

University of East Anglia, Norwich

BCRE LABORATORY
CONTAINMENT LEVEL 2+ SUITE

GENERIC STANDARD OPERATING PROCEDURES (SOPs)

Code of Practice for Working at Containment Level 2+ in BCRE

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Document History:

This section shows the approval and revisions of this document since its first issue:

Version	Comments	Authors	Date approved	Date of next review
01	First issue of document	J Waters	08/12/15	08/12/17 or prior
02	Minor modifications	J Waters	09/06/16	09/06/17 or prior
03	Modification to include 'Exceptional Operation' and revision to clarify areas of suite and their use. Also clarifying reporting structure for project registrations	J Waters / E Manners	03/02/17	03/02/18 or prior

1.0 Code of Practice for working with Clinically Unknown biological samples with potential to contain biological agents or microbiological samples

In accordance with the HSE recommendations “*Biological Agents: Managing the risks in laboratories and healthcare premises*”, subject to appropriate risk assessment, all work with clinical material from patients with the potential to carry undiagnosed infections but where there is no intention to deliberately propagate any biological agents, should be carried out in a CL2+ lab. The Bob Champion Research and Education Building (BCRE) at the University of East Anglia (UEA) Containment level 2+ (CL2+) laboratory (214/0.39) will be used to process, according to the following codes of practice, any clinical materials with the potential to carry undiagnosed infections. No intentional culturing work with any pathogen (HG2 or above) shall be undertaken within these facilities unless it is agreed by all current users to enter into ‘exceptional operation’ mode designated for this sole purpose for a defined time period (see ‘Exceptional Operation’ in section 2.4). No culturing of bacteria known or likely to contain pathogens above HG2 is to be undertaken in these facilities.

1.1 Introduction

This is a Controlled Document and any changes may be made by the Bob Champion Research and Education Building (BCRE) Laboratory Facilities manager and passed through the University of East Anglia Biological Hazards and Genetic Manipulation Committee review panel (BHGMC). This document sets out the Operational Management and Safety Issues for working at Containment level 2+ in the BCRE. Standard Operating Procedures are also included which determine individual generic operations necessary for understanding the safe working practices within the facility. A secure master copy of the document with all authorized changes tracked is held by the laboratory facilities manager in BCRE 214/1.39.

1.2 Legal Duties

1. The implementation in 1995 of the EC Biological Agents directive via the Control of Substances Hazardous to Health regulations 1994 (CoSHH) introduced for the first time, legal requirements for all types of Laboratories.
2. The Advisory Committee on Dangerous Pathogens (ACDP) issued guidance on work at all containment levels and a categorization (the Approved List) of biological agents which forms part of CoSHH. ACDP also issued document “*Biological Agents: Managing the risks in laboratories and healthcare premises*”.

3. Local Codes of Practice form part of the process of giving information on safe working. Employers have a responsibility to make the policy and codes freely accessible. All newcomers and temporary workers must be made aware of them.
4. Workers have a duty to co-operate with their employer by applying agreed Local Rules and Procedures. Workers also have a duty to report defects and deficiencies in management arrangements.

1.3 Approval of New Projects Requiring Containment level 2+ Facilities

1. No work can proceed and no clinical material from patients with the potential to carry undiagnosed infections must arrive on site until written approval is received from the BCRE Safety Officer and the Health and Safety Executive (HSE) has received statutory notification where applicable.
2. Applications to work with clinical material from patients with the potential to carry undiagnosed infections in the BCRE should be made to the Biological Hazards and Genetic Manipulation (BHGMC) Committee review panel by submission of Microbiological Risk Assessment Form (MRA) *and/or* by completion of a Human Tissues Scheme of Works and Risk Assessment forms (HTSW) (*forms available on UEA safety website*) as appropriate. Final approval for new work will be granted by Microbiological and Genetic Modification safety officer or Human Tissues Safety Officer as appropriate and the BCRE Safety Officer.
3. Application must also be submitted to the University's Occupational Health Department (OHD) by copy of MRA and HTSW forms and a Pre-employment Questionnaire (PEQ) for all staff working in CL2+ must be completed.
4. Where applicable UEA Safety Services will notify HSE following approval by the BHGMC.
5. The PI has full responsibility as Project Supervisor for the Health and Safety of all persons working on or affected by the project.
6. The Project Risk Assessment and/or Scheme of Work must adhere to the Local Rules and Standard Operating Procedures set out for the CL2+ laboratory, as well as detailing any specific requirements necessary for safe working with any individual organism / sample type.

Note:

Applicants should be prepared for the process to take up to 90 days from submission for each application to be processed. Once the project has been approved, where HSE notification is a requirement, the HSE requires 20 days prior notice of intention to start work.

Information and guidance on submitting proposals can be found at:
<https://intranet.uea.ac.uk/uss/intranet/safetysubjects/bioagents>

This Code of Practice assumes compliance with the following documents:

“University of East Anglia Statement of Health and Safety Policy”.

“Control of Substances Hazardous to Health Regulations (COSHH)”.

“Health and Safety at Work Act”.

“The Advisory Committee on Dangerous Pathogens – The management, design and operation of microbiological containment laboratories”

“Biological agents: Managing the risks in laboratories and healthcare premises”.

All documents are available on request to the Director of Safety Services and copies can be provided by the BCRE Laboratory Facilities Manager.

2.0 Containment level 2+

2.1 The Facility

1. The Containment level 2+ facility is a purpose-built suite situated on Level 0 of the BCRE. Access is restricted to authorized personnel. 'The CL2+ suite' (defined as CL2 lab 0.37, Lobby 0.38 and CL2+ lab 0.39) comprises of a CL2 laboratory area (lab 0.37) leading via a changing lobby (0.38) to the self-contained CL2+ laboratory (lab 0.39). There is a pass through autoclave which bridges between the two laboratory areas. The 'clean' side of the autoclave can be accessed from the CL2 lab. The CL2+ laboratory houses a ducted Class II Microbiological Safety Cabinet (MSC).
2. The CL2 laboratory area of the CL2+ suite is managed under the conditions of access and management of this CL2+ Standard Operating Procedure, but work procedures conducted in the CL2 area (lab 0.37) may follow the BCRE Laboratory Code of Practice for CL2 facilities. All activities within the CL2+ laboratory (lab 0.39) must strictly adhere to procedures documented within this Standard Operating Procedure.
3. Air Handling – The suite is maintained at air pressure not positive to the environment. The MSC is an integral part of the air extract system.

2.2 Facility Management

1. Overall responsibility for the CL2+ suite rests with the Safety Officer of the Bob Champion Research and Education Building. For safety issues the Safety Officer is responsible to the BHGMC.
2. The BCRE Laboratory Facilities Manager is responsible to the Safety Officer for the day to day management of the suite and holds delegated authority from the Safety Officer to enable the safe running of the suite. The BCRE Laboratory Manager is responsible for implementing the Local Rules for the CL2+ Suite.
3. The BCRE Laboratory Facilities Manager will authorize the use of the laboratories and co-ordinate bookings for approved projects.
4. Whilst a number of CL2+ projects may be 'live' during any period of time, the CL2+ lab (0.39) will be used for the sole access for the group working on one project at any time. Booking systems will prevent two current projects from being active simultaneously within the CL2+ lab. At any time following cessation of all ongoing CL2+ work, the CL2+ lab (0.39) must be decontaminated according to any project specific decontamination procedure prior to reverting to use as a managed CL2 laboratory facility.
5. The PI as defined on the project specific risk assessment holds full responsibility for the safe operation of all project work in the suite. The PI is accountable to the Safety Officer for this responsibility.

2.3 General procedures within facility

1. Processing of clinical material from patients with the potential to carry undiagnosed infections above HG2, specifically excluding culture, may only be undertaken by those persons who are approved to do so and must be carried out within the CL2+ laboratory (0.39).
2. Any clinical material from patients with the potential to carry undiagnosed infections which have been inactivated or proved HG2 or below may be removed from CL2+ laboratory and processed elsewhere subject to a satisfactory risk assessment approved by the BHGM committee.
3. Prior to receipt onto UEA property, all clinical material from patients with the potential to carry undiagnosed infections must be double contained. Samples must remain double contained until they are inside the MSC located in the CL2+ laboratory.
4. Access to the CL2+ laboratory suite is strictly restricted to authorized personnel only. The BCRE Laboratory Manager will arrange proximity card activation for approved personnel and arrange de-activation of their card following cessation of the work.
5. Access to the CL2+ suite will only be granted to personnel who have completed appropriate training. Generic suite safety training will be conducted by the laboratory manager and staff must be signed off on training records by PI and laboratory manager as having received suite generic training. The PI must ensure that all staff for which they are responsible during their project receive sample / project specific training which must be appropriate and suitable to ensure staff have sufficient competence to work safely within the CL2+ suite.

2.4 Exceptional Operating Procedures within Facility

1. Any requirement for culturing of HG2 pathogens within the CL2+ Suite falls within 'Exception Operation' but must still be subject to all above requirements for CL2+ operation being met.
2. Access for culture work will only be granted following approval from the Laboratory Manager in consultation with all PI's holding active projects.
3. During activity of a project to include culture work, all Clinical project work in CL2+ laboratory (0.39) will be suspended. All access rights to other project staff will be temporarily cancelled during Exceptional Operation.
4. The CL2+ Lab to include all equipment and MSC hood must be fully decontaminated prior to entering 'Exceptional Operation' as per current Risk Assessments for active projects.

5. All laboratory procedures undertaken within the CL2+ Lab during Exceptional Operation must follow standard CL2+ procedures detailed in this SOP regardless of the nature of the sample.
6. Any transportation of HG2 pathogens into or out of the CL2+ suite during 'Exceptional Operation' must follow standard Secondary Containment rules. Samples or cultures in sealed tubes must be securely transported within sealed outer containers, the outer box must be disinfected prior to removal from the CL2+ lab.
7. The CL2+ lab, to include all equipment and MSC hood, must be fully decontaminated post culture activities as per disinfection routines described in MB RA for culture work, prior to any clinical sample projects return to the lab.

2.5 Suite Safety, Management and Emergency Contact Details

The names of all current users of the CL2+ suite and PI contact details for active projects must be displayed inside the CL2+ suite entrance door.

At any time the CL2+ lab is in use for CL2+ projects, access will be restricted to the active project groups & management only. During active phases, project details and contacts will be displayed at all times.

The CL2+ suite telephone number is x3937. This phone (located in lab 0.37) should be used as needed in emergency to make appropriate contacts with PI / safety personnel.

All up to date Emergency Contact details must be displayed inside the CL2+ suite at all times. Contacts must include:

- BCRE Safety Officer
- BCRE Laboratory Manager
- BCRE Laboratory Manager Deputy (Senior Laboratory Technician)
- BCRE First Aiders
- All PI's with projects active within the Suite.

2.6 Training and Supervision

1. Competence must be demonstrated and/or appropriate training must be given before any project is allowed to begin. Previous experience should not be automatically taken as a demonstration of a person's competence to work on a particular project.
2. Prior to an individual working in the CL2+ suite his/her training will be reviewed by the Laboratory Manager and signed off by the appropriate PI.
3. The PI is responsible for the development of a pathogen/sample-specific training programme for themselves, and all associated personnel. This

must form part of their Standard Operating Procedure (SOP) and be submitted with their MRA / HTRA to the BHGMC and must include:

Basic documented training for the CL2+ suite.

Further sample-specific training by the PI and a general familiarization of working with clinical material from patients with the potential to carry undiagnosed infections.

If the PI is not considered experienced enough to supervise this training, then more specific training for the co-workers must be sought. This may mean external training on a recognized course OR in a laboratory where the particular pathogen / sample type is used. In such cases, the PI and all members of that project, working at CL2+, must attend.

4. Training must be an ongoing and documented process. Training records (appendix 3) will be reviewed by the Laboratory Facilities Manager and a secure copy kept by the appropriate PI. A secure copy of any Facilities specific training documentation will be kept in the CL2+ laboratory folder in 0.37.
5. All persons who enter the suite must receive sufficient and appropriate information, instruction or training about the hazards that they might encounter. Such persons may include support staff, maintenance & security staff & emergency services as well as lab workers.

2.7 Health Surveillance and Sickness Absence Monitoring

1. All persons working with clinical material from patients with the potential to carry undiagnosed infections will be the subject of Health Surveillance conducted by the University's Occupational Health Service in the form of a health surveillance questionnaire completed annually (see appendix 2). Any change in the health status of any person working with these samples in CL2+ facility must be reported to OH and PI immediately. Records will be maintained for a minimum of 40 years
2. The initial Health Screen may recommend immunization of workers and where appropriate any available immunization should be carried out.
3. All persons working with clinical material from patients with the potential to carry undiagnosed infections must report immediately to their PI any absences planned or otherwise during work with samples or for up to two weeks post potential exposure. The PI must follow up with workers any absences and contact occupational health with details of any absence due to sickness where there is any possible link to working environment.

2.8 Visitors & Maintenance Work

1. Visitors are not permitted to enter the CL2+ Laboratory when active.

2. **A permit-to-work** MF 214/02 (appendix 7) form is required before any building maintenance work can take place either within the suite or on its associated plant. Most building maintenance can be carried out without entering the suite but where access is required the working area must be made-safe by validated means.
3. **Permits-to-work** will be issued by the Building Facilities Manager or Laboratory staff and must be signed off by the Laboratory Manager prior to any access being granted. Any Building Services & any visiting maintenance engineers entering suite when the suite is not in shutdown must sign permit-to-work associated with work undertaken.
4. All equipment must be decontaminated prior to removal from the CL2+ laboratory or maintenance being undertaken and a Certificate of Decontamination signed and issued by the user and authorised by laboratory manager must be provided. A copy shall be given to the engineer to retain and a copy posted in the area of work.

3.0 Local Rules for the Containment level 2+ Suite

1. The door to the Suite is kept locked at all times. Card Access to the Suite is restricted to nominated personnel only. (See General Procedures).
2. Working in the CL2+ laboratory out of hours is not recommended. Out of hours working can only be done if two authorized workers are present. The PI in charge of the project must authorize any out of hours work and will take signed responsibility for implementing the arrangements for backup.
3. No more than four people may work within the CL2+ laboratory at any one time. Undergraduate students are not permitted to enter the CL2+ lab under any circumstances.
4. The CL2+ laboratory is subject to ALL regulations applicable to the CL2 BCRE Laboratories. Notably, eating, drinking, smoking, applying cosmetics and mouth pipetting are strictly forbidden.
5. Long hair must be tied back before entering CL2+ Laboratory.
6. Protective hospital blue labcoats will be provided inside the CL2+ laboratory and must be worn at all times. Blue labcoats must remain inside the CL2+ laboratory. Lab coats must be autoclaved should any contamination be suspected or disinfected by validated means prior to removal from the suite and sending for laundry.
7. Protective gloves must be worn at all times in the suite as specified in appropriate RA. Protective eye-wear must be worn, if specified in appropriate RA.
8. All work in the CL2+ suite on clinical material from patients with the potential to carry undiagnosed infections must be conducted within the Microbiological Safety Cabinet (MSC) unless a specific derogation applies. Such derogation will only be given after approval of the Microbiological Risk Assessment / Human Tissues Scheme of Works. Any work approved in the MRA/HTSW which needs to take place outside of the MSCs must be suitably contained.
9. Any procedures likely to produce aerosols e.g. vortexing cultures, must always be carried out within the MSC or within other contained equipment as defined within the specific work risk assessment.
10. The MSC must be cleaned with disinfectant specified for that sample type and all equipment removed at the end of each work session.
11. The MSC must not be used to store equipment or consumables.
12. At the end of each work session, all work surfaces must also be cleaned according to current disinfection protocol for that sample type.

13. Sterile plastic ware must replace glass at all times, unless there is genuinely no alternative to using glass. If this is thought to be the case, the use of glass must be detailed on a protocol accompanying the MRA on submission.
14. Sharps should not be used in the CL2+ suite. In exceptional circumstances, and where there is no other alternative, use must be detailed on a protocol accompanying the MRA on submission.
15. Secondary containment measures should be adopted for all sample tubes. Sample volumes must be minimized to reduce risk in the event of a spillage. Volumes must be justified in the MRA/HTRA and approved by the BHGMC.

4.0 Standard Operating Procedure CL2+/1. Entry and Exit procedures

1. It is suggested that you prepare a check list & gather together everything you will need to take in with you. Remember, equipment will not leave the CL2+ lab (0.39) except through the autoclave or following appropriate disinfection following a validated method.
2. Entry into the CL2+ laboratory is via the card-ax door into the CL2 lab 214/0.37. Card access is limited to named personnel only. No other workers must enter using that card. Entry to the CL2+ procedure room is via the lobby (214/0.38).
3. White lab coats used in CL2 lab 214/0.37 must be removed prior to entry into the lobby.
4. Enter name, date and time in, on Signing In and Out Record Sheet held in lobby 0.38 (appendix 6).
5. On entering the CL2+ laboratory immediately put on a blue labcoat provided on the coat stand inside the CL2+ lab door.
6. Protective nitrile gloves are available beside labcoats and must be worn on entering CL2+ lab.
7. Before starting any laboratory work, apply a second pair of gloves, and/or other Personal Protective Equipment (PPE) according to the specific Microbiological Risk Assessment (MRA) for your sample type.
8. Switch on MSC following start-up routines as detailed in section 5.0 “Standard Operating Procedures CL2+/2 - start up procedures” and follow procedures through routine checks. Check cabinet has stabilized prior to starting any work.
9. Wipe out cabinet with disinfectant that is listed in the MRA / HTSW for your project.
10. Any samples taken into CL2+ suite must be transported double contained in appropriately sealed containers.
11. Check that autoclave bags and autoclave boxes are available for waste. Check that discard jars / bags are in place and that they contain correct disinfectants where appropriate.
12. Have surface disinfectant as listed in MRA / HTSW available in spray bottle.
13. Ensure that extra gloves are available should the outer pair become contaminated.
14. Follow procedures laid down in the MRA / HTSW for your project.

15. When working in Class 2 cabinets, always be aware that the downward flow of air can easily be disrupted and aerosols may escape. Adjust working practices to minimise this risk.
16. On completing work, spray all containers that are to leave cabinet with disinfectant listed in MRA / HTSW.
17. Clean cabinet and surrounding area as agreed in MRA / HTSW. Place all cleaning materials in autoclave bag inside autoclave box.
18. Collect all waste into autoclave bag. Loosely close top of autoclave bags. Where stated in MRA / HTSW, add disinfectant to any liquid to be discarded to specified final concentration. Leave everything for 10 minutes or time agreed in the MRA or from validation of disinfectant for that project.
19. Change outer gloves after procedures are complete. If appropriate replace with a clean pair of outer gloves to prepare samples for removal and ensure secondary containment of samples according to the specific MRA / HTSW or replace samples for storage.
20. Place all autoclave waste into metal autoclave bin. Loosely fit lid. Place $\frac{3}{4}$ full bins in autoclave. Choose the correct autoclave cycle needed and pack boxes accordingly. (SOP CL2+/6) Load autoclave with all waste boxes. Start cycle.
21. Remove outer gloves and dispose in autoclave waste bin. Remove laboratory coat and leave on coat stand inside CL2+ lab. Remove inner gloves and dispose in autoclave waste bin.
22. Where contamination of laboratory coat is suspected, place coats in autoclave bin and autoclave on laundry cycle.
23. Wash hands in adjoining lobby before entering 'outer' CL2 lab.
24. Sign out in lobby and pass into CL2 lab to exit (putting on white labcoat in CL2 lab if any further work is to be performed in this area).
25. All procedures and operating practices in the CL2 lab (0.37) in the suite follow procedures as described in BCRC Laboratory Code of Practice.

5.0 Standard Operating Procedure CL2+/2. Start-up Procedures and Operation of CL2+ Laboratory and Microbiological Safety Cabinet (MSC)

5.1 Operation of Microbiological Safety Cabinet

1. Lift glass cabinet front by push and hold of the upwards facing arrow until the window stops, release button.
2. Immediately press FAN icon.
3. After a few seconds to stabilise flow, the display will show 'SCANLAF' along with the date and time. No alarms will be active.
4. The cabinet is safe to use once the flow has stabilised and no alarms are sounding. The MSC is fitted with an alarm system that gives an audible and visual warning to the operator if the airflow falls below the recommended setting. If cabinet fails to operate, report fault to BCRE Laboratory Manager immediately.

5.2 Routine Checks

1. Check that the seal around the cabinet door is clean and in good condition.
2. **DURING ACTIVE CL2+ PROJECTS ONLY:** At first use each week check the inward and downward air flow readings using hand held anemometer and record on MSC weekly Air Flow Log Sheet (appendix 5) as per 'AirFlow Test' in 5.2.3 below. Do NOT use a safety cabinet unless the airflow reading has been taken within the last week and it gives a satisfactory reading (see tolerance values detailed below and in appendix 3).
3. **DURING ACTIVE CL2+ PROJECTS ONLY:** The following air velocity measurements must be carried out at the face and inside the cabinet every week by User or Technical staff.

Testing

Both tests must be performed after 5.1 is satisfactorily completed.

Inflow Test

Hold the anemometer at an angle to match angle of window at the front of cabinet. Take 3 equidistant readings across the window (left, centre, right). Readings should be taken at the middle of the opening. Each reading must fall between 0.5m/s - 0.80m/s.

Downflow Test

The down flow is read at three points inside the cabinet. The reading points are all located across one plane inside the cabinet estimated at a height of 100mm above the top of the open window and 200mm

inside the window (as close to this as possible when estimated by eye is acceptable). One reading at the right hand end, one central and one to the left. Each reading must fall between 0.25m/s and 0.5m/s

If any individual reading falls outside of tolerance, the MSC hood must not be used, an OUT OF USE sign must be displayed on the hood and this must be reported as a fault to the Laboratory Manager immediately.

5.3 Servicing and Filter Change

1. The CL2+ Microbiological Safety Cabinet will be serviced regularly at 6 monthly intervals with KI test performed annually by a qualified and registered service engineer.
2. Service reports from MSC servicing will be held by the Building Facilities Manager.
3. Filters will be changed in accordance with manufacturer's recommendations.

6.0 Standard Operating Procedure CL2+/3. Safe Operation of Equipment

As part of any Risk Assessment at CL2+, the equipment required for any project must also be considered for its potential to act as a source of infection for those using or maintaining it. Such equipment should be identified for each project and procedures put into place to decontaminate it regularly, or when it is serviced or maintained.

6.1 Centrifuges

1. Centrifuges must be operated according to the manufacturer's instruction and training given. Buckets must be paired by weight and filled with equal number of containers. Only centrifuges with aerosol-sealed rotors/buckets must be used for clinical material from patients with the potential to carry undiagnosed infections.
2. Only plastic disposable closed tubes should be used (check that they can withstand the speed of centrifugation before use, some may buckle above 3000 rpm).
3. If a breakage is suspected when the machine is running, the motor must be switched off and the rotor left stationary for 30mins before opening centrifuge. The buckets must then be unloaded inside MSC. Fill bucket with appropriate disinfectant and leave overnight inside cabinet. Next day, remove broken tube and disinfectant into autoclave waste bin.
4. Report all spillages & breakages to Laboratory manager. All spillages must be recorded on Hazardous Incident Form submitted to USS, available at: <https://intranet.uea.ac.uk/uss/intranet/safetysubjects/accidentillhealth>
5. If in any doubt whatsoever as how to proceed, make the area safe posting appropriate signage to stop further access and contact Laboratory Manager.
6. IF BUCKET IS FOUND TO BE DAMAGED WHEN CENTRIFUGE IS OPENED, TREAT AS SPILLAGE OUTSIDE MSC AND FOLLOW EMERGENCY PROCEDURE.
7. If it is only suspected that a bucket may be damaged, leave centrifuge closed and evacuate – inform Laboratory Manager immediately.

- 6.2 Cabinets/shakers** - Where possible glassware should not be used in the CL2+ laboratory. If a tube is found to be broken, treat as spillage outside MSC and follow emergency spillage procedure.
- 6.3 Automatic Pipette Fillers** – always use plugged pipettes, take care not to allow media or culture to enter pipette filter. Change pipette filter regularly and dispose of via autoclave waste.
- 6.4 Water baths** - constant temperature water baths can become contaminated. Therefore, an appropriate disinfectant should be added to the water and changed regularly. Solid heated block incubators are recommended as a safer alternative to water baths in CL2+.
- 6.5 Computer equipment** – may become contaminated by gloves. Therefore, always change gloves before using computer in CL2+ lab. Wipe keyboard regularly with appropriate disinfectant or wipe.
- 6.6 Incubators**– it is the responsibility of the worker using the incubator to ensure that water levels are topped up where necessary and that the incubator is cleaned at regular intervals. A disinfectant spray as detailed in project specific SOP should be used regularly to prevent any contamination.

7.0 Standard Operating Procedure CL2+/4. Specimen Reception, Storage and Recording.

1. Where clinical material from patients with the potential to carry undiagnosed infections are due to be received via courier, at least 1 week prior to delivery to BCRE, Laboratory manager and IATA trained Technician shall be informed of the arrangement for delivery of samples.
2. Where clinical materials from patients with the potential to carry undiagnosed infections are transported into BCRE by a member of the research team (eg from a local institute), the PI must ensure that they are locally available during transport and receipt of package. There must be an appropriate transportation risk assessment in place to support the movement of any clinical samples and this must be attached to the project specific SOP for submission to BHGMC.
3. BCRE reception must be notified by the consignee when any package containing clinical material from patients with the potential to carry undiagnosed infections is expected to arrive and must be made aware that they must not receipt any sample package.
4. BCRE reception and BCRE technical support team must be provided information in writing with contact details of the PI responsible for the sample type and of the contact details of the person(s) responsible for collecting the package. Only the PI or a trained investigator nominated by the PI may receipt the samples. If the PI or named investigator cannot be contacted on arrival of sample package, the package must not be accepted from the courier.
5. The receipting member of staff will take the package immediately to the CL2 lab (214/0.37) adjacent to the CL2+ lab and will notify the PI of the arrival of the package if not already alerted.
- 6. On no account should any unpacking take place outside the CL2+ facility.**
7. Ordering / receipt of clinical material from patients with the potential to carry undiagnosed infections should be from agreed sources and must be fully detailed in the project specific SOP (as submitted to and authorised by the BHGMC) and must conform to packaging and labelling regulations. The Sender must be advised to clearly mark packages FOR DELIVERY TO CONSIGNEE ONLY.
8. Any consignment with damaged packages should not be accepted from the courier.

7.1 Sample storage and removal of Samples

1. All clinical material from patients with the potential to carry undiagnosed infections must be 'stored safely'. Storage is restricted to the CL2+ laboratory until samples are proven to contain no pathogen risk above HG2. Fridges and freezers must be labelled with a Biohazard sign and the stored samples clearly listed on the outside.
2. As soon as work on any project is finished, it is the responsibility of the PI to ensure that all remaining samples are discarded or, where detailed in project specific SOP's that HG2 samples are removed to CL2 laboratory facilities/storage for ongoing study. It is the PI's responsibility to ensure that all storage records are accurate and up-to-date.
3. The CL2+ facility will only maintain / store CL2+ material for a project whilst the project is running.

8.0 Standard Operating Procedure CL2+/5. Cleaning Procedures and Disinfectants

1. Cleaning and routine maintenance of the CL2+ lab should be identified in the MRA/HTSW and SOP's for each project. This is an important part of the training given to all users working on approved projects.
2. This is particularly important when more than one group will be using the facility, because the use of disinfectant and working practice may differ slightly according to the samples processed.
3. It is the responsibility of each project group to leave the CL2+ laboratory safe and ready for the next use and to show that this has been done by signature of the Containment level 2+ Signing In /out Log (appendix 6) in lobby 0.38.
4. At the cessation of work in the facility, each project worker must clean the cabinet and any equipment used with a disinfectant that is specified for the individual project.
5. Leave cabinet free of all equipment
6. Remove all waste and autoclave according to SOPCL2+/6.
7. Each group must be aware of all SOP's and rules relating to the use of the facility and be prepared to work within those guidelines.
8. The BCRE Laboratory Manager will ensure all general laboratory supplies are available and issue a supply of clean gowns and PPE as necessary and will ensure that appropriate supplies of disinfectants are available for use.

8.1 Housekeeping

1. Deep cleaning of the CL2+ laboratory (0.39) must be performed at the termination of each individual activity phase.
2. Persons carrying out the cleaning procedure should enter the CL2+ laboratory in accordance with SOP CL2+/1, being appropriately dressed with labcoat and gloves.
3. All discard bins, autoclave bags and contaminated laboratory coats should be treated according to SOP CL2+/6.
4. All general disinfectants should be made up according to manufacturer's instructions & following the appropriate RA for the planned work.
5. All bench areas, spillage trays and inside the MSC should be washed weekly using agreed disinfectant. The floors and shelves should be washed as necessary with appropriate disinfectant.

6. All working surfaces, shelves, drawers, cupboards, fridges and freezers should be checked every 3 months or at cessation of a project for old samples, out of date consumables etc., and any found should be disposed of according to SOP CL2+/6.
7. Fridges and freezers should be defrosted when necessary.
8. At the end of each project/group of projects, the laboratory must be decontaminated by validated method and the room signed off by the Laboratory Manager as safe for the next user.
9. If two or more projects are to run together in the facility this must be taken into consideration and approved in discussion with the individual PI's and BCRE Laboratory Manager.

9.0 Standard Operating Procedure CL2+/6. Disposal of Contaminated Waste and Use of Autoclave.

1. The following treatment cycles are pre-coded into the autoclave

FIXED MEDIA	–	121°C/15 minutes
EMPTY GLASSWARE	–	121°C/15 minutes
PLASTIC DISCARD	–	126°C/20 minutes
MIXED/FLUID DISCARD	–	126°C/20 minutes
FABRICS	–	134°C/5 minutes
2. No variation of these treatment cycles is permitted. All waste cycles have been calibrated and performance tested for use with the standard autoclave bins provided for the CL2+ laboratory.
3. Pre-run checks must be carried out prior to operation of the autoclave:
 - a. There are no outstanding error messages given on the display
 - b. Check the door seal is clean and undamaged
 - c. There is paper in the chart recorder and previous run printout was legible
 - d. The chamber is free from obstruction / previous waste.
 - e. Ensure the temperature probe is safely retained at the side of the chamber and will not obstruct shelf or be damaged when load is loaded / removed from chamber.

Standard Operating Procedure for Autoclaving Waste / Sterilising Solutions & Equipment

Using LTE Touchclave DE 300k Pass Through Autoclave, BCRE 0.39

Key Safety precautions/equipment that you will require:

- All members of staff using the autoclave must first read and sign the associated risk assessment and have read this SOP and have the procedure demonstrated to them by an experienced member of staff.
- Lab coat and gloves must be worn *at all times*.
- Nitrile and heat resistant gloves are to be available for use *at all times*.
- Eye protection must be used when opening autoclave after a cycle.
- All waste from lab 0.39 must be autoclaved prior to removal from CL2+ lab.

Brief Instructions for use:

- *NB Autoclave door on 'dirty' side should be left open after run (door on clean side should be closed and sealed after each run to enable loading on dirty side).* Turn autoclave on at black toggle switch. Allow warm up.
- Load Autoclave ensuring all containers are loaded upright, never overfill, there must be enough space for steam to efficiently circulate through chamber. Never overfill liquid flasks to be autoclaved (leave 20 % header volume in any liquid vessel). Autoclave items of similar volume / type together.

Never seal any container used for autoclaving liquids, leave screw cap bottles loose.

- Place temperature probe in load as appropriate – for a solid cycle the probe can be left loose on shelf or placed inside the box of solid load, for a liquid cycle choose an appropriate size conical/ beaker (ensure water level is consistent with the items to be sterilised) and place the temperature probe in the flask.
- Lift door gently into closed position, whilst holding door up gently, choose 'Lock' on touch screen.
- Press 'Start' on touchscreen - choose appropriate cycle (use arrows to scroll up and down to select cycle) & choose enter - you will be asked to input your authorisation code. NB Cycle parameters for

each listed cycle are displayed in autoclave room, **ALWAYS** pick appropriate cycle for items to be autoclaved, if unsure please ask. Cycle parameters cannot be changed without 'supervisor' authorisation (see senior tech).

- ***In event of any concern during a cycle or if any danger is detected the autoclave should be switched off immediately at the red/yellow & grey isolation Switch on the wall on the 'dirty' side and reported.***
- When the cycle is complete, if there is no fault with the cycle, open the door on the 'clean' side by pressing the release.
- Use handle to draw door downwards ***Eye Protection must be worn as door opened*** if there is any possibility the load will still be warm, avoid standing too close at this point, step out of the way to reduce the chance of incident by ejecting water, steam or items. ***Items inside may still be hot, use the heat resistant gloves if needed.***
- Remove all items, leave autoclave empty. Use a trolley to transport the items if they are large bottles/flasks or if they are still hot.
- Switch the autoclave off on the front panel if it not to be used again in the near future.

In the event of a cycle failure seek assistance from senior technician – all failures must be reported. Operators should not attempt to override any errors or cycles. If a cycle is not completed or a fault icon is given, all contents should be re-autoclaved (disregard any change in the autoclave tape). All failures will be monitored by technical staff. Should there be a problem with any of the contents, for example should a container crack and leak solution, a technician must be alerted as a decontamination procedure must be performed.

IMPORTANT NOTES ABOUT USE OF CONTAINER / BAG / VESSEL:

Ensure all items autoclaved are processed inside a metal autoclave box. Not all glass is suitable for use in autoclave. Ensure glass vessels are free from cracks or faults as these will significantly increase risk of fracture of vessels.

Never place uncontained bags in autoclave. Do not seal bags - sealed bags do not allow steam to penetrate loads.

Use Autoclave tape to confirm sufficient temperature has been reached (this is not to be used as an indicator of successful sterilisation).

10.0 Standard Operating Procedure CL2+/7. Procedure in the Event of a Spill

10.1 Minor Spills within MSC

1. All work undertaken with unknown biological samples in CL2+ laboratory must be carried out in the MSC unless specified otherwise in the project risk assessment.
2. A minor spill is a spill of less than 10 ml totally contained within the MSC.
3. In the event of a minor spillage leave the MSC fan running, leave spill for the time as agreed in the appropriate risk assessment.
4. After appropriate time apply appropriate concentrated disinfectant, cover with paper towel. Mop up and dispose of paper towels in discard bin in cabinet then autoclave waste.
5. Report spillage to Laboratory manager. Fill in Hazardous Incident Report, available at: <https://intranet.uea.ac.uk/uss/intranet/safetysubjects/accidentillhealth>

10.2 Major spill within MSC

1. If the spillage inside the MSC cannot be readily treated as above
2. Leave spill without clearing up and leave MSC fan running
3. Evacuate CL2+ laboratory in accordance to exit procedures in CL2+/1
4. Fix “No Entry” sign to CL2+ lab door.
5. Report immediately to Laboratory manager who will contact PI. They will assess the situation and arrange fumigation/decontamination of MSC.
6. Complete and submit Hazardous Incident Report.
7. Inform Occupational Health Department by dialling **2172**.

10.3 Spillage outside of MSC

1. In the event of any spillage outside cabinet or in shaker, all work must cease immediately. Evacuate CL2+ laboratory immediately.
2. The safety cabinet should be left running
3. Articles of clothing suspected of being contaminated must be removed and left in the room (214/0.39) as the person(s) moves to the exit door (tivek suits

are available in CL2+ lab lobby (214/0.38) for cover up as necessary). However staff must not put themselves at unnecessary risk from aerosol inhalation by remaining in the room for longer than is absolutely necessary.

4. Close door to laboratory as you leave. Fix no entry sign to inner door (214/0.39)
5. Wash hands thoroughly in ante-room.
6. Leave CL2+ lab via lobby into CL2 lab (214/0.37), closing doors as you leave.
7. Report to Laboratory manager who will contact PI and Safety Officer.
8. Where skin contamination of individual is suspected, use shower where appropriate (214/0.33). Where shower is used Laboratory Manager must be notified. Appropriate decontamination of shower area will be arranged by Laboratory Manager as necessary.
9. Complete and submit Hazardous Incident/Accident report.
<https://intranet.uea.ac.uk/uss/intranet/safetysubjects/accidentillhealth>
10. Staff in the room where the spillage occurred must be referred to the UEA Occupational Health Department.
11. The Laboratory manager will also inform the Occupational Health Advisor of the spillage.
12. The laboratory manager must also inform the Director of Safety Services who will also be responsible for informing the HSE if required under the Reporting of Injuries, Diseases or Dangerous Occurrence Regulations (RIDDOR).

10.4 CL2+ Laboratory Disinfection procedures

In the event of any spillage outside MSC cabinet where CL2+ laboratory is evacuated, following evacuation and consultation with Laboratory Manager and appropriate PI and following clearing of the spillage, the laboratory should be disinfected by swabbing down with appropriate validated disinfectant with appropriate contact times and dilutions in accordance with the specific project risk assessment.

11.0 Standard Operating Procedure CL2+/8 Emergency Evacuation in Event of Fire

On hearing the fire alarm:

1. The Heating Ventilation and Air Conditioning (HVAC) system will automatically shut down when fire alarm is activated.
2. Close culture containers and make safe as far as possible.
3. Close window of MSC and switch off cabinet.
4. Evacuate CL2+ laboratory through normal lobby.
5. Remove lab coat and other PPE in accordance with normal exit procedure, where time allows wash hands before vacating suite.
6. If a fire breaks out in the immediate vicinity, evacuation should be immediate and removal of laboratory coats and washing hands is not a priority. If at all possible carry out an autoclave bag and container of disinfectant wipes and if it is safe to do so make all cultures and equipment safe.
7. Evacuation takes place by the nearest available fire exit as detailed during Lab Health and Safety Induction.
8. Avoid touching colleagues or door handles if unable to wash hands.
9. THE PRIORITY IS TO EXIT THE BUILDING.
10. Assemble at Fire Assembly point and inform Fire Warden of your situation.

12.0 Standard Operating Procedure CL2+/9. Emergency Evacuation in Event of Power Failure

1. The CL2+ suite is not on an emergency power circuit. If there is a power failure within the BCRE, the CL2+ suite will also lose power. Loss of power will cause the HVAC system to close down and as the MSC cabinets are an integral part of this system they will also shut down.
2. The emergency lighting is battery operated and is designed to remain on for a short time to facilitate safe exit.
3. If the power fails whilst working in the CL2+ laboratory, and/or the MSC cabinet fails, only attempt to make safe your cultures if this course of action has been agreed in the SOPs' for your project. If there is a risk of aerosol infection or it is not practicable to do this leave immediately.
4. The room should be vacated immediately in accordance with SOP CL2+/1 and a DO NOT ENTER sign (available in the CL2+ lobby 214/0.38) must be posted on the CL2+ entrance door.
5. The incident must be reported as soon as practicable to the Laboratory Manager and any risks posed to the personnel involved assessed.
6. Inform Safety Services and Occupational Health if necessary

13.0 Standard Operating Procedure CL2+/10. Emergency Evacuation in the Event of Illness or Injury

The Laboratory Manager must arrange appropriate training for all BCRE First Aiders about the specific hazards they may face on entering in the CL2+ suite.

In event of any injury / illness of staff in CL2+ laboratory, users must:

- Summon first aid assistance by contacting first aider as on First Aid Emergency poster displayed in CL2+ lobby (214/0.38).
- Summon assistance from Laboratory Manager and Supervising PI (Emergency numbers displayed on 'EMERGENCY CONTACT' details displayed in CL2+ Lobby (214/0.38)

13.1 Minor Illness / Injuries

1. Do not hesitate to seek help if you are injured or taken ill within the CL2+ Laboratory
2. Leave the CL2+ laboratory if possible using usual exit procedure as detailed in SOP CL2+/1.
3. First Aid treatment will be given as a priority and must take precedence over normal containment procedures, subject to risk assessment.
4. The Laboratory manager will supply access / risk advice to First Aider as appropriate.

13.2 Serious Illness, Accident or Incidents

1. In the event of a serious accident, the priority is to administer first aid.
2. Where appropriate the emergency services should be contacted by **dialling 999** and inform the University Security Lodge by dialling **2352**
3. The laboratory manager must be contacted and must ensure that the First Aider and any emergency services have access to the facilities and the PI or laboratory manager must inform everyone involved of any risks they might encounter.
4. Inform Director of University Safety Services at first available opportunity.

14.0 Standard Operating Procedure CL2+/11. Working Out of Hours

5. Normal Working Hours are 7.00 am until 7.00 pm and hazardous work in the BCRE CL2+ must take place within this period unless specifically approved by the responsible PI. All persons working outside of these hours must have the permission of their PI and the SO. Permission will only be granted in exceptional circumstance and is subject to approval of a project specific out of hours risk assessment.
6. The laboratory manager must be informed at least 24 hours before any out of hours working
7. The PI and the worker must agree a procedure for another person to be informed when that person starts and finishes work in the unit or where necessary arrange for a second person to be present.
8. In the event of a serious accident the emergency services should be contacted by **dialling 999** and the University Security Lodge by dialling **2352**. The Laboratory Manager and PI Emergency Contacts displayed in the CL2+ lobby should be used to alert appropriate safety contacts.

15. Standard Operating Procedure CL2+/13. Training procedure prior to working in CL2+ Suite

In compliance with Section 2.3 of this document it is the PI's responsibility to ensure project/sample specific training for all staff working on that project. In conjunction with this training all personnel, including the PI must undergo a general training programme covering the SOP's and the safe use of the facility. This training will be undertaken by the Laboratory Manager. On satisfactory completion of the training the worker must sign to say that they have received and understood this training. The Laboratory Manager must also sign to say that the training has been given and competence demonstrated. On completion of this training the staff members card access to the Suite will be authorised.

The following topics will be covered in accordance with the corresponding SOP's.

1. Entry and exit procedures, including appropriate PPE and safe removal and disposal of PPE after completing the work. Signing in and out.
2. Operation and safe working procedures for the MSC cabinets. Sample specific considerations and constraints imposed by SOP's.
3. Considerations and safety training on all equipment required for the project.
4. Fire and emergency evacuation training – what to do and who to contact in the event of an emergency. Reporting accidents and incidences. Reporting near misses.
5. Out of hours working.
6. Operation of the autoclave and removal of waste from the Suite.
7. Housekeeping and general cleaning of the facility which must be carried out by the personnel working in the unit.
8. The receiving of samples. Informing receipting technicians and reception staff. Collection and unpacking of specimens.
9. Recording and storing of samples.
10. Training record sheets (appendix 3)

Appendix 1 - Appropriate Forms for Seeking Authorisation to work in CL2+.

Current '*Microbiological Safety Rules*' and '*Risk Assessment Form for Working with Microorganisms at UEA*' can be found at:

<https://intranet.uea.ac.uk/uss/intranet/safetysubjects/bioagents>

Current '*Local Rules for Working with Human Tissues*' and appropriate Human Tissue application forms to include: '*Appendix I – Human Tissues Risk Assessment form*' and '*Appendix III Scheme of Works*' can be found at:

<https://intranet.uea.ac.uk/uss/intranet/safetysubjects/Human+Tissues>

Appendix 2 – UEA Occupational Health Guidance Rules

OH Health Surveillance for CL2+ work

- Appropriate Human Tissue Scheme of Work and Risk Assessment must include names of personnel who would be working with clinical material from patients with the potential to carry undiagnosed infections.
- Prospective CL2+ staff would be required to complete a Pre-employment questionnaire (PEQ) or update an existing one.
- OH will review the health information from the PEQ and will alert the PI if any of the following are detected:
 1. Any increased risk to a specific person due to their personal medical history.
 2. Any immunisation or specific health protection requirements.
 3. Any on-going surveillance needed (unusual)
- OH would carry out any immunisation
- No staff member is to work with clinical material from patients with the potential to carry undiagnosed infections without submission of OH questionnaire.
- Staff working in CL2+ would be required to report to OH any pregnancy or any change in their health status requiring the advice of a doctor.
- OH would evaluate any change in health status and if necessary recommend the cessation of work with clinical material from patients with the potential to carry undiagnosed infections. Any OH recommendation must be followed.

Spillage of Clinical Material from Patients with the Potential to Carry Undiagnosed Infections

In order to fully monitor illness in CL2+ personnel all spills must be reported to OH. The information needed will include:

- Sample type
- Detail of the spillage including an estimate of the amount.
- What staff were exposed, how the exposure occurred and to what degree.

All staff exposed to any spill should be referred to OH for assessment and advice.

Funding/Costings

The new revised agreement between UEA and the University Medical Services provides a core funding for basic OH services to all departments within the University. Departments that require services beyond the basic service are charged for the additional services using an advantageous marginal charging model made possible by the central core funding. EDU, MED, AHP and NAM already benefit from the application of this model. The cost of the PEQ and any vaccines must be re-charged to the appropriate project and a budget code must therefore be provided to OH on application.

Appendix 3

PERSONAL TRAINING RECORD

FOR STAFF WORKING IN THE BCRC CL2+ Suite 214/0.39

PERSONAL DETAILS			
Name		School	
Position		Supervisor	

PERSONAL TRAINING RECORD – signed paper copies of any training documentation to be filed with personal training records in room 214/1.39			
BCRC CL2 Laboratory Induction	Trained by:		Date:
BCRC CL2+ Laboratory Induction	Trained by:		Date:

EXPERIENCE – in particular include any relevant experience or informal training to work with clinical material from patients with the potential to carry undiagnosed infections.

QUALIFICATIONS – detail any qualifications relevant to work with clinical / unknown samples – please give dates and details (copies of any certificates / documentation should also be filed)

ADDITIONAL GENERIC READING – to be completed prior to work in the CL2+ suite, user to sign in confirmation of reading and understanding of the below documents and in agreement to abide by the safety guidance given therein.

GENERIC SOP'S – 'Code of Practice for working at CL2+ in BCRC'	
PROJECT SPECIFIC CoSHH FORMS – both generic and procedure specific	

PROJECT SPECIFIC TRAINING – List sample types, give Micro / Human Tissues authorisation reference number, Authorised to use & Authorisation information

SAMPLE TYPE – include authorisation ref no.	SIGNATURE – I have read all project specific SOP's and risk assessments associated with this project*	AUTHORISING PI SIGNATURE

* User to sign in confirmation of reading and understanding of the approved SOP's and RA's for the given project and in agreement to abide by the safety guidance given within.

Appendix 4

Certificate of Decontamination of CL2+ Laboratory Equipment

Equipment Details	Manufacturer	Model	Serial no

IMPORTANT

It is the responsibility of the user to ensure that equipment [detailed above] is, so far as is reasonably practicable, in a clean and 'safe' condition, i.e. free from Biological (including GM) and Chemical contamination prior to removal from suite or working on my an authorised person/engineer.

The equipment has been exposed to:

biological agents / clinical material / hazardous chemicals *(delete as appropriate)*
and appropriate decontamination has been carried out as detailed below.

DECONTAMINATION PROCEDURES: Decontamination of the equipment described was achieved by the following activity (give detail of the decontamination activity, it's validation details for appropriate contaminant and the nature of any residual contamination*):

Signed:

Date:

Contact the person below if you have any queries regarding the content of this certificate.

RESIDUAL RISK (MUST be completed if complete contamination cannot be achieved): Complete decontamination of the equipment described above cannot be achieved.

Nature of residual contamination:

Take the following precautions when handling/moving:

Signed:(User)

Date:

Contact the person below if you have any queries regarding the content of this certificate.

AUTHORISATION: Equipment Safe to remove from suite OR be worked on by an authorised engineer (*authorisation must be by appropriate PI or Laboratory Manager*):

Signed:

Date:

Suite Preparation Requirement (to be completed by Laboratory Manager or appointed deputy):

These works will take place (*delete as appropriate*):

- a) During normal operation of the CL2+ labs. Attending contractors have been appropriately trained as detailed in 'PERMIT REQUIREMENTS a).'
- b) During normal operation of the CL2+ labs. The works area has been 'made safe' by
Attending contractor will be given brief induction training and will be closely supervised by (*print supervising staff member*):
- c) With suite in shutdown following appropriate decontamination.

Training Requirement (*To be completed by external contractor or UEA EST staff who will perform works*)

Requirements for maintenance conditions above:

- a) I have received and understood training detailing entry and exit policy, emergency procedures and general working policy, I have been given training and have understood the authorisation requirements.
- b) I agree to abide by the safe systems of work detailed in brief training provided by laboratory staff or laboratory manager and understand I will remain under close supervision during the works.

Name: print..... sign.....

Authorisation (*to be completed by the CL2+ manager or named deputy before work can commence*)

This area has been made safe by validated decontamination method... Yes / No / N/A

The following actions have been taken to make the working area safe:

.....
.....

Name: print: sign: Date:

This form to be filed in, room 214/1.39 and a copy displayed on external CL2+ door during works.