

## **Urgent Filed Safety Notice**

VivaDiag SARS-CoV-2 IgM/IgG Rapid Tests (VivaDiag COVID-19 IgM/IgG Rapid Tests)  
FSCA202003271

Replace the IFU (package insert)

Date: 27<sup>th</sup> Mar 2020

Attention: Replace the IFU (package insert) of VivaDiag COVID-19 IgM/IgG Rapid Tests immediately

### **The affected devices:**

<b>Name of device</b>	<b>Batch lot</b>	<b>Quantity</b>	<b>Catalog No.</b>
<u>VivaDiag COVID-19 IgM/IgG Rapid Tests</u>	E2002002, SE2003001 SE2003002, SE2003003	40860 pcs	VID35-08-011

### **Description of the problem:**

1. The products name of "VivaDiag COVID-19 IgM/IgG Rapid Test" on the IFU, kit box and label of is not correct, and should be changed to "VivaDiag SARS-CoV-2 IgM/IgG Rapid Test"
2. There is no significant information of "professional use only" and "not for first record virus detection" on the IFU, kit box and label
3. The European Representative has been changed from Landlink GmbH (Dorfstrasse,2/4, Emmendingen, Germany) to Lotus NL B.V. (Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands) from date 29<sup>th</sup> Feb.2020
4. VivaChek has revised the package insert (IFU with above changes (1,2&3)--documents no. 1604003005 (ver 05).

### **Advice on the action to be taken by the user:**

1. for the products of above batch lots, please print out the attached package insert (IFU)-documents no. 1604003005 (ver 05) and replace the old package insert. Please make sure this new package inserts (IFU) available for every user and sent with each box of products.
2. please note VivaDiag SARS-CoV-2 IgM/IgG Rapid Test IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS AND CLINICAL LABS ONLY. IT IS NOT FOR AT-HOME TESTING.

Sincerely,



Julie.Zhou (R.A manager)

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