



B O R D I E R

**A F F I N I T Y
P R O D U C T S**

Notification letter

Instructions for use and labels revision

Dear Madam/Sir,

In the next months, **all our products** will be packed with reviewed instructions for use (IFUs) and labels. To be compliant with the new EU-regulation 2017-746, some changes have been made.

Main changes are listed below:

IFUs:

- Reviewed products names.
- New validation criteria for cut off control.
- Updated validation criteria for negative control.
- Improvement of part "Performances" by defining "Analytical performances" and "Clinical performances".

Labels:

- Reviewed products names.
- UDI barcode implementation.
- European Authorized Representative (EC-REP).

Please find attached a sample of IFU with modifications in red and a sample of labels with modification circled in red.

Please note that the composition of kits has not been modified and that the protocols and performances of the tests are unchanged.

The new IFUs will be used in all lots produced after January 1st, 2023 (lot number beginning with "23xxx") and they will be published on our website in March 2023.

Do not hesitate to solicitate us by asking IFUs of the products you use.

I stay at your disposal for any questions or comments.

Crissier, February 20th, 2023,

Nicolas Beyls
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