Urgent Filed Safety Notice

VivaDiag SARS-CoV-2 lgM/lgG Rapid Tests {VivaDiag COVID-19 lgM/lgG Rapid Tests)
FSCA202003271
Replace the IFU (package insert)

Date: 27th Mar 2020

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

The affected devices·

Name of device	Batch lot	Quantity	Catalog No.
VivaDiag COVID-19 lgM/lgG Rapid Tests	E2002002,SE2003001 SE2003002,SE2003003	40860 pcs	VID35-08-011

Description of the problem:

1. The products name of "VivaDiag COVID-19 lgM/lgG Rapid Test" on the IFU, kit box and label of is not correct, and should be changed to "VivaDiag SARS-CoV-2 lgM/lgG 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 29th Feb.2020
4. VivaChek has revised thepackage 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 lgM/lgG Rapid Test IS INTENDED FOR USE BY HEALTHCARE PROFESSIONALS AND CLINICAL LABS ONLY. IT IS NOT FOR AT-HOME TESTING.

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