



Ref.00023

Ghent, October 2020, 8th

URGENT FIELD SAFETY NOTICE

Subject:

INNOTEST HIV Ag mAb <96T,CE>; product code 80563; batch 406796 and 407492
Decreased reactivity for serum / plasma sample s

Dear Customer,

We have informed you two weeks ago on an issue of decreased reactivity of the fNNOTEST HIV Ag mAb assay (80563, batch 406796 and 407492) using a Field Safety Notice (FSN) with reference 00017. This new Field Safety Notice (with reference 00023) includes updated recommendations on re-evaluation of results and is initiated in consultation with the European authorities. This Field Safety Notice replaces the previous version with reference 00017.

We inform you that you should (i) stop using the above-mentioned product lots, and (ii) re-evaluate or follow-up patient samples (serum or plasma) with reactivities below the cut-off in the case that the samples were not scored positive using an alternative method.

As mentioned in our previous communication, a recent change in formulation for REACH compliance has been identified as the cause of this decrease in reactivity. An alternative formulation has already been identified and will be implemented by end December 2020. We have product with the former formulation available and expect release by our Notified by October 2020, 21st. A Fujirebio Europe representative will contact you to organize replacements.

We kindly ask you to transfer this updated FSN to all those who need to be aware within your organisation and to maintain awareness on this FSN until everyone is informed.

We kindly ask you to return a signed copy of this letter to the coordinates indicated below.

We sincerely apologize for any inconvenience this might cause you. Do not hesitate to contact our Customer Support department (customer.support@fujirebio.com; tel. +32 9 329 16 11) in case you have any further questions.

Please sign this letter and return a scan to us confirm receipt of this document.

vigilance@fujirebio.com	
Name:.....
Laboratory:
Customer ship-to number (if known):
Signature:

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