Dringender Sicherheitshinweis

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

BfArM-Fallnummer: 22487/20

Betreff: Ersetzen Sie die Produkte von Batch SE2010037

Datum: Jan 12, 2021

Die betroffenen Geräte auf dem deutschen Markt:

Name des Geräts	Batch	Quantität	Katalognummer
VivaDiag SARS-CoV-2 Ag Rapid Tests	SE2010037	1,200 pcs	VCD05-01-011

Beschreibung des Problems:

ANSM (Fallnummer: I2014389) hat VivaChek über 7 Wachsamkeitsberichte über falsch positive Ergebnisse mit verschiedenen Chargen des VivaDiag SARS-CoV-2 Ag-Schnelltests (REF: VCD05-01-011) informiert, die meisten davon in Bezug auf den Batch SE2010037 und SE2011044.

Bei der Untersuchung aller Chargenprotokolle durch VivaChek wurde festgestellt, dass das von der SOP geforderte Reinigungsprotokoll nach jeweils 3 Stunden kontinuierlichem Schneiden in den Chargenprotokollen in den Batch SE2010037 / SE2011037 / SE2011044 des Herstellungsprozesses fehlte.

Durch den Test und Vergleich von 300 klinischen Proben durch zurückbehaltene Proben aller Chargen; In jeder Batch von SE2010037, SE2011044, SE2011037 wurde eine unvollständige T-Linie identifiziert. Die Ergebnisse korrelieren mit den aus Frankreich eingegangenen Beschwerden und weisen daher auf eine Verletzung der Reinigungs-SOP hin, die zur Ansammlung von Rückständen führt und die T-Linie durch die Komponenten der C-Linie weiter kontaminiert, was zu falsch positiven Ergebnissen führen kann.

Aus dem Verkaufsrekord geht hervor, dass VivaChek 1.200 Tests der Batch # SE2010037 nach Deutschland verkauft hat und zwei weitere Batch # SE2011037, # SE2011044 in Deutschland nicht verkauft wurden.

Hinweise zu den vom Benutzer zu ergreifenden Maßnahmen:

1. Für die Produkte VivaDiag SARS-CoV-2 Ag Schnelltest (REF: VCD05-01-011) der Batch SE2010037, Wenn Sie dieselben falsch positiven Ergebnisse finden, stellen Sie diese bitte sofort unter Quarantäne und wenden Sie sich an Ihren direkten Lieferanten Ersatz.

2. Der Schnelltest wurde nicht für die Diagnose von COVID-19 entwickelt und verwendet. In den meisten Ländern ist die PCR-basierte Diagnosemethode als “Goldstandard“ für die Bestätigung einer COVID-19-Infektion weithin anerkannt. Wenn Zweifel an den Testergebnissen des Schnelltests bestehen, sollten Folgetests mit einer Molekulardiagnostik (PCR) in Betracht gezogen werden.

VIVACHEK Biotech (Hangzhou) Co., Ltd.

[redacted]

VivaChek Response to email from AEMPS dated Jan 07, 2021

BfArM case number: 22487/20

Date: Jan 12,2021

Dear Sir/Madam,

Regarding to your email dated on Jan 05, 2021, please refer to our reply below in green.

Subject: acknowledgement of receipt regarding VivaDiag SARS-CoV-2 Ag Rapid Test - case # 22487/20

Acknowledgement of receipt

Field Safety Corrective Action concerning VivaDiag SARS-CoV-2 Ag Rapid Test

Serial-/Lot-No.: / Batch SE2010037

BfArM case number: 22487/20

Your reference: C20112501

Dear Sir or Madam

We acknowledge the receipt of your report of 04.01.2021. It is registered under the above-mentioned BfArM case number.

In future correspondence, please quote this number.

For further processing we need additional information, **provided it has not yet been submitted with your initial report**

[redacted]

of all the batches"

- the Field Safety Notice in German and English

Response by VivaChek: Please kindly refer to "Attachment B-FSN in English", and "Attachment C-FSN in Germany"

- a copy of the relevant risk analysis

  Response by VivaChek: Please kindly refer to “Attachment D-VCD05-Risk Management Report”.

- a statement as to the planned corrective actions including a time schedule thereof

Response by VivaChek: Please kindly refer to “Attachment E- statement of planned corrective actions and time schedule”

- information on the corrective measures taken to prevent recurrence of this product failure in the future.

Response by VivaChek:

For Corrective Action Plan: Please refer to CAPA—"Attached 9 CAPA for False Positive of SARS-CoV-2 Ag Test”- page 6 section “Corrective Action Plan”

1) Production Supervisor Jay Hua, QC Supervisor Lily Hu, and HR Director Amelie Xu to hold a face-to-face communication with the responsible Operator and Inspector, and take disciplinary action to them, and archive the meeting record and disciplinary action record in both CAPA and Employee File.
2) Optimized and validated the program in strip cutting machine #3336 to add an error proofing action that the cutting machine will be stopped automatically for reminding cleaning activity after 54,000 continuous cuttings.
3) Update the PFMEA to add the error proofing action in the cutting process and re-perform risk evaluation for VivaDiag SARS-CoV-2 Ag Rapid Test.

For Preventive Action Plan: Please refer to CAPA—"Attached 9 CAPA for False Positive of SARS-CoV-2 Ag Test”- page 7 section “Preventive Action Plan”

1) Update and validate the program in the other strip cutting machine #3338 to add an error proofing action that the cutting machine will be stopped automatically for reminding cleaning maintenance after 54,000 continuous cuttings.
2) Perform three walkthrough assessments in Workshop to audit whether other manufacturing operation instruction are fully followed for VivaDiag SARS-CoV-2 Ag Rapid Test;
3) Production Supervisor Jay Hua and QC Supervisor Lily Hu to hold a face-to-face communication with other all manufacturing Operators and Inspectors for the implementation of operation instructions relating to VivaDiag SARS-CoV-2 Ag Rapid Test.

4) Review whether there are any other programs in manufacturing equipment for VivaDiag SARS-CoV-2 Ag Rapid Test that need to be optimized and revalidated for the error proofing actions.
5) Update CF-0037 Final Inspection Specification (Rev 01) to increase sample size and test fifty (50) VivaDiag SARS-CoV-2 Ag rapid tests for the negative test item.

- if only certain lots or serial numbers are concerned, please explain for which reason you can restrict the corrective measures to these lot or serial numbers

Response by VivaChek:

Yes, we identified the impacted scope to three batches #SE2010037, #SE2011037, #SE2011044.

Firstly, go through the complaint investigation based on the false positive cases received from France we separate the complaint into two categories:

Concentrated complaint: the results have been confirmed by PCR (based the report from ANSM).

Non concentrated compliant: the results have been confirmed by PCR. The Non concentrated compliant was considered as are separated occurrence

We identified the root cause of concentrated false positive complaints are due to the violation of the SOP CD-0006 by the operator, leading to a low percentage of the contamination of the T Line by the C Line components via static electrical residue accumulation effect.

Based on photo evidence from the complaints investigation (please see attachment F-C20112501-Complaint Report, page 6-7), it was identified that the false positive is resulted from the one cleaning step for the cutting machine surface and blade was missing, and the operator was identified, she, however, only has been involved in the three batches mentioned among all batches sold in EU. Also, based on the batch record review, no other operators made the same mistake, please refer the CAPA root cause analysis (Attached 9 CAPA for False Positive of SARS-CoV-2 Ag Test Page 3)

To verify this identified root cause,

To verify this identified root cause, we used the retained samples from our warehouse and tested by known negative specimens, around 1/300 false positive rate was obtained as expected (attached 7). Based on photo evidence from the complaints, batch records and clinical validation, we also performed scenario recurrence study, it was demonstrated that once the cleaning step is missed, the false positive rate will increase from 0 to 2/500 (Attached 8, Section 6). The impact of the root cause identified in current investigation is limited to batch number of SE2010037/SE2011037/SE2011044.

For those non-concentrated complaints received in France, we have not received any complaint from other EU countries. In those cases, the total false positive rate complies with specification of sensitivity and specificity indicated in our IFU. We performed clinical validation on all other 33 batches exported to France (Attached 7), and results complied with the specification. For a thorough investigation, we reviewed DHRs and performed clinical evaluation on all other 84 batches exported to the EEA, including France and German and results met the specification, the total false positive rate complied with sensitivity and specificity performance indicated in our IFU (Reports available upon request).

At moment we can conclude that the impact of the root cause identified in current investigation is limited to batch number of SE2010037/SE2011037/SE2011044. We also inspected all other batches exported to the EU and no abnormality was found and all complied with specification.

For more details, please refer to Attachment F-C20112501-Complaint Report and supporting attachments -Attached1 to Attached 9.

- the current German instructions for use and brochures on the product, including updates

Response by VivaChek: Please kindly refer to

Attachment “1604021002 VivaDiag SARS-CoV-2 Ag package insert “ is the German instruction for use of the products,

Attachment “1604020902 VivaDiag SARS-CoV-2 Ag package insert is the German instruction for use, for one distributor (company name: MSP).

Please name the Authorised Representative in Europe, and the Notified Body responsible for the certifications which cleared the way for the CE marking.

Response by VivaChek:

1. The name of Authorised Representative in Europe is:

[redacted]

The certification body BSI Group issued the ISO13485 for VivaChek Company，and VivaDiag SARS-CoV-2 Ag rapid test was classified as “ others “ , the CE mark was went through the self-declaration conformity route without Notified Body involvement.

We expect your response within one (1) week upon receipt of this letter.

[redacted]

The German Ordinance on a Medical Devices Safety Plan [section 3(1) and section 7(2)] requires manufacturers to report electronically using the form that is published on BfArMs website to extract the report information electronically and to avoid that we need to re-type the information provided in the report into our database.

If not already done we ask you to use the relevant form from our website from the following links for further reporting:

- for incident reporting: https://www.bfarm.de/SharedDocs/Formulare/EN/MedicalDevices/mir_form.pdf?__blob=publicationFile&v=4
- for FSCA reporting: https://www.bfarm.de/SharedDocs/Formulare/EN/MedicalDevices/fsca_reports.pdf?__blob=publicationFile&v=5

Please note that once you hit the button 'send xml' the form is write protected. For your convenience and further processing you should store the form before hitting the button. Please add to the email a copy of the write protected form.

You may use any electronic signature that is available including the Adobe built in but it is not mandatory to use one.

Yours sincerely

Medical Devices Division

Bundesinstitut für Arzneimittel und Medizinprodukte

Kurt Georg Kiesinger Allee 3

D 53175 Bonn

Fon: +49 (0) 228 99 307 - see extension numbers above

Fax: +49 (0) 228 99 307 - 5300

email: md-vigilance@bfarm.de

The BfArM is a federal institute within the portfolio of the Federal Ministry of Health