Ministero della Salute

DIREZIONE GENERALE DEI DISPOSITIVI MEDICI E DEL SERVIZIO FARMACEUTICO
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Agli Assessorati Alla Sanità delle Regioni e delle Province Autonome

c.a Direttori Generali

DGDMF.4/P/I.1.C.V.1/2020/16

OGGETTO: Avviso di sicurezza - Segnalazione IVD relativa al test rapido VivaDiag Sars-CoV-2 Ag

Si fa seguito alla nota del 24/12/2020, prot. n. 84567, ad oggetto "Segnalazione IVD - sospensione dell'importazione e immissione in commercio, divieto di utilizzo, messa in quarantena e ritiro in Francia del test rapido *VivaDiag Sars-CoV-2 Ag"*, trasmessa da questa Direzione generale in seguito alla segnalazione della Federazione nazionale unitaria titolari di farmacia, Federfarma, su un incremento di falsi positivi prodotti dal test.

Al riguardo si allega l'avviso di sicurezza del fabbricante VivaChek che invita a quarantenare i lotti SE2010037 e SE2011037 venduti in Italia ed a contattare il distributore locale per la loro sostituzione.

Nel raccomandare la massima diffusione del presente avviso sul territorio regionale, si comunica che, in ogni caso, lo stesso sarà pubblicato nell'apposita sezione del portale del Ministero della salute.

Cordiali saluti,

Il Direttore Generale
*Dott. Achille Iachino

Responsabile del procedimento
Dott.ssa Rossana Mosca
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**firma autografa sostituita a mezzo stampa ai sensi dell'art. 3, comma 2, del D.Lgs.vo n. 39/1993.*

VivaChek

MEDDEV2.12-1-ev.8 Vigilance

Urgent Field Safety Notice

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

Subject: Replace the products of Batch SE2010037, SE2011037

Date: Jan 06, 2020

The affected devices in global market:

Name of device	Batch	Quantity	Catalog No.
VivaDiag SARS-CoV-2 Ag Rapid Tests	SE2010037	156,525 pcs	VCD05-01-011
VivaDiag SARS-CoV-2 Ag Rapid Tests	SE2011044	269,350 pcs	VCD05-01-011
VivaDiag SARS-CoV-2 Ag Rapid Tests	SE2011037	362,850 pcs	VCD05-01-011

The affected devices in Italy market:

Name of device	Batch	Quantity	Catalog No.
VivaDiag SARS-CoV-2 Ag Rapid Tests	SE2010037	16,050 pcs	VCD05-01-011
VivaDiag SARS-CoV-2 Ag Rapid Tests	SE2011037	30,250 pcs	VCD05-01-011

Description of the problem:

ANSM (case number: I2014389) has informed VivaChek about 7 vigilance reports about false positive with different batches of VivaDiag SARS- CoV-2 Ag Rapid Test (REF: VCD05-01-011), most of them regarding batches SE2010037 and SE2011044.

During VivaChek's investigation of all batch records, it was found that the evidence of the implementation of cutting machine cleaning activity which is required to be performed by SOP # after every 3 hours of continuous cutting were missing in the batch records in the manufacturing process batches #SE2010037, #SE2011037, #SE2011044.

Through the test and comparison of 300 clinical samples by retained samples of all batches; one uncompleted T line was identified in each batch of #SE2010037, #SE2011037, #SE2011044. The findings correlate to the complaints received from France and therefore it indicates the violation of cleaning SOP leading to the accumulation of residue on the blade and cutting machine surface. it can further contaminate the T line by the components from C line, results the uncompleted T line which is easy to be read as false "positive".

From our sale record, VivaChek has distributed VivaDiag SARS-CoV-2 Ag Rapid Test (REF:VCD05-01-011) with batch #SE2010037 of 16,050 tests, and batch #SE2011037 of 30,250 tests in Italian market. VivaChek has not distributed batch #SE2011044 in Italian market.

Advice on the action to be taken by the user:

VIVACHEK Biotech (Hangzhou) Co., Ltd.

Level 2, Block 2, 146 East Chaofeng Road, Yuhang Economy Development Zone, Hangzhou, Zhejiang, China 311100

1. For the products, VivaDiag SARS- CoV-2 Ag Rapid Test (REF: VCD05-01-011), of batch #SE2010037 and #SE2011037 sold in Italy, please quarantine immediately, and contact your direct supplier for replacement.

2. Rapid Test is not designed and used for the diagnosis of COVID-19, in most countries, PCR based diagnostic method is the widely accepted as the "Gold Standard" for the confirmation of COVID-19 infection. So, if any doubt on the testing results from Rapid Test, follow-up testing with a molecular diagnostic (PCR) should be considered.

VIVACHEK Biotech (Hangzhou) Co., Ltd.

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