

Date: 22.12.2022

## Addendum to the Urgent Field Safety Notice dated 20.12.2022

Product: BIOHIT ColonView quick test (REF 602250.02)

Lot number: 22062004

Dear Partner,

Further to the Urgent Field Safety Notice dated 20.12.2022 which contained field safety corrective actions, Biohit Oyj has assessed the need to review results obtained from the following product and lot.

Product: **BIOHIT ColonView quick test (REF 602250.02)**

Immunochemical quick test for the qualitative detection of human hemoglobin and hemoglobin/haptoglobin complex in fecal sample

Lot number: **22062004 (exp. 2023-12)**

It has been determined that a review of previously generated results using the specified kit lot is not required on the following bases:

- The observed issue is related to weakly positive hemoglobin samples only. Other positive sample concentrations are performing as expected in the quality assurance tests.
- According to the product's instructions for use, the stool samples should be collected from three different stools, meaning that the probability of a false result is lower than using one sample only. In addition, the final diagnosis is made based on the patient anamnesis and other information available to, and evaluated by, the medical doctor.

If the specified kit lot has been used, a minor possibility for a false negative result still exists. In such a case there would be no immediate health consequences. However, as the test detects fecal occult blood and is designed to aid in the diagnosis of GI pathologies (such as colorectal cancers and large adenomas that bleed), the actual diagnosis and treatment could be delayed.

For further information, please contact our customer service via email at [cs@biohit.fi](mailto:cs@biohit.fi)

With best regards,

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