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**Checklist of laboratory documentation**

**Policies**

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| **Document in place?** | **Document number** | **Document name** |
|  | POLICY\_001 | Quality policy and Manual |
|  | POLICY\_002 | (your department) communication plan |
|  | POLICY\_003 | Health and Safety Policy |
|  | POLICY\_004 | Induction Manual laboratory staff |
|  | POLICY\_005 | Induction Manual non-laboratory staff |
|  | POLICY\_006 | Overview of containment level 3 laboratories |
|  | POLICY\_007 | Procedure for risk assessment |
|  | POLICY\_008 | Storage and removal of waste |
|  | POLICY\_009 | Procedure for disinfection |
|  | POLICY\_010 | Procedure in the event of a biological spillage or chemical event |
|  | POLICY\_011 | Procedure in the event of an incident including inoculation |
|  | POLICY\_012 | Document Control and archiving policy  |

**Forms**

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| **Document in place?** | **Document number** | **Document name** |
|  | FORM\_001 | Daily preparation of Tristel |
|  | FORM\_002 | Induction form checklist for lab staff |
|  | FORM\_003 | Induction form checklist for non-lab staff |
|  | FORM\_004 | Weekly housekeeping log |
|  | FORM\_005 | Maintenance log for big BSL3 |
|  | FORM\_006 | Monthly maintenance log for BSL3 laboratories |
|  | FORM\_007 | MGIT maintenance |
|  | FORM\_008 | Monthly BSL3 emergency respirator checks |
|  | FORM\_009 | Decontamination form |
|  | FORM\_010 | Equipment and room temperature log |
|  | FORM\_011 | Fumigation form |
|  | FORM\_012 | Monthly stock inventory |
|  | FORM\_013 | Clinical trials stock monitoring and QC checklist |
|  | FORM\_014 | Continuous quality improvement form (CQIF) |
|  | FORM\_015 | Visitor/engineer admission form (permit to work) |
|  | FORM\_016 | Premises and Environment horizontal audit checklist |
|  | FORM\_017 | BSL3 health and safety horizontal audit checklist |
|  | FORM\_018 | Organisation and management horizontal audit checklist |
|  | FORM\_019 | Examination audit checklist |
|  | FORM\_020 | Authorised BSL3 laboratory personnel |
|  | FORM\_021 | Control of documents and records horizontal audit checklist |
|  | FORM\_022 | Travel risk assessment form |
|  | FORM\_023 | Personnel horizontal audit checklist |
|  | FORM\_024 | Equipment horizontal audit checklist |
|  | FORM\_025 | Out of hours working |
|  | FORM\_026 | BSL2 health and safety horizontal audit checklist |
|  | FORM\_027 | Evaluation and audits horizontal audit checklist |
|  | FORM\_028 | Vertical audit checklist |
|  | FORM\_029 | Internal audit schedule |
|  | FORM\_030 | Equipment error/fault log form |
|  | FORM\_031 | Class II Microbiological Safety Cabinet maintenance (laboratory name/number) |
|  | FORM\_032 | Annual inventory biostore log |
|  | FORM\_033 | Audit summary report form |
|  | FORM\_034 | Decanting items during equipment failure or defrosting |
|  | FORM\_035 | Thermometer verification form |
|  | FORM\_036 | Clinical trials file note |
|  | FORM\_037 | Permission log to handle potential XDR M. tuberculosis strains |
|  | FORM\_038 | Document reading log |
|  | FORM\_039 | Form log |
|  | FORM\_040 | Equipment verification form |
|  | FORM\_041 | Laboratory visit log |
|  | FORM\_042 | Document sign out form |
|  | FORM\_043 | Laboratory checklist for periods of extended shutdown |
|  | FORM\_044 | Clinical trial laboratory site file audit checklist |
|  | FORM\_045 | Checklist of non-(your department)staff/projects using (your department) laboratory |

**SOPs**

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| **Document in place?** | **Document number** | **Document name** |
|  | SOP\_001 | Maintenance of QC strains |
|  | SOP\_002 | Sterilisation of paperwork for removal from the BSL3 laboratory |
|  | SOP\_003 | Handling lyophilised strains |
|  | SOP\_004 | Running agarose gels and gel extraction |
|  | SOP\_005 | Decontamination of an individual from the BSL3 laboratory |
|  | SOP\_006 | Using the biohazard spill kit |
|  | SOP\_007 | Using the chemical spill kit |
|  | SOP\_008 | Operation of microbiological safety cabinets |
|  | SOP\_009 | Operation of autoclaves |
|  | SOP\_010 | Room fumigation in collaboration with the external contractor |
|  | SOP\_011 | Fumigation of microbiological safety cabinets |
|  | SOP\_012 | Single/multiplex PCR |
|  | SOP\_013 | COVID-19 sample processing |
|  | SOP\_014 | DNA extraction from sputum using chelex |
|  | SOP\_015 | Sample preparation and use of the Curetis Unyvero system |
|  | SOP\_016 | Procedure for immunofluorescent staining of urothelial cells |
|  | SOP\_017 | Minimum Inhibitory Concentrations by agar proportion |
|  | SOP\_018 | Document control procedure and archiving |
|  | SOP\_019 | Identification and control of non-conformities |
|  | SOP\_020 | Procedure for internal and external audit |
|  | SOP\_021 | Handling and storage of *M. tuberculosis* (including XDR strains) |
|  | SOP\_022 | Control of patient-identifiable data |
|  | SOP\_023 | Servicing, maintenance and calibration of equipment |
|  | SOP\_024 | Defrosting freezers, including BSL3 freezers |
|  | SOP\_025 | Preparation and sterilization of 7H9 media and 7H10 agar |
|  | SOP\_026 | Preparation and sterilization of 50% glycerol |
|  | SOP\_027 | Temperature monitoring |
|  | SOP\_028 | Stock monitoring procedure |
|  | SOP\_029 | Clinical trials chain of custody |
|  | SOP\_030 | Clinical trials data reporting |
|  | SOP\_031 | Preparation and maintenance of the laboratory site file |
|  | SOP\_032 | External quality assurance (EQA) |
|  | SOP\_033 | Staff training and competence |
|  | SOP\_034 | (your institution) clinical trial staff training and competency assessment |

**Competency assessment forms (CAFs)**

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| **Document in place?** | **Document number** | **Document name** |
|  | CAF\_001 | CL3 decontamination training |
|  | CAF\_002 | Induction and competency assessment for containment level 3 laboratories |
|  | CAF\_003 | Autoclave training assessment form |
|  | CAF\_004 | Operation of microbiological safety cabinets |
|  | CAF\_005 | Fumigation of microbiological safety cabinets with formaldehyde |
|  | CAF\_006 | Training and competency assessment form |
|  | CAF\_007 | Clinical trial competence assessment form |
|  | CAF\_008 | COVID-19 competence assessment form |
|  | CAF\_009 | Temperature monitoring training assessment form |

**Risk assessments**

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| **Document in place?** | **Document number** | **Document name** |
|  | RA\_001 | Defrosting freezers (BSL3) |
|  | RA\_002 | Screening novel anti-tuberculosis compounds (BSL3) |
|  | RA\_003 | Nucleic acid extraction from samples containing HG2 organisms (BSL2) |
|  | RA\_004 | Operation of centrifuges (BSL2 and 3) |
|  | RA\_005 | Preparation and use of Tristel disinfectant (BSL2 and 3) |
|  | RA\_006 | Preparation of 5M GTC (BSL3) |
|  | RA\_007 | RNA extraction from human plasma using phenol chloroform (BSL2) |
|  | RA\_008 | Safe handling of HG2 organisms and material containing them (BSL2) |
|  | RA\_009 | Singleplex/multiplex PCR (BSL2) |
|  | RA\_010 | Preparation and sterilization of media (BSL2) |
|  | RA\_011 | Decontamination of an individual after a spill in BSL3 (BSL3) |
|  | RA\_012 | Extraction of nucleic acid from biological material containing HG3 organisms (BSL3) |
|  | RA\_013 | Fumigation of class I and class II microbiological safety cabinets (BSL2 and 3) |
|  | RA\_014 | Running agarose ethidium bromide gels and gel extraction (BSL2) |
|  | RA\_015 | Storage of items in the -70 freezer (BSL2 and 3) |
|  | RA\_016 | Operation of autoclaves in (your department) (BSL2 and 3) |
|  | RA\_017 | Safe handling of HG3 organisms and material containing them (BSL3) |