

Field Safety Notice

ID: FSN0120, March 2020

The change of shelf-life of the product GeneProof Hepatitis C Virus (HCV) PCR Kit

Description of the situation

In accordance with terms of IVDD 98/79 EC a EN ISO 13485:2016 certification Geneproof performs regular quality controls on all manufactured products and their batches, including follow-up stability studies. During a routinely performed follow-up stability study, the lower functionality of the component MasterMix used for above mentioned PCR kit was observed.

Affected products:

Catalogue number	LOT No. Of the MasterMix	LOT No. of the Kit	Shelf-life declared at the product	New shelf-life in accordance with the shelf-life stability study
HCV/PLUS/025 HCV/PLUS/050 HCV/PLUS/100	401019	401019A	2020-04	2020-01
HCV/PLUS/025 HCV/PLUS/050 HCV/PLUS/100	401066	401066A	2020-04	2020-01
HCV/PLUS/025 HCV/PLUS/050 HCV/PLUS/100	401115	401115A	2020-07	2020-04
HCV/PLUS/025 HCV/PLUS/050 HCV/PLUS/100	401155	401155A	2020-08	2020-05
HCV/PLUS/025 HCV/PLUS/050 HCV/PLUS/100	401292	401292A	2020-08	2020-05
HCV/PLUS/025 HCV/PLUS/050 HCV/PLUS/100	401297	401297A	2020-10	2020-07
HCV/PLUS/025 HCV/PLUS/050 HCV/PLUS/100	401306	401306A	2020-11	2020-08
HCV/PLUS/025 HCV/PLUS/050 HCV/PLUS/100	401374	401374A	2020-12	2020-09

Risk to Health, Impact Assessment:

As a result of this issue, a laboratory may obtain an invalid output of the sample measurement at its analysers, or the quantification could be incorrect. The probability of a clinically significant impact due to this issue is extremely low. The risk of a negative impact on diagnosis is virtually zero thanks to internal controls system.

Impact: Inaccuracy of quantification of positive samples – standard curves of the calibrators with R^2 less than 0.98

Actions taken by the manufacturer:

1. Manufacturer, the company GeneProof a.s. has decided to reduce shelf-life of the product from 12 months to 9 months containing the above mentioned batches of MasterMix and thus eliminate any risk of an invalid output.
2. Except for affected *GeneProof Hepatitis C Virus (HCV) PCR Kit* the company GeneProof a.s. offers also new generation of CE IVD product for Hepatitis C detection - **GeneProof Hepatitis C Virus (HCV) Diagnostic PCR Kit**. Shelf – life of this product is 12 months.

Actions to be taken by the customer/user

We would like to request the distributors and medical facilities (laboratories) that have received the above lots of the product affected:

- for documented change of shelf-life in your QMS for further use and kit handling
- for informing those responsible persons who might be affected by the above actions

Please keep this notice in your laboratory records.

We duly apologize for an inconvenience which this situation may have caused. We believe you will understand and appreciate our liability to continually improving our products and services and our commitment to constantly controlling the quality of our products.

If you have any questions about this matter, please contact the ordering department at sales@geneproof.com or the support department at support@geneproof.com of GeneProof, a.s.

Yours sincerely,

GeneProof a.s.



Confirmation of Receipt of the Field Safety Notice No. FSN0120

The change of shelf-life of the product GeneProof Hepatitis C Virus (HCV) PCR Kit

Please, kindly confirm your acceptance of the above FSN and send the Confirmation back to the email address jiri.benes@geneproof.com.

We acknowledge herewith receipt of the above FSN and confirm that we will pass it on to our customers.

Name of person completing this form:	
Name of the Company / Institution:	
Address (Street, City, ZIP Code):	
Country:	
Phone:	

Date: _____ Signature and stamp: _____

Thank you for your kind co-operation and effort.

GeneProof a.s.

GeneProof a.s.

+420 543 211 679 • info@geneproof.com

Videňská 101/119, 619 00 Brno-Dolní Heršpice, Czech Republic

www.geneproof.com