Please forward this letter to: customers and distributors of VIDIA

In Vestec on 10.3.2025

URGENT SAFETY NOTICE FOR THE FIELD FSN2025-01

For the product Rapid-VIDITEST Giardia Lot no. GW-038, REF OD-028

Dear Customers,

VIDIA Ltd. has initiated a field corrective action for the above product. This letter contains important information for your immediate attention.

A description of the problem including the identified cause: Following a customer complaint, it was determined that the Rapid-VIDITEST Giardia card packaging contained a Clostridium difficile antigen detection card. Investigation has determined that there was a mix-up in packaging, the incriminated lot will be recalled from the market. The cause of the non-conformity is under investigation.

Determined risk: Patient diagnosis and treatment may be delayed due to a missing test, patient harm due to test mix-ups ('false diagnosis') does not occur, the internal cartridge is visibly marked. The non-conforming lot will be replaced.

Action to be taken:
1. Do not use the lot in question, return it to the manufacturer if possible.
2. If the non-conforming lot cannot be returned, please dispose of it.
3. If you have used the non-conforming lot, inform the physician who received the mismatched result of the substitution.

Information to be transmitted: Please pass this information on to all users of the above product.

Thank you for your cooperation! We apologize for any inconvenience. For further information, please do not hesitate to contact us at: kvalita@vidia.cz

Kind regards

Ing. Michaela Poláková
PRRC, VIDIA spol. s r.o.

Vidia spol. s r.o.
Nad Safinou II 365, 252 50 Vestec
Czech Republic

info@vidia.cz

+420 261 090 565

www.vidia.cz