
Marketing – Customer Support
PRIMA Product News**Date: 24th June 2026****Ref: PPN 03-2026-EN-PL****Subject: IVDR Certification of the HIV 1/2 TEST**

Dear Partner,

PRIMALAB is pleased to inform you that the HIV 1/2 TEST has successfully obtained certification under the IVDR Regulation (EU) 2017/746.

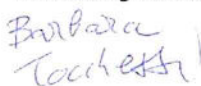
We would like to clearly emphasize that the characteristics and intended use of the HIV 1/2 TEST remain unchanged. No modifications have been introduced to the test device, procedure, or overall user experience.

The product has been transitioned to IVDR certification, ensuring full regulatory compliance while maintaining the same high-quality standards.

We also inform you that you will have a transition period during which you may continue to order the IVDD version of the product until its discontinuation in December 2027.

You are kindly advised to contact us as soon as possible in order to plan the creation of new product codes and avoid supply delays

We remain at your disposal for any further information, technical details, or clarifications regarding this transition. We are also available to provide all the necessary documentation, both technical and non-technical as well as any additional support you may require.

Alberto Zavattoni
Product ManagerBarbara Tocchetti
Marketing LeaderLaura Bologna
RA Specialist

We thank you for the trust you put in our products and take this occasion to remind you that on our website (www.primalabsa.ch) you can find all the information regarding the other product lines.