

Urgent Field Safety Note

Trade name of the affected product:

BORRELIA VIRCLIA® IgG MONOTEST

FSCA identifier: FSCA_26/01/2018

Type of measure: Recall from the market

Date: January, 26th 2018

To the attention to distributors/End-users of Vircell products:

As a Vircell distributor that, according to our traceability records, has received kits corresponding to the Reference VCM009, BORRELIA VIRCLIA® IgG MONOTEST, BATCH: 17C009005, we send you this Field Safety Note (FSN) to communicate this information to the end users who have received this product batch.

Vircell, S.L. has decided to execute a Field Safety Corrective Action (FSCA) regarding the batch 17C009005, due to possible false negative results which have been reported to us by one customer.

While the research is being performed, we request you to block preventively the distribution of above mentioned batch and inform the end users to whom, -according to your records- this batch has been distributed, to cease temporarily its use.

The present Note shall be sent to every person who shall be aware of the same within your organization or any other organizations where the affected products have been transferred to.

Vircell apologizes for any inconvenience that this issue may cause both the distributor and the end user.

Please, should you have any question related to this topic, do not hesitate to contact us at the following e-mail address: customerservice@vircell.com

Yours sincerely,



Joaquín Mendoza
Technical Responsible
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