Urgent Field Safety Notice

VivaDiag SARS-CoV-2 Ag Rapid Tests (code: VCD05-01-011), **JAZMP ref.: 301-279/2020**

Subject: Replace the products of Batch SE2010037

Date: Jan 06, 2020

The affected devices in global market:

Name of device	Batch	Quantity	Catalog No.
VivaDiag SARS-CoV-2 Ag Rapid Tests	SE2010037	156,525 pcs	VCD05-01-011
VivaDiag SARS-CoV-2 Ag Rapid Tests	SE2011044	269,350 pcs	VCD05-01-011
VivaDiag SARS-CoV-2 Ag Rapid Tests	SE2011037	362,850 pcs	VCD05-01-011

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:

ANSM (case number: I2014389) has informed VivaChek about 7 vigilance reports about false positive with different batches of VivaDiag SARS- CoV-2 Ag Rapid Test (REF: VCD05-01-011), most of them regarding batches #SE2010037 and #SE2011044.

During VivaChek's investigation of all batch records, it was found that the cleaning record after every 3 hours of continuous cutting required by the SOP were missing in the batch records in the manufacturing process batches #SE2010037, #SE201103 and #SE2011044.

Through the test and comparison of 300 clinical samples by retained samples of all batches; one uncompleted T line was identified in each batch of #SE2010037, #SE201103 and #SE2011044. The findings correlate to the complaints received from France and therefore it indicates the violation of cleaning SOP leading to the accumulation of residue, further contaminating the T line by the components from C line, which may lead to false positive results.

From VivaChek record, we have delivered 7,675 tests of VivaDiag SARS- CoV-2 Ag Rapid Test (REF: VCD05-01-011), batch #SE2010037 in Slovenia and another two batches #SE2011044, #SE2011037 have not been sold in Slovenia market.

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 sold in Slovenia, please quarantine immediately, and contact your direct supplier 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.

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