

Viral Inactivation and Stabilisation Buffer Inactivir® SDI STANDARD

The Life Science Group (LSG) Viral Inactivation and Stabilisation Buffer Inactivir® SDI STANDARD has been developed in collaboration with the University of Bedfordshire. It is non-guanidine formulation that is based on established viral inactivation methods 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® SDI STANDARD 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 current RNA extraction protocols and can be used without disruption to current processing protocols. Samples treated with VIB SDI STANDARD can also be used directly in standard 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 without dilution, making RNA extraction protocols simpler and increasing sensitivity due to the increased volume of sample purified.

This buffer acts as a stabiliser since the formulation will denature the enzymes (including RNAses) which are responsible for the degradation of RNA and DNA. The chaotropic nature of the solution means it cannot be added directly to PCR reactions.

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 SDI STANDARD Viral Inactivation Buffer using 3 volumes product to 1 volume sample for 1 or 15 minutes reduced SARS-CoV-2 titre by $\geq 4.3 \log_{10}$ TCID₅₀/ml, to below the limit of detection of the tests.

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Life Science Production

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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-019¹ plus 50 ul of Hela cells (~10⁶ 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 primers² across the time course.

As shown in Fig 1, the buffer demonstrates excellent preservation of viral test RNA both at 21 °C or 35 °C, with only a 1 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.

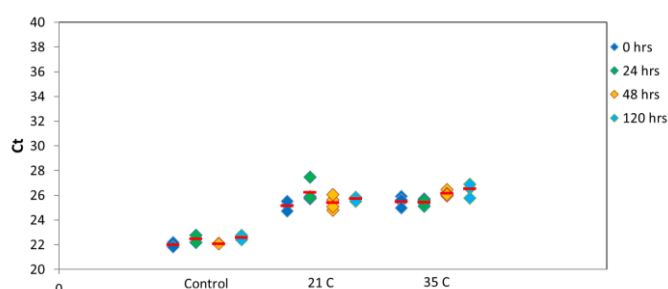


Figure 1: Ct values determined from samples incubated at 21 °C or 35 °C for up to 120 hours. Averages are shown by red bars. Two individual replicates were anomalous (pink) and disregarded for analysis.

Product Presentation

Product Code	Product Description	Size
VIB-005A	Viral Inactivation Buffer Inactivir SDI STANDARD	500mL
VIB-005C	Viral Inactivation Buffer Inactivir SDI STANDARD	50 mL
VIB-005E	Viral Inactivation Buffer Inactivir SDI STANDARD	10 mL
VIB-005U	Viral Inactivation Buffer Inactivir SDI STANDARD	3 mL

¹ <https://crm.jrc.ec.europa.eu/p/EURM-019>

² <https://www.cdc.gov/coronavirus/2019-ncov/lab/rt-pcr-panel-primer-probes.html>

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

Inactivation reagents should not be assumed to be 100% effective against SARS CoV-2.

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