

Date: 25.10.2022

Addendum to the Urgent Field Safety Notice dated 13.10.2022

Product: BIOHIT ColonView (REF 602250.02)

Lot number: 22072005

Dear Partner,

Further to the Urgent Field Safety Notice dated 13.10.2022 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 (REF 602250.02)**

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

Lot number: **22072005 (exp. 2024-01)**

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

- The test detects fecal occult blood by measuring two analytes, hemoglobin (Hb) and hemoglobin/haptoglobin complex (Hp/Hb). The current issue concerns only the Hb test, meaning that the Hb/Hp test performs as expected. The probability of a false negative result is low because a positive outcome in either Hb or Hb/Hp test alone is sufficient for detection of fecal occult blood and the specificity of these two analytes has been shown to be similar in clinical studies.
- The observed issue is related to weakly positive Hb 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

With best regards,



Daniela Söderström
Quality and Regulatory Affairs Director

