

0PUBLIC HEALTH ENGLAND

STANDARD OPERATING PROCEDURE



DIVISION: OPERATIONS

DEPARTMENT: [REDACTED]

TITLE: Storage of Material in [REDACTED]

SOP NO. [REDACTED]

AUTHOR: [REDACTED]

AUTHORISER: [REDACTED]

EFFECTIVE DATE: 25.10.2016

ISSUED TO: [REDACTED]

REVIEW DATE: 21.10.2019

SUMMARY

This document covers the procedure for the aliquotting of infectious material in [REDACTED] and storage in the Ultra-low temperature archive.

Material is stored in lockable -80°C freezers and details maintained on a restricted access database.

SAFETY

The [REDACTED] is used for agents classified at ACDP Hazard Group 4 and/or at DEFRA category 4.

All infectious work is undertaken in a series of interlinked Class III Microbiological Safety Cabinets, within a negative pressure envelope.

PPE comprising disposable Tyvek overall, nitrile gloves, safety glasses and protective shoes worn at all times in the laboratory, Kevlar liners also worn when handling material in the cabinet-line. Thermo protective gloves worn when using Ultra-low temperature archive.

Access to this laboratory is restricted to experienced staff trained to use the facility, and supervised trainees. No other staff, visitors or contractors are permitted access unless a risk assessment determines that it is safe for them to do so and only when accompanied by a trained member of staff.

Staff using the facility must follow the local code of practice for that room, specific SOPs and risk assessments to ensure that the highest safety standards are met at all times.

Refer to [REDACTED]

SOP NO. [REDACTED]

COPY NO. [REDACTED]

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1.0 CROSS REFERENCE

SOP

- [REDACTED] – Waste management in [REDACTED]
- [REDACTED] - Working procedures in [REDACTED] & Cabinet line

Risk Assessments

- [REDACTED] – Use of [REDACTED] & cabinet line
- [REDACTED] – Processing and storage of infectious material in CL4 laboratory
- [REDACTED] – Use of temperature controlled facilities
- [REDACTED] - Use of Dunk Tank in the CL4 laboratory
- [REDACTED] – Use of Sodium hypochlorite dunk tank

Worksheets

- [REDACTED] – Primary containment checklist
- [REDACTED] – CL4 Code of Practice
- [REDACTED] – [REDACTED] Training portfolio
- [REDACTED] – Storage Vessel Integrity Assessment
- [REDACTED] – CL4 Laboratory Activity Log

2.0 EQUIPMENT

- 0.5ml & 2.0ml Screw capped skirted tube with O-ring seal (Sarstedt or equivalent)
- Filter tips from 1-1000ul volume
- Variable pipettes from 1-1000ul volume (Finn, Gilson or Eppendorf)
- Sterile pastettes (Alpha labs)
- Electronic/digital dispensing pipette (Eppendorf or equivalent)
- Sterile stepper syringes (Eppendorf)
- Temperature resistant (to -80°C) cryo-labels (cryobabies or equivalent)
- 7ml Polypropylene (PP) container
- Net bag
- Zip-lock bags
- 5x2 and 5x1 Cryotube Minibox (Cole Palmer or equivalent)
- Vinyl tape
- Blue paper towel or absorbent material
- Butyl gauntlet (BM Polyco, Cat # 18800 B 9.5 6/10)
- Polythene sleeving
- Safety scissors

3.0 REAGENTS

- 70% Ethanol (v/v) or equivalent commercial disinfectant wipe (e.g. Azowipes)
- Sodium hypochlorite (1000ppm) (Haz Tabs (Guest Medical) or equivalent)

4.0 PERSONNEL

All Medical Microbiologists, Clinical Scientists, Biomedical Scientists, Healthcare Scientists, students and visitors who have been suitably trained.

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5.0 TRAINING

All staff using the laboratory must have completed or be in the process of completing the [REDACTED] Training portfolio for [REDACTED].

Only staff members that have been signed off as competent in the training portfolio to work in [REDACTED] may enter the suite unaccompanied to undertake non-infectious work. All other staff **MUST** be accompanied at all times by a member of staff deemed as competent to work in [REDACTED].

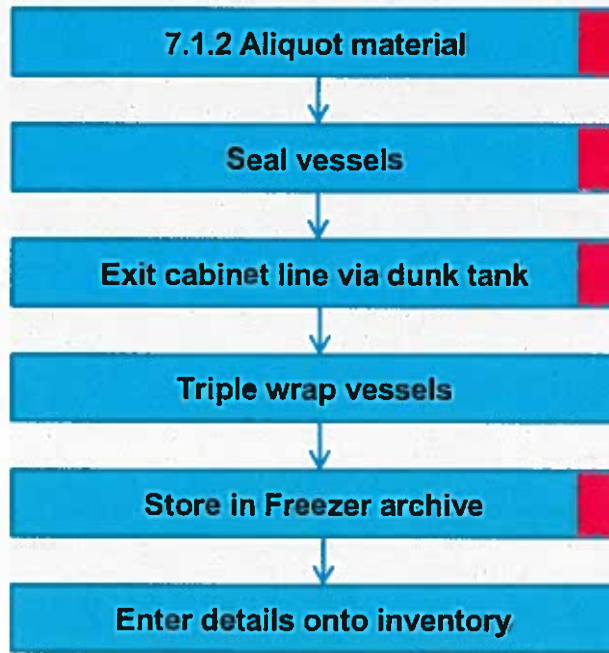
The 2nd member of staff or 'Buddy' **MUST** have been trained in the procedures undertaken and provide confirmation that the procedure is being completed according to the SOP.

6.0 USEFUL NOTES

- All infectious work **MUST** be undertaken with a minimum of 2 trained members of staff in the laboratory.
- Each member of staff can undertake their own workstream independently.
- A dedicated 2nd worker or 'Buddy' must enter the laboratory when there is only 1 workstream to be undertaken.
- It is the role of the 'Buddy' or 2nd worker to provide assistance in opening and holding containers, passing reagents and consumables in and between the cabinet line components when required or during periods of inactivity from their own work. The Buddy or 2nd worker will also act as a witness to confirm the procedure is undertaken correctly.
- A regular flow of communication **MUST** be maintained when there are 2 or more workers in the laboratory, to check for problems and ensure all staff members are OK.
- Record all errors, incidents and failures on [REDACTED] – Quality & error log.
- Ensure the minimum quantity of consumables and reagents are taken in the laboratory to minimise the volume of waste generated.
- Label tubes with material details prior to taking into laboratory if possible. Include name of material, date and user as a minimum.
- Check integrity of storage vessels before transport to the laboratory (e.g. cracks, broken lids, absence of O-ring).
- Storage conditions may change depending on the sample type, frequency of use and further downstream processing requirements.
- Infectious material **MUST** only be stored in screw capped tubes with O-ring.
- The electronic inventory is stored on a secured server with access restricted to those individuals deemed appropriate by senior staff.
- Aliquotting of infectious material **MUST** be conducted directly over the plastic spill trays in each cabinet



7.0 Process Map



Refer to associated Risk Assessment or Safety Note



8.0 METHOD

! The handling, transport and storage of infectious material can ONLY be undertaken with a MINIMUM of 2 members of staff in the laboratory !

8.1 Aliquoting material in cabinet-line

Check cabinet-line air pressure and air change indicators are green before commencing work.

8.1.1 Label 2.0ml tubes with temperature resistant labels that includes at least a:

- Material identifier
- preparation date
- user initials.

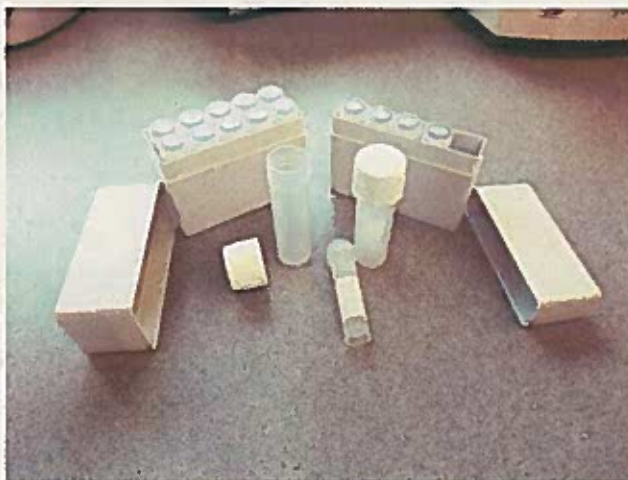
8.1.2 Place the labelled 2.0ml screw-cap tubes into a 'Sarstedt' rack with gripping teeth and add required volume of sample, material or reagent using a pipette, sterile pastette or stepper syringe.

8.1.3 Ensure O-ring seal is intact and lid tightened to prevent material leaking from tube. See fig below

The volume of material in each tube may vary depending on the process requirements and storage conditions of each aliquot and is subject to assessment by the primary worker.

Manipulate swabs, tissues and non-liquid material with disposable sterile forceps.

8.1.3 Place aliquots into 2x5 or 1x5 cryotube miniboxes and a small number into separate 7.0ml Polypropylene containers or bijoux's as or if required.



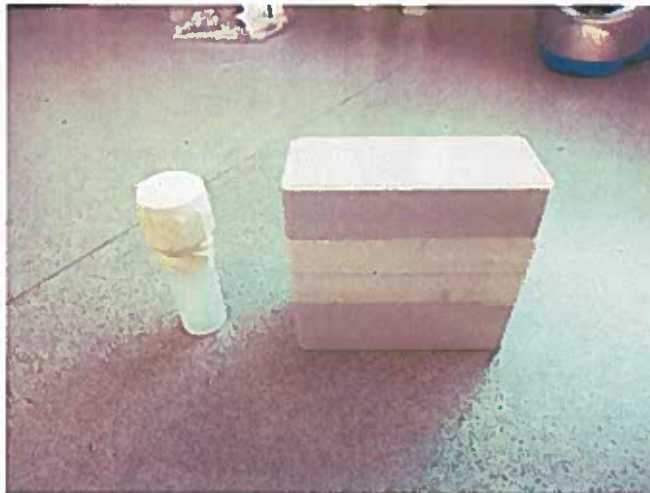


The number of tubes stored in either container may vary depending on the process requirements of each aliquot and is subject to assessment by the primary worker. However the bulk quantity is usually stored in the miniboxes and a smaller working stock aliquots in the bijoux's. The Working stock can then be replenished from the Bulk stock when required.

8.1.4 Spray and wipe external surfaces of miniboxes and bijoux's with 70% Ethanol.

Only use safety scissors to cut tape.

8.1.5 Secure each storage vessel with a length of vinyl tape.



Stow gauntlets outside cabinet-line to prevent impeding waste transporter

8.1.6 Place sealed vessels into net bags (or equivalent) to allow for surface decontamination by chlorox and transport to dunk tank.

8.2 Removal from Cabinet-line through dunk tank

8.2.1 Check primary containment checklist () to ensure Sodium hypochlorite in dunk tank is at least 10,000ppm.

8.2.2 Immerse and submerge bag containing vessels into dunk-tank and leave for minimum of 5 minutes.

8.2.3 Push under partition and leave submerged for a further 5 minutes.



If evidence of integrity breach from primary container detected, immediately place vessels back into cabinet-line through dunk tank for disposal or repackaging. Rinse sink with liquid disinfectant.

Ensure the same number of vessels is removed from the dunk tank as was initially immersed.

Add more water to dunk tank if liquid level less than 2cm above partition.

8.2.4 Remove from dunk tank (with butyl gauntlet and sieve), transfer to sink and rinse with water.

8.2.5 Dry with absorbent material.

8.3 Triple wrapping and storage

8.3.1 Place each vessel or box into polythene sleeve or bag and place beneath raised arm of heat sealer.

8.3.2 Ensure there is a finger width of plastic between the storage vessel and sealing face.

8.3.3 Close and press down on the sealing arm whilst simultaneously pulling the storage vessel gently away from the sealing face until the triple wrapped package detaches cleanly.

Check polythene wrapping integrity and reseal if required.

8.3.4 Place absorbent material on the floor beneath the freezer to catch ice and melt water. Dispose as for laboratory waste.

Thermo protective gauntlets MUST be worn when using freezer.

8.3.5 Remove racking from low temperature archive (freezer) location and place on laboratory table.

8.3.6 Place vessel or box in racking location and return to allocated freezer.

8.3.7 Record sample and storage details on CL4 Laboratory freezer inventory and CL4 Activity Log ().



8.4 Pathogen and Sample inventory

Low temperature storage archive consists of 3x slim-line -80°C Ultra-low temperature freezers containing 2x stainless steel hotels per shelf holding 5x steel trays.

8.4.1 Open password protected Excel spreadsheet inventory.

8.4.2 Enter sample details onto relevant tab of electronic database, ensuring the maximum sample information is recorded.

7.4.2 Ensure all material transactions either into or out of the inventory database are recorded.

7.5 Freezer maintenance

7.5.1 Periodically empty the freezer of excessive powdered ice by sweeping into a suitable container and disposing to the laboratory sink.

SUMMARY OF REVISIONS

Retraining Required	Yes	No	(delete appropriate)
Ensured safety notes stated before relevant activity, updated Hypochlorite conc. To 10,000ppm			