

Date: 13.10.2022

Urgent Field Safety Notice

Product: BIOHIT ColonView (REF 602250.02)
Lot number: 22072005

Dear Partner,

Biohit Oyj has decided to make the following field safety corrective action as a precautionary measure.

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)**

We have recently noticed that the test line intensities of the specified kit lot are lower than normal and do not fulfill the quality assurance results. Therefore, there is a risk for misdiagnosis, since false negative results are possible in case of weak positive samples. The detailed Root Cause Analysis is under process.

Due to this issue, we kindly ask you to take the following measures:

1. Please immediately discontinue distribution of the above-mentioned lot to your customers.
2. Please dispose of any kits of the above-mentioned lot that may exist in your warehouse. Kindly inform us how many kits have been disposed of.
3. Please inform your customers about this issue and ask them to dispose of all kits of the above-mentioned lot. Kindly inform us how many kits have been disposed of.
4. Please confirm that you have received this information and have informed your customers by signing the *Immediate Customer Information Form* attached.

We sincerely apologize for any inconvenience this causes to you and your customers.

With best regards,



Daniela Söderström
Quality and Regulatory Affairs Director



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