Viral Inactivation and Stabilisation Buffer (VIB) Inactivir® PLUS (REACH Compliant)

The Life Science Group (LSG) Viral Inactivation and Stabilisation Buffer Inactivir® PLUS (REACH Compliant) has been developed in collaboration with the University of Bedfordshire. It is a guanidine and detergent-based inactivation buffer based on published data that has been formulated to provide a buffer that will inactivate viruses responsible for pandemics such as Covid-19 and seasonal influenza and epidemics such as SARS, MERS and Ebola.

This product has been developed to inactivate the pathogen in the transport tube containing a patient or other potentially pathogenic sample. It will lyse cells and denature any virus in the sample, rendering the virus inactive and non-pathogenic. This results in a non-pathogenic sample for transport and testing with the added advantage that viral samples are stabilised due to the denaturation of degrading enzymes that may be present. Samples do not need to be maintained at +4°C, removing the requirement for a cold chain in handling and thereby greatly reducing transport costs.

The use of samples collected in VIB Inactivir® PLUS (REACH Compliant) will increase laboratory throughput by reducing the requirement for Category 2+/3 handling of potentially pathogenic samples, increasing the speed and ease of testing. This VIB is widely compatible with standard silica-based RNA extraction protocols and can be used without disruption to current processing protocols. Samples treated with VIB Inactivir® PLUS (REACH Compliant) can also be used directly in silica-based RNA extraction protocols without the need to add further denaturing buffer in the first extraction step. This allows samples to be added directly to binding material without dilution. This simplifies RNA extraction protocols and increases sensitivity due to the increased sample volume purified.

Viral Inactivation Buffer Inactivir® PLUS (REACH Compliant) has been developed with an optimised buffering system to improve RNA stability. To ensure REACH compliance, an alternative detergent to Triton X100 is used, and has been validated to ensure that efficacy has not been compromised.

Viral Inactivation Buffer Inactivir® PLUS (REACH Compliant) has been shown to maintain samples at -20°C for up to 10 weeks.

Validation data

This formulation has been validated with a range of RNA extraction protocols for detection of SARS-nCoV-19 RNA using QPCR according to published CDC protocols for detection. This buffer has been validated by Public Health England (PHE) who demonstrated that Treatment with Inactivir PLUS (REACH Compliant) Viral Inactivation Buffer using 3 volumes product to 1 volume sample for 1 minute and 15 minutes reduced SARS-CoV-2 titre by 5.1 log10 TCID50/ml and ≥5.5 log10 TCID50/ml, respectively.

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Viral preservation data

The stability of nCoV-19 RNA (EURM-19 reference standard) has been tested over an extended time period with samples stored at both room temperature (21 °C) and an elevated temperature of 35 °C to mimic potential extremes in the supply chain.

To mimic the contents of a typical swab sample containing human and bacterial cells, samples were tested in duplicate of 25 ul of a 1/1000 dilution of Covid-19 reference material EURM-019[1] plus 50 ul of Hela cells (~$10^{\wedge 6}$ ml^{-1}) in Phosphate Buffered Saline (PBS) and 20 ul of E. coli (~1 OD stock). From these 200 ul aliquots were removed and analysed according to the published CDC protocol using N2 primers[2] across the time course.

As shown in Fig 1, the buffer demonstrates good preservation of viral test RNA both at 21 °C or 35 °C, with a less than 2 Ct maximum difference at 120 hrs at 35 °C. There is the expected 10 fold (3-4 Ct) difference from the controls to the samples due to the dilution of samples during the RNA purification step of analysis.

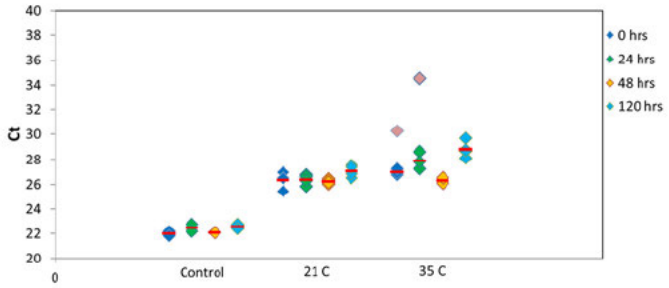

Figure 1: Ct values determined from samples incubated at 21 °C or 35 °C for up to 120 hours. Averages are shown by red bars. Two individual replicates were anomalous (pink) and disregarded for analysis.

Product Presentation

Product Code	Product Description	Size
VIB-002A	Viral Inactivation Buffer Inactivir® PLUS (REACH Compliant)	500mL
VIB-002C	Viral Inactivation Buffer Inactivir® PLUS (REACH Compliant)	50 mL
VIB-002E	Viral Inactivation Buffer Inactivir® PLUS (REACH Compliant	10 mL
VIB-002U	Viral Inactivation Buffer Inactivir® PLUS (REACH Compliant)	3mL

For transport of viral swab use only. Not approved for application to humans or animals, or for use in clinical or *in vitro* procedures. Contains hazardous reagents. Please consult SDS for list of precautionary measures.

https://crm.jrc.ec.europa.eu/p/EURM-019
https://www.cdc.gov/coronavirus/2019-ncov/lab/rt-pcr-panel-primer-probes.html

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