

Field Safety Note

Trade name of the affected product:
HEPATITIS E VIRCLIA® IgM MONOTEST
FSCA identifier: FSCA_02/10/2018
Type of measure: Informative note

Date: October, 3rd 2018

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

As a Vircell distributor that, according to our traceability records, have received kits corresponding to the Reference VCM067, HEPATITIS E VIRCLIA® IgM MONOTEST, 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 reference VCM067, due to the fact that, a customer has reported to us a mistake in the Instructions for Use (IFU) in the section of Interpretation of results in other languages different to English and Spanish. Since in the case of the automatic processing of the reagents, the interpretation is performed directly by the software of the equipment, **this informative note only affects you if you perform the technique manually.**

The instructions for use of this kit are supplied through the Web Site www.vircell.com, and have been corrected immediately, so the instructions for use available in the Web Site are the correct ones.

If the instructions for use have been downloaded or printed, please destroy them immediately.

The interpretation of results that was included in the erroneous translation was:

INTERPRETATION OF RESULTS:

Antibody index= (sample RLU/calibrator RLU)

Index	Interpretation
<0.9	Negative
0.9-1.1	Equivocal
>1.1	Positive

Samples with equivocal results must be retested and/or a new sample obtained for confirmation.

Samples with indexes below 0.9 are considered as not having antibodies of the specificity and class measured by this kit.

Samples with indexes above 1.1 are considered as having antibodies of the specificity and class measured by this kit.

However, the correct interpretation that currently appears in the instructions for use in all languages is:

INTERPRETATION OF RESULTS:

Antibody index= (sample RLU/calibrator RLU)

Index	Interpretation
<0.4	Negative
0.4-0.5	Equivocal
>0.5	Positive

Samples with equivocal results must be retested and/or a new sample obtained for confirmation.

Samples with indexes below 0.4 are considered as not having antibodies of the specificity and class measured by this kit.

Samples with indexes above 0.5 are considered as having antibodies of the specificity and class measured by this kit.

To avoid confusion among the end users, the edition of the instructions for use in all the languages of this reference has been updated, and the new edition is 2018-10-03.

There is no impact for users of this reagent with the VirClia automatic system. The interpretation of the results given by the VirClia software and indicated in the PDF results automatically generated by it, corresponds to the correct interpretation of the results.

The user's manual indicates that the result obtained from the automatic assays is the one given in the results report of the equipment's software. In such manual, the parameterization of the LIS is not indicated, so Vircell is only responsible for the results report issued by the equipment in the automatic assays and not for subsequent actions.

Performing interpretations not recommended by Vircell of these results is considered an Use Error and should not be done.

We request that if you use the product automatically verify that you have always reported the results / interpretation issued by the Virclia system and if you use the product manually, evaluate the need to review previously issued results.

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, fill the annexed Verification Form and send to Vircell to the following e-mail address: customerservice@vircell.com

The National Competent Authority in your country has been informed of this FSCA.

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
Vircell, S. L