

**VPD**VPD, BLED D.O.O., Pot na Lisice 4, 4260 Bled,
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Urgent Field Safety Notice

Date: Jan 11, 2021

Dear partner,

Upon notice from VivaChek Biotech (Hangzhou) Co., Ltd., please quarantine the following products immediately and replace the products:

The affected devices in Slovenia market:

Name of device	Batch	Quantity	Catalog No.
VivaDiag SARS-CoV-2 Ag Rapid Tests	SE2010037	7,675 pcs	VCD05-01-011

Description of the problem: see Urgent Field Safety Noticed from VIVACHEK Biotech (Hangzhou) Co., Ltd. (Attached)

Advice on the action to be taken by the user:

1. For the products, VivaDiag SARS-CoV-2 Ag Rapid Test (REF: VCD05-01-011), of batch SE2010037, please quarantine immediately and contact VPD, Bled, d.o.o., Pot na Lisice 4, 4260 Bled, Slovenia for replacement.
2. Rapid Test is not designed and used for the diagnosis of COVID-19, in most countries, PCR based diagnostic method is the widely accepted as the "Gold Standard" for the confirmation of COVID-19 infection. So, if any doubt on the testing results from Rapid Test, follow-up testing with a molecular diagnostic (PCR) should be considered.
3. If you are a distributor, the content of this letter must be communicated to all customer
4. Attached please find a Replacement form. You need to enter the quantity in stock in this list. The completed list needs to be mailed to: ziga.galicic@vpd.si.
For further questions, please contact Martina Horvat (e-mail: martina.horvat@vpd.si).

We sincerely apologize for the inconvenience caused by the replacement. Thank you very much for your understanding and cooperation in this matter.

VPD, BLED, d.o.o.

Martina Horvat
Vigilance and Regulatory Representative