

November 22, 2018

Urgent Field Safety Notice

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,

Daniela Söderström

Daniela Söderström
Quality and Regulatory Affairs Director

