



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 revision

Dear Sir/Madam,

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

Main changes are listed below:

- Intended use simplification
- "Background" part creation
- Addition of recommendation concerning diluted reagents stability
- "Specimen collection and preparation" part creation
- "Warnings and precautions" part improvement
- New validation criteria of negative control for products 9300, 9350, 9500 and 9650
- Results interpretation in "Cut-off Index"
- Grey zone recommendation
- Improvement of parts "Sensitivity and specificity", "Interferences", "Precision" and "Limitations"

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

The new IFUs will be used for all lots produced after January 2018 (lot number beginning with "18xxx") and they will be published on our website from January 2018.

Do not hesitate to contact us for any questions or comments.

Crissier,

14 December 2017

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