

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 direct importer 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.

VIVACHEK has distributed following batches & quantities of VivaDiag SARS-CoV-2 Ag Rapid Test (REF: VCD05-01-011) to your company as listed in Attachment 1.

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 VIVACHEK by Email to julie.zhou@vivachek.com as soon as possible.
- 3) Once VIVACHEK receives your inventory information, logistic company will contact you to organize the quarantined products and further steps.

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 Customer		Nom Name	
Adresse Street address		Code postal Zip code	
Ville City		Pays Country	
Téléphone Phone		Email	
Fonction Position		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

Produit	Numéro de lot	Quantité (Tests)	Localisation
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).

Attachment 1

Distribution batches & quantities of VivaDiag SARS- CoV-2 Ag Rapid Test (REF: VCD05-01-011) to your company.

Importer/Distributor	Address	Order No.	Batches	Quantity (test)
Inter Raccords	Tour d'Asnieres 4 Avenue Laurent Cely 92600 Asnieres-sur Seine, 521 682 484	11020001	SE2011074	10,000