

Biological Risk Management and Containment

Sendai and Replication- defective Viral Vectors

Storage and Use

Containment Laboratory Guidelines

Version 2- February 2021



This document was originally Version 1 which was extensively reviewed and approved in February 2021.

Record of Amendments to Version 2

Date	Page number	Nature of amendment

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1. Who is this reference document for?

This document is intended for **principal investigators (PIs), sector managers, designated laboratory person (DLPs)**, technical staff and students who use laboratories within University of Auckland containment and transitional facilities who use replication-defective and/or Sendai viral vectors.

2. Good practice guidelines for the storage and use of replication-defective and/or Sendai viral vectors

There are a number of HSNO approvals for packaging replication defective viral vectors given by the EPA (ERMA 200732, GMD03091 and GMD03096) and the University of Auckland Biological Safety Committee (UABSC). In addition there is an outcome based approval (APP202619) for the use of disabled Sendai virus modified with Yamanaka Factors for the generation of induced Pluripotent Stem Cells.

In order to meet additional controls on these HSNO approvals the following work practices will be observed.

3. Work practice when working with replication-defective viral vectors

3.1. Storage of vector stocks

Stocks of Sendai and Replication-defective Adeno-associated, Adenoviral and Retroviral* vectors will be stored:

- a) In a locked freezer or within an access controlled laboratory.
- b) Within labelled boxes with clear warnings that the boxes contain viral vectors

3.2. Production of replication-defective viral vectors

When Replication-defective Adeno-associated, Adenoviral and Retroviral* vectors are produced and packaged:

- a) The work will be conducted in Class II biological safety cabinets (BSCs).
- b) Gloves must be worn.

- c) Equipment that has come in contact with viral vectors will have been in contact with media containing lower titre viral vector and must be chemically decontaminated prior to or immediately after removal from the Class II BSC (refer to sections below pertaining to Decontamination).

*The term “replication-defective retroviral vectors” includes replication-defective lentiviral vectors.

3.3. Work with Sendai and Replication-defective Adeno-associated, Adenoviral and Retroviral vectors

The following will apply to work with Sendai and Replication-defective Adeno-associated, Adenoviral and Retroviral vectors:

- 1) The work will be conducted in Class II BSCs.
- 2) Gloves must be worn.
- 3) Equipment that has come in contact with concentrated stocks of viral vector will be chemically decontaminated either inside the Biological Safety Cabinet (where high titre stocks are used) or immediately upon removal from the Biological Safety Cabinet when packaging (refer to sections below).
- 4) Adeno-associated viral vectors will be handled in separate laboratory areas from Adenoviral vectors. If the same laboratory areas must be used, all equipment and work surfaces must be thoroughly decontaminated and there must be at least 24 hours separation between work with Adeno-associated viral vectors and Adenoviral vectors.

3.4. Decontamination Agents for work with Sendai and Replication-defective Adeno-associated, Adenoviral and Retroviral vectors

Sendai and Retroviral vectors are enveloped viral vectors while AAV and Adenoviral vectors and non-enveloped viral vectors.

Non-enveloped viral vectors are more difficult to decontaminate than enveloped viral vectors. Accel is an effective decontamination agent for enveloped viral vectors and is to be used at final dilution of 1:10.

3.5. Decontamination of equipment and medium that has come in contact with concentrated stocks of viral vector during cell transduction

To ensure consistency in practice, the following will apply to cell transduction with concentrated viral vector:

- 1) Minimum of 500 ml of Accel diluted to 1:10 will be made up in a container which is placed inside the Biological Safety Cabinet (BSC).
- 2) All pipette tips used for applying the viral vector are placed in this beaker of 1:10 Accel for decontamination inside the Biological Safety Cabinet.
- 3) Aspiration **MUST** not be used to draw off media containing viral vector. Used media with viral vector will be dispensed into beaker which is then made 1:10 with Accel.
- 4) Minimum holding times of 20 minutes will apply before removal from the BSC.

3.6. Decontamination of equipment and medium during production of viral vector

To ensure consistency in practice, the following will apply to packaging:

- 1) All used pipettes are placed in the container with 1:10 Accel to be decontaminated immediately upon removal from the Biological Safety Cabinet.
- 2) Used plates and flasks are to be decontaminated with Accel (1:10) immediately upon removal from the Biological Safety Cabinet.
- 3) Aspiration **MUST** not be used to draw off media containing viral vector. Used media with viral vector will be dispensed into beaker which is then made 1:10 with Accel.
- 4) Minimum holding times of 20 minutes will apply before disposal of decontaminated equipment.

4. Definitions

Designated laboratory person (DLP) means the trained person in each research group who has been given the authority to receive purchase requests made in SQERM and to make a formal request for a purchase order via PeopleSoft. In containment and transitional facilities DLPs will have additional training to enable them to scrutinise documentation for restricted items and provide support to researchers.

Designated person in charge means a staff member in any of the following roles: sector manager, facility manager, floor manager, technical manager or an appointed delegate.

Principal Investigator (PI): In the context of hazard containment and transitional facilities, a principal investigator is the holder of an independent grant administered by the University and the lead researcher for the grant project, usually in the sciences, such as a laboratory study or a clinical trial. The phrase is also often used as a synonym for "head of the laboratory" or "research group leader." The PI is responsible for assuring compliance with applicable University standards and procedures, and for the oversight of the research study and the informed consent process. Although the PI may delegate tasks, they retain responsibility for the conduct of the study.

Sector manager means a manager who has responsibility for containment procedures within a designated area of the containment facilities. This person is either a floor manager (FMHS) or a technical team leader (SBS).

Technical manager means the research laboratory technical manager (FMHS) or technical manager (SBS).