

Urgent Field Safety Notice

VivaDiag SARS-CoV-2 Ag Rapid Tests (code: VCD05-01-011)

BfArM case number: 22487/20

Subject: Replace the products of Batch SE2010037

Date: Jan 12, 2021

The affected devices in German market:

Name of device	Batch	Quantity	Catalog No.
VivaDiag SARS-CoV-2 Ag Rapid Tests	SE2010037	1,200 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 evidence of the implementation of cutting machine cleaning activity which is required to be performed by SOP # after every 3 hours of continuous cutting were missing in the batch records in the manufacturing process batches #SE2010037, #SE2011037, #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, #SE2011037, #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 on the blade and cutting machine surface. it can further contaminate the T line by the components from C line, results the uncompleted T line which is easy to be read as false positive.

From the sales record, VivaChek has sold 1,200 tests of batch #SE2010037 to Germany, and another two batches #SE2011037, #SE2011044 have not been sold in Germany.

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, if you find same false positive results, 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.