PUBLIC HEALTH ENGLAND

STANDARD OPERATING PROCEDURE

DIVISION: OPERATIONS

DEPARTMENT: [redacted]

TITLE: Receipt and transport of clinical samples into [redacted]

SOP NO. [redacted]

AUTHOR: [redacted]

AUTHORISER: [redacted] EFFECTIVE DATE: [redacted]

ISSUED TO: REVIEW DATE: [redacted]

SUMMARY

This document covers the procedure for the receipt and transport of clinical material that is suspected of or is known to contain ACDP or SAPO Hazard group 3 and 4 viruses into [redacted] suites. The sample requirements are assessed at CL2 and then processed in the Containment Level 3 or 4 laboratories as appropriate.

SAFETY

The [redacted] CL3 and CL4 laboratories at [redacted] are used for agents classified at ACDP Hazard Group 3 or 4 and/or at SAPO category 3 or 4 (Refer to Table 1).
Infectious work in the CL3 laboratory is undertaken inside a Class III Microbiological Safety Cabinet maintained within a negative pressure envelope.
All infectious work in the CL4 laboratory is undertaken in a primary containment system consisting of a series of interlinked Class III Microbiological Safety Cabinets maintained within a negative pressure envelope. Envelope maintained by independent HVAC system and air tight interlocked doors through suite.
Access to both laboratories is restricted to experienced staff trained to use the facility, and supervised trainees.
No other staff, visitors or contractors are permitted access whilst the laboratory is operational unless a risk assessment determines that it is safe for them to do so and only when accompanied by trained staff.
Staff using either laboratory must be equipped with 2-way radio with man-down alarm.
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] and '[redacted]' for emergency protocols and practices.

Further details within SOP.

1.0 CROSS REFERENCE

SOP

- [redacted] – Waste disposal at CL3
- [redacted] – Data handling, reporting & local retention procedures for clinical samples in [redacted]
- [redacted] – Dealing with mismatched specimens/requests
- [redacted] – Specimen Reception
- [redacted] - Packaging and transport of infectious or potentially infectious material from [redacted] to other sites in the UK or overseas, and local transport within [redacted] site
- [redacted] – Receipt & processing of samples for Ebola testing
- [redacted] – Waste management in [redacted]
- [redacted] – [redacted] entry & exit procedure
- [redacted] – Working procedures in [redacted]
- [redacted] – Processing clinical material in [redacted]
- [redacted] – Working procedures in [redacted]

Worksheets

- [redacted] Specimen Screening and Quarantine Policy
- [redacted] Code of Practice
- [redacted] Code of Practice
- [redacted] Training portfolio
- [redacted] Quality and error log
- [redacted] CL3 Laboratory Training manual

Risk Assessments

- [redacted] entry & exit procedure
- [redacted] – Working in a Class III MSC
- [redacted] – Use of [redacted] & cabinet line
- [redacted] – Processing clinical samples in [redacted]
- [redacted] – Receipt & unpacking of clinical specimens in [redacted]
- [redacted] – Processing clinical material in [redacted]

2.0 EQUIPMENT

- Sealable box
- LIMS labels
- As required for sample processing and waste disposal

3.0 REAGENTS

- None required

4.0 PERSONNEL

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

5.0 TRAINING

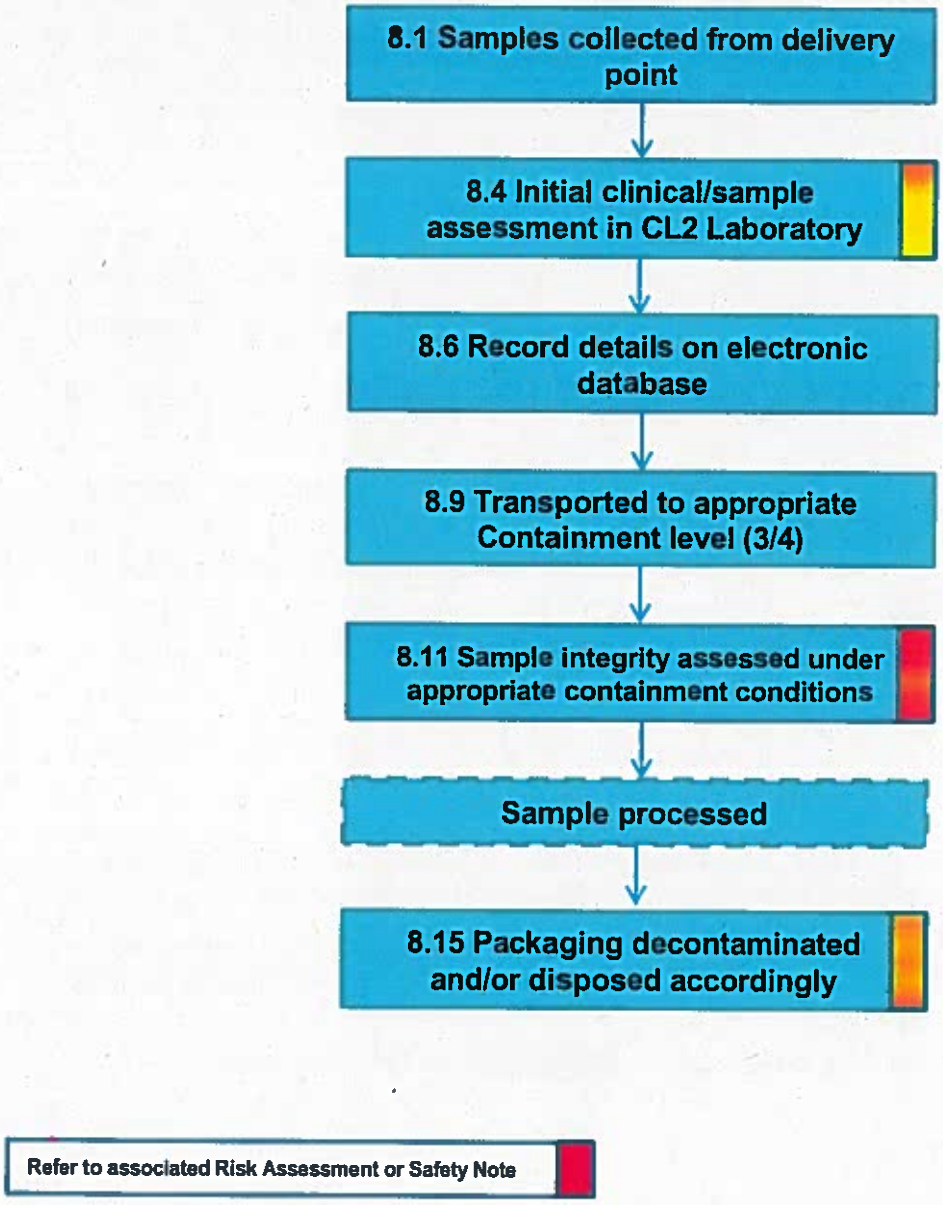
All staff using the laboratory must have completed or be in the process of completing the [redacted] Training portfolio [redacted]

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

6.0 USEFUL NOTES

- Not all samples received in [redacted] contain suspected or actual pathogenic organisms and may be handled at lower containment levels or conditions pending a risk assessment.
- Clinical material should only be handled at the appropriate containment level (refer to Appendix 1 for details).
- Record all errors, leaks or breakages on [redacted] Quality & error log

7.0 PROCESS MAP



8.0 METHOD

Safety Note:	ALL clinical samples received into HCM MUST be risk assessed by a senior member of staff with respect to clinical and travel history before they are handled at the required Containment level. Derogation of the handling of the sample at a lower containment level CAN ONLY be authorised by a senior member of staff. Processing of the sample CAN ONLY be undertaken after discussion with a senior member of staff.
Tech Note:	High risk samples will be delivered to [redacted] via a dedicated courier after discussion between a senior member of staff and the requesting laboratory. All other samples will be delivered to Central Specimen Reception (CSR).

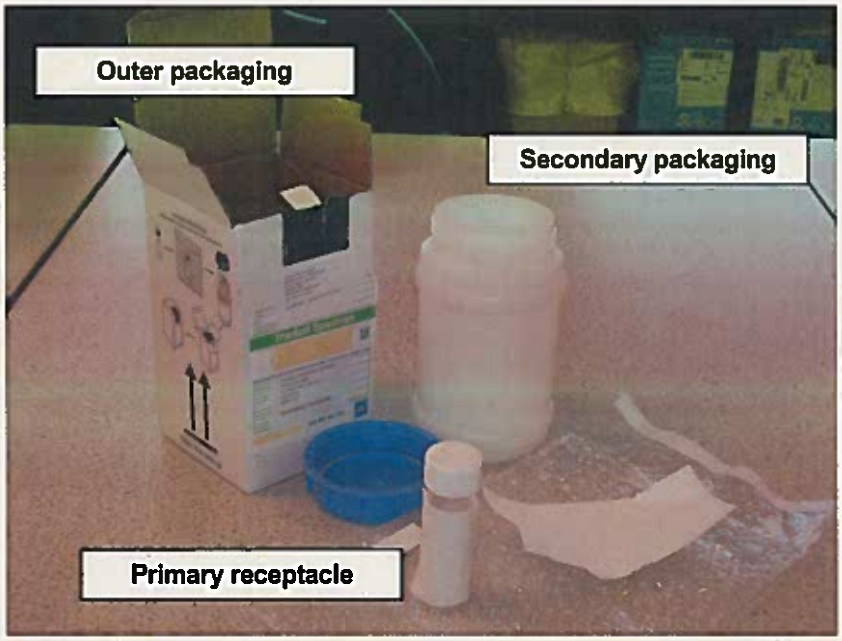
8.1 Collect samples from:

a. reception or security station if delivered via courier with prior arrangement
b. CSR after notification from staff

8.2 Transport to Containment Level 2 (CL2) laboratory 3C47 in original packaging.

8.3 Wearing PPE (lab coat, nitrile gloves and safety glasses) open the outer package on the bench (see Figure 1) and remove the request form.

Figure 1: Sample packaging



Tech Note:	If the request form is contained within the secondary packaging it must be removed inside a MSCIII cabinet in CL3 or CL4 laboratory and fumigated prior to removal from the laboratory.

8.4 Review request form.

Safety Note:	An initial assessment of the sample type and clinical history can now be undertaken by a senior member of staff to determine at which containment level the sample can be processed. Handling conditions and procedures can change on a sample to sample basis at the discretion of the senior staff member subject to risk assessment.

8.5 Check the secondary packaging for signs of damage or integrity breach. DO NOT OPEN.

Safety Note:	If ANY damage or breach is evident on the secondary packaging, replace and close the outer packaging. Inform a senior member of staff immediately.

8.6 Enter sample details onto [redacted] Daybook database

8.7 Print [redacted] labels to attach to the sample and the request form.

Tech Note:	Further labels can be requested from a member of staff outside the laboratory suite if required when processing the sample.

8.8 Prepare consumables and reagents required to process the sample and place in autoclave bag with labels and sample.

8.9 Transport secondary packaging and consumables to the appropriate containment level laboratory (3/4).

8.10 Place sample into clean MSC III in [redacted] or Cabinet line in [redacted] – refer to documents [redacted] and [redacted] for further details.

Safety Note:	Samples processed in the Containment Level 3 laboratory may be handled on the bench as determined by sample requirements, clinical history and pending a risk assessment. All samples handled at CL4 MUST be processed inside the cabinet line.

8.11 Open secondary packaging and remove sample. Examine for evidence of leakage or integrity breach.

Safety Note:	If ANY leak or breach is evident on the sample container, make safe, stop working and inform a senior member of staff immediately.

8.12 Check the details on the primary receptacle (sample) match those stated on the request form. If the details are different, ring the sending laboratory for confirmation.

8.13 Attach [redacted] label to sample vessel if suitable or new vessel after transfer.

8.14 Process the sample accordingly for downstream analysis.

8.15 All absorbent material or packing inside the secondary packaging MUST be fumigated then disposed according to local procedures.

8.16 Fumigate the secondary packaging, including any absorbent material or wadding, out of the MSC III / cabinet line, rinse in soapy water and return to CSR or sending laboratory.

Safety Note:	If the secondary container is heavily soiled or damaged then discard after fumigation.

9.0 Appendices

Appendix 1: Laboratory containment level at which material suspected or known to contain viral pathogens, should be processed (# denotes SAPO pathogen).

Material known or strongly suspected to contain....	Minimum Laboratory Containment Level	Material known or strongly suspected to contain....	Minimum Laboratory Containment Level
Congo Crimea Haemorrhagic Fever Virus	4	Japanese Encephalitis Virus #	3
Cowpox	2	St Louis Encephalitis Virus #	3
Ebola Virus	4	Venezuelan Equine Encephalitis Virus #	3
Herpes B Virus	4	Eastern and Western Encephalomyelitis Virus #	3
Lassa Fever Virus	4	West Nile Virus #	3
Lymphocytic Choriomeningitis Virus (LCMV)	3	Rift Valley Fever Virus #	3
Marburg Virus	4	Vesicular Stomatitis Virus #	3
Monkeypox	3	Highly Pathogenic Avian Influenza #	4
Smallpox	4	Rabies and genus Lyssavirus #	4
Vaccinia Virus	2	Nipah Virus #	4
Newcastle Disease Virus #	4	Hendra Virus #	4
Aujeszky's Disease Virus #	3	Novel Coronavirus	3

SUMMARY OF REVISIONS

Retraining Required	**~~Yes~~ No (delete appropriate)**
New SOP	
Supersedes documents	[redacted]