

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,

*Daniela Söderström*

Daniela Söderström  
Quality and Regulatory Affairs Director

