

To whom it may concern

Subject: **Advisory Notice**

Product: **abia HBs Ag, cat. No. DK.013.01.3, lot DK013031; cat. No. DK.013.05.3, lot DK013033**

03.07.2024

Dear Customer,

we have revealed a non-conformity in the printed batch of IFUs (version IU.013.00.3/4 of 2021-12-20) that could be packed into the kits abia HBs Ag, lots DK013031 and DK013033.

Pages 3, 4, 9 and 10 were erroneously inserted from another IFU due to a mistake on the side of our subcontractor. Thus, IFU sections "Kit contents", "Safety notes", "Performance characteristics", "Limitations of test" and "References" refer to another abia product, not to abia HBs Ag.

Meanwhile, all other IFU sections, incl. "Preparation of reagents", "Test procedure" and "Calculation and interpretation of the results", are correct and refer to the product abia HBs Ag.

We kindly ask you to check your hard IFU versions and compare them to the electronic IFU (please find enclosed to this Advisory Note). In case you find any discrepancies described above in hard IFUs, please refer to the electronic IFU.

This non-conformity refers only to lots DK013031 and DK013033.

We kindly ask you to inform all concerned parties.

We apologize for any possible inconveniences. Please do not hesitate to contact us in case of any further questions.

Kind regards,
Ekaterina Mayorova
Quality Management Representative



Enclosures:

IFU, abia HBs Ag, version IU.013.00.3/4 of 2021-12-20)

I have read and understood this Advisory Notice, and I assume the obligation to inform all concerned parties.

Date

Signature / Full name