

## **Urgent Field Safety Notice**

**BfArM Case Number: 05458\_21**

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

Subject: Request Distributors to Notify Customers on the Samples Collection and Test

Date: Apr 19, 2021

**The Affected Devices:**

Name of device	Catalog No.	Batch
VivaDiag SARS-CoV-2 Ag Rapid Tests	VCD05-01-011	SE2011077
VivaDiag SARS-CoV-2 Ag Rapid Tests	VCD05-01-011	SE2011108

**Description of the Problem:**

- 1) The Germany authority BfArM informed Vivachek there were several false positive results of VivaDiag SARS-CoV-2 Ag Rapid Test in nursing institutions in Germany, and the batches were SE2011077 and SE2011108.
- 2) 40 pcs of retained test devices from each lot number SE2011108, SE2011077 were drawn out from the Retention Samples Room, VivaChek performed the investigation and tests on retained samples which represented the inspection requirement and quantity required in the CF-0037 *Final Inspection Specification for VivaDiag SARS-CoV-2 Rapid Test Device*. The test results show that 1/40 test device from the lot number SE2011108 had a slight color on T line (read as G2 per the controlled document WI20-1033-RE-02 *Intensity Grading Card*, it was interpreted as negative if the color intensity is below G3) using the sticky oropharyngeal specimen, and the other 79/80 rapid devices tested and interpreted as negative with no color signal on test lines.

It may contribute the possibility of false positive on VivaDiag SARS-CoV-2 Rapid Test if very sticky specimen is collected and tested.

- 3) In addition, PCR tests probably be negative for the COVID-19 variants based on the below document / literature review:  
Genetic Variants of SARS-CoV-2 May Lead to False Negative Results with Molecular Tests for Detection of SARS-CoV-2 - Letter to Clinical Laboratory Staff and Health Care Providers, FDA, January 8, 2021; and,  
Latest COVID-19 Variant Discovered in France Isn't Detected by Standard PCR Tests, Joshua Cohen, Editor's Pick, Mar 17, 2021.

**Advice on the Action to be Taken by the User:**

VivaChek kindly notify the distributors it may contribute the possibility of false positive if a yellow and non-flowing sticky specimen is collected and tested, then molecular diagnostic test needs to be performed for confirmation if a positive result observed on the rapid test.

We kindly request distributors to collect the potential hazard and hazard situation of VivaDiag SARS-CoV-2 Rapid Test from your customers and communicate with VivaChek monthly, this information is the input of proactive post-market surveillance and risk management. VivaChek will review the new potential hazard and hazard situation received from you and update the risk management report accordingly where appropriate.