

June 6, 2017

Attn:  
PPD Central Lab  
61 Science Park Road  
#02-12-14 Galen  
117525 Singapore

Dear Customer,

Biohit Oyj has made a decision to recall the below specified device from the market.

## A. Company Particulars

*Name of company:* Biohit Oyj  
*Name of contact person:* Daniela Söderström  
*Contact number:* +358 9 773 861  
*Fax number:* +358 9 773 2867  
*Contact email address:* [info@biohit.fi](mailto:info@biohit.fi), [cs@biohit.fi](mailto:cs@biohit.fi)  
*Address:* Laippatie 1, FI-00880 Helsinki, Finland

## B. Product Description

*Medical device name:* Pepsinogen II (ELISA kit)  
*Catalogue number:* 601 020.02  
*Batch number:* 32PB1608 (exp. 04-2018)  
*Name of product owner:* Biohit Oyj  
*Country of manufacture:* Finland

## C. Hazards Associated with the Medical device

### *Reasons for the recall:*

During recent testing, we have noticed some anomalies with the conjugate reagent in the specified kit lot. Therefore, absorbance values are too low, and specifically, Calibrator 3 is  $< 1.0$  when measured at 450 nm (target  $\geq 1.0$ ); results of internal QC samples are still within the acceptance criteria.

### *Nature and cause of the medical device defect:*

The defect relates to the conjugate reagent of kit lot 32PB1608; root cause is being investigated.

*Clarification of the potential hazard associated with the continued use of the medical device and the associated risk to the patient, user or other person:*

There is a risk that the kit performance is not sufficient to give accurate test results.

*Any possible risks to patients associated with previous use of affected medical devices:*

Results obtained up to now are fully usable provided that the absorbance value of Calibrator 3 is at least 1.0 (as required by the quality control certificate of the kit).

## D. Actions to be Taken

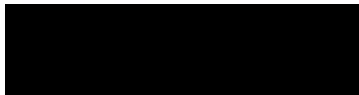
We do not recommend to use this kit lot anymore; please take necessary action to make sure that the use of kit lot 32PB1608 is ceased.

## E. Other Details

Please pass the recall notice to all those who need to be aware of it.

We apologize for any inconvenience this may cause.

With best regards,



Daniela Söderström  
Quality and Regulatory Affairs Director, Biohit Oyj



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## Confirmation Form

We have acknowledged the recall and will act accordingly.

Signature: \_\_\_\_\_

Name: \_\_\_\_\_

Position/Company: \_\_\_\_\_

Date: \_\_\_\_\_

*Please return the confirmation form to the sender of this recall notice.*