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

Lot numbers: 16LA1803, 21LA1804, 30LA1805

Dear Partner,

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

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

Kit lots: **16LA1803 (exp. 04-2019), 21LA1804 (exp. 05-2019), 30LA1805 (exp. 07-2019)**

We have recently noticed some anomalies with the kit lots 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 positive results for healthy patients). According to our investigations so far the anomalies seem to be related to kit stability, but 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 lots to your customers.
- In addition, please inform your customers about possible false positive 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 collect the remaining kits of lots 16LA1803, 21LA1804, 30LA1805 back from your customers.
- Also, please inform us about both the number of kits you have in your stock and the number of kits you have collected from your customers by filling in the attached *Distributor Inventory Form*.
- All remaining kits should be sent back to Biohit Oyj.

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

With best regards,



Daniela Söderström
Quality and Regulatory Affairs Director

