GeneProof
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FIELD SAFETY NOTICE

GeneProof Cytomegalovirus (CMV) PCR Kit – Calibrator D (LOT 406621D, empty vial)

Date	2025-09-18
Field Safety Notice Ref	FSN 00325
Field Corrective Action Ref	FSCA 00325
For Attention of	Customers who use GeneProof Cytomegalovirus (CMV) PCR Kit
Contact Details of Local Representative	INEL - MEDICINSKA TEHNIKA d.o.o. Turinina 5 10010 Zagreb Republika Hrvatska info@inel-mt.hr

Transmission of this Field Safety Notice

This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred.

Please transfer this notice to other organisations on which this action has an impact.

Please maintain awareness on this notice and follow-up for a period consistent with applicable legislation to ensure effectiveness of the corrective action.

Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority.

Manufacturer Information

GeneProof a.s.
Vídeňská 101/119, Dolní Heršpice,
619 00 Brno, Czech Republic
regulatory@geneproof.com
www.geneproof.com

* Fields indicated by * are considered necessary for all FSNs. Others are optional.

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1. INFORMATION ON AFFECTED DEVICES

1.1. Device type(s)* *In vitro* diagnostic medical device	1.2. Commercial name(s)* GeneProof Cytomegalovirus (CMV) PCR Kit
1.3. Unique Device Identifier(s) (UDI-DI) N/A	1.4. Device Model/Catalogue/part number(s)* CMV/GP/025; CMV/GP/100
1.5. Software version N/A	1.6. Associated devices N/A

1.7. Primary clinical purpose of device(s)*

The intended purpose of the device is related to the medical context and clinical conditions under which the device may be used. CMV is implicated in infectious mononucleosis. CMV implicated diseases can present in many ways including fever, pneumonia, pneumonitis, colitis, hepatitis, myocarditis, esophagitis, gastrointestinal ulcerations, diarrhoea, retinitis, visual impairment, blindness, polyradiculopathy, transverse myelitis, encephalopathy, encephalitis, seizures, and coma. Congenital CMV infections can result in non-specific symptoms and include rhinitis, pharyngitis, myalgia, arthralgia, headache and fatigue.
The GeneProof Cytomegalovirus (CMV) PCR Kit is an *in vitro* nucleic acid amplification test intended for quantification and detection of Cytomegalovirus (CMV; Human beta herpesvirus 5) by real-time polymerase chain reaction (PCR) method. The clinical specimens used for detection are CSF, plasma, serum, urine, whole blood. The GeneProof Cytomegalovirus (CMV) PCR Kit can be used in combination with a manual or automated extraction system. The kit is designed for human *in vitro* diagnostics and provides both qualitative and quantitative detection. The kit is intended for diagnostics, an aid to diagnosis and for monitoring, and it is designed for professional use in laboratories with trained staff.

1.8. Affected serial or lot number range

Affected Component: Calibrator D (LOT 406621D)

Affected Products: 2540467, 2540524, 2540568, 2540790, 2540483, 2540675, 2540693 (all LOTs in expiry)

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2. REASON FOR FIELD SAFETY CORRECTIVE ACTION (FSCA)*

2.1. Description of the product problem*

It has been identified that part of the packaging of the lots specified in Chapter 1.8 contains an empty vial of **Calibrator D (10^1 IU/µl, transparent cap)**. Calibrator D is an integral part of the four-point calibration set (A–D), which is used to establish the calibration curve for the quantification of CMV DNA in accordance with the Instructions for Use (IFU). In the absence of Calibrator D, it is not possible to establish the calibration curve and to perform quantitative analysis.

2.2. Hazard giving rise to the FSCA*

This defect prevents the performance of the quantitative test but does not lead to the issuance of incorrect results. The empty vial is easily identifiable during reaction preparation and, therefore, there is no risk of its inadvertent use. Qualitative results (positive/negative) remain unaffected by this defect.
The only practical impact is a delay in the release of the laboratory result until a replacement product is available.

2.3. Probability of problem arising

Negligible

2.4. Predicted risk to patient/users

Delay in the release of quantitative laboratory results; qualitative results (positive/negative) are not affected by the defect.

2.5. Further information to help characterise the problem

The identified issue concerns empty vials of Calibrator D (lot 406621D) in certain lots. Calibrator D is an essential component of the four-point calibration set (A–D), which is required for the quantification of CMV DNA. The issue can be detected by the user during test preparation, as the vial is visibly empty and cannot be pipetted. As a result, it is not possible to establish a calibration curve and perform quantitative analysis. No false results are expected; the issue exclusively affects quantitative analysis. Qualitative detection (positive/negative) is not impacted by the defect. The clinical impact is a delay in the release of quantitative results until a replacement product is provided.

2.6. Background on Issue

The root cause is now under further investigation.

2.7. Other information relevant to FSCA

N/A

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3. Type of Action to mitigate the risk*

3.1. Action To Be Taken by the User

☒ Identify Device ☒ Quarantine Device ☐ Return Device ☐ Destroy Device

☒ On-site device modification / inspection
☐ Follow patient management recommendations

☐ Take note of amendment / reinforcement of Instructions for Use (IFU)

☐ Other ☐ None

A) If the kit is used only for qualitative detection (positive/negative):

- No special measures are required.
- The results of qualitative detection are not affected by this defect.

B) If the kit is used for quantitative determination (viral load):

- **Check all kits from the affected lots (see section 1.8) to ensure that the vial of Calibrator D (LOT 406621D) is not empty.**
- If an empty vial is identified:
  - mark the kit as defective and place it in quarantine,
  - **document the finding with a photograph and record the LOT number and REF,**
  - provide this information to **GeneProof a.s**. or to your distributor,
  - based on agreement:
    - either return the kit (no cold chain required), **or dispose of it in the laboratory after approval by the manufacturer/distributor and proper documentation**,
  - GeneProof will provide a replacement kit (one-to-one exchange).
- **Warning: Calibrator D from another lot must not be used as a substitute, as such a combination has not been validated within QC.**

If quantitative results were mistakenly issued without the use of Calibrator D, they must be considered invalid and reviewed in accordance with your institutional procedures for corrections or revisions of laboratory reports. This scenario is considered unlikely in practice, as the empty vial is easily identifiable during test preparation.

We kindly ask the end users (laboratories) to confirm that the actions in FSN 00325 have been taken and implemented (in the attached Customer Reply Form).

If you have any further questions, please contact support@geneproof.com

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3.2. Particular considerations for: IVD
Is follow-up of patients or review of patients' previous results recommended?
Follow-up of patients is not considered necessary, as the defect prevents the performance of the quantitative test and does not lead to the issuance of incorrect results. If quantitative results were mistakenly issued without the use of Calibrator D, they must be considered invalid and reviewed in accordance with your institutional procedures for corrections or revisions of laboratory reports. This scenario is considered unlikely in practice, as the empty vial is easily identifiable during test preparation.

3.3. By when should the action be completed?
2025-10-15

3.4. Is customer Reply Required? * (If yes, form attached)
YES

3.5. Action Being Taken by the Manufacturer*

- ☐ Product Removal
- ☐ Software upgrade
- ☒ Other
- ☐ On-site device modification/inspection
- ☐ IFU or labelling change
- ☐ None

The manufacturer will provide replacement of the affected products (with empty vials of Calibrator D) on a one-to-one basis. Replacement will be arranged based on photographic documentation and LOT/REF information provided by the user. Defective kits may, upon approval by the manufacturer/distributor, either be returned (no cold chain required) or disposed of in the laboratory following proper documentation.

3.6. Date of action completion by Manufacturer
Without undue delay

3.7. Is the FSN required to be communicated to the patient /lay user?
No

3.8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet?
N/A

4. General Information

4.1. FSN Type* New	4.2. For updated FSN, reference number and date of previous FSN N/A
4.3. For updated FSN, key new information N/A	4.4. Further advice or information already expected in follow-up FSN? * No
4.5. If follow-up FSN expected, what is the further advice expected to relate to N/A	4.6. Anticipated timescale for follow-up FSN N/A
4.7. List of attachments/appendices Customer Reply Form	

Mgr. Kamil Šplíchal

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QA/RA Director
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