

FIELD SAFETY NOTICESubject:

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

Dear Customer,

We have identified an issue on decreased reactivity of the INNOTEST HIV Ag mAb assay (80563, batch 406796 and 407492). We received 1 customer complaint until now. As Fujirebio strives to market reliable and high-quality products, an internal investigation was initiated.

Based on the outcome of our internal investigation, we have confirmed a decrease in reactivity for abovementioned IT HIV Ag mAb batches. As part of the investigation, several seroconversion panels have been tested to assess the impact of this decrease in reactivity of low reactive samples. In 1/5 seroconversion panels, we found a reactivity below the cut-off for a previously confirmed positive sample.

Therefore, we recommend to follow-up patient samples with reactivities below the cut-off in the case that the sample was not scored positive using an alternative method. However, re-evaluation of results might be required depending on the setting (e.g. high risk patient group) and the HIV testing algorithm. Retesting or active follow-up should be considered depending on results from other tests performed in the algorithm (e.g. HIV 4th generation test, HIV viral load, antibody confirmation tests) and the probability of missing out an HIV diagnosis.

A root cause investigation has been conducted in the meantime. 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 are currently in consultation with our Notified Body to market product with the former formulation. If approved, this product will be available by end of October 2020.

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.

Customer.support@fujirebio.com

Name:.....

Laboratory:

Customer ship-to number (if known):

Signature:

Yours sincerely,
Marijke De Roeve
Quality & Compliance Director

Rikkert Maertens
Marketing Director