

Date: Dec 24, 2020

Subject: URGENT – RECALL

Product: VivaDiag SARS- CoV-2 Ag Rapid Test (REF: VCD05-01-011) (hereafter called PRODUCT)

Batches: All batches

Manufacturer: VivaChek Biotech (Hangzhou) Co., Ltd. (hereafter called VIVACHEK)
Level 2, Block 2, 146 East Chaofeng Road, Yuhang Economy Development Zone, Hangzhou, Zhejiang,
China 311100

To pharmacies, sub-distributors, dealers, wholesalers who have the stock of PRODUCT:

Following the decision by the ANSM published on 22 Dec 2020, VIVACHEK drafted this document for the URGENT recall of VivaDiag SARS-CoV-2 Ag Rapid Test (REF: VCD05-01-011) in France.

Action to be taken:

- 1) Please ensure that the mentioned PRODUCT not be used and put any remaining stock in quarantine zone with appropriate storage conditions.
- 2) Please complete the attached Acknowledgement Form and return it to your **direct supplier** and copy VIVACHEK by Email to julie.zhou@vivachek.com as soon as possible.
- 3) Please ask your **direct supplier** to collect the remaining stock.

Action to be taken for PRODUCT already in use:

No special action will be taken for PRODUCT already in use.

Please feel free to report any feedback regarding VivaDiag SARS-CoV-2 Ag Rapid Test (REF: VCD05-01-011) to VIVACHEK in order that the appropriate actions can be taken.

We regret for any inconvenience may cause and appreciate your understanding of our long-term commitment to ensure patient safety and customer satisfaction.

Thank you for your cooperation on this matter. The return of the Acknowledgment Form as attached to VIVACHEK is an indispensable component assuring that VIVACHEK has effectively communicated with affected customers regarding this recall.

For any questions or additional information, please send email to: julie.zhou@vivachek.com.



Best Regards,

Julie Zhou
Director - Regulatory Affairs
VivaChek Biotech (Hangzhou) Co., Ltd.

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**ACKNOWLEDGEMENT FORM
ACCUSE DE RECEPTION**

Please complete the information below and send to julie.zhou@vivachek.com as **soon as possible**.

Merci de compléter les informations ci-dessous et de renvoyer ce document à julie.zhou@vivachek.com dans les plus brefs délais.

Client <i>Customer</i>		Nom <i>Name</i>	
Adresse <i>Street address</i>		Code postal <i>Zip code</i>	
Ville <i>City</i>		Pays <i>Country</i>	
Téléphone <i>Phone</i>		Email	
Fonction <i>Position</i>		Signature	

With this form I confirm that I have received, read and understood the information provided. I have identified all products concerned.

Par cet accusé de réception je confirme avoir reçu, lu et compris les informations fournies. J'ai identifié tous les produits concernés.

Inventory

Inventaire

<i>Produit</i>	<i>Numéro de lot</i>	<i>Quantité (Tests)</i>	<i>Localisation</i>	<i>Fournisseur direct (nom de la société, correspondant, numéro de téléphone/portable)</i>
VivaDiag SARS- CoV-2 Ag Rapid Test (REF: VCD05-01-011)				

The recall will be terminated when above information is provided, and the amount listed by you are verified and received by VIVACHEK or designated legal representative (100% reconciliation).

Le rappel sera clôturé lorsque les informations demandées seront complétées et les dispositifs reçus (100% réconciliation).