BIOHIT HealthCare

Innovating for Health

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, 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 ≥ 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:

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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,

[redacted]

Daniela Söderström
Quality and Regulatory Affairs Director, Biohit Oyj

BIOHIT OYJ * LAIPPATIE 1 00880 HELSINKI FINLAND * BIOHIT OYJ

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.