



INNOGENETICS
BIOTECHNOLOGY FOR HEALTHCARE

FIELD SAFETY NOTICE

Subject:

INNOTEST β -AMYLOID₍₁₋₄₂₎ <96T, CE>, product code 80324
(Batchnumber 196524, 204108, 206189)
INNOTEST β -AMYLOID₍₁₋₄₂₎ <96T, RUO>, product code 80177
(Batchnumber 196526, 201230, 204109, 206205)
Quantification of β -Amyloid₍₁₋₄₂₎

Gent, 5 July 2010

Dear Customer,

Following a recent customer observation, we have identified a quality issue with the quantification in cerebrospinal fluid (CSF) of β -Amyloid₍₁₋₄₂₎ using the indicated batches of the above mentioned products.

More specifically, the β -Amyloid₍₁₋₄₂₎ concentrations measured in CSF, using the indicated batches, can be lower in comparison to earlier batches. As such, the previously in the laboratory validated clinical cut-off value might be incorrect, lowering diagnostic accuracy (potential false positive test results) for samples with concentrations close to this clinical cut-off value.

With reference to the package insert, only the combined use of β -Amyloid₍₁₋₄₂₎ and CSF-tau marker concentrations allows differentiation between Alzheimer's disease (AD) and normal aging or other neurological diseases such as depression, provided that each laboratory validates the discrimination line described in the test performance section of the same package insert.

As such, the corresponding patient risk directly created by this observed quality issue has been evaluated as being low. You can keep using the concerned batches. Results obtained can still be used for patient diagnosis provided they are combined with quantification of CSF-tau in the sample. When only β -Amyloid₍₁₋₄₂₎ concentrations are decreased and thus indicative for AD, but CSF-tau concentrations are not increased, the patient result should be seen in the light of the total clinical history of the patient.

Innogenetics also advises to test external controls with every run in order to be able to assure consistency of results.

This letter supersedes any previous communication on this subject, if any. Please note that the relevant competent authorities have been informed of this issue.

We sincerely apologize for any inconvenience this might cause you. Innogenetics is actively working on a solution for this problem and will provide you with further instructions in the shortest possible time-frame.

Customer Support is at your service in case you have any further questions on this subject. Please do not hesitate to contact us for more information at customer_support@innogenetics.com or call +32 9 329 16 16 (business days from 9.00 h to 17.00 h).

Sincerely,

Quality and Compliance Director

Manager Post Market Surveillance