

SJH CENTRE for LABORATORY MEDICINE & MOLECULAR PATHOLOGY			
Edition No.:	05	Laboratory Procedure	Doc No: LP-GEN-0002
Author	Christina Ryan	Date: 13 th May 2024	Date of issue:
Authorised By	Fiona Kearney	Date: 24 th July 2024	7 th August 2024



SPECIMEN TRANSPORTATION

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1.	SCOPE	3
2.	RESPONSIBILITIES	3
3.	REFERENCES.....	3
4.	DEFINITIONS	4
5.	DOCUMENTATION.....	4
6.	GENERAL.....	5
7.	PROCEDURE	5
7.1	TRANSPORT OF SPECIMENS	5
7.1.1	<i>Procedure for Packaging, Labelling and Dispatch of Laboratory Specimens.....</i>	<i>6</i>
7.2	PROTECTION OF THE SPECIMENS FROM DETERIORATION	13
7.3	RECORDING OF DISPATCH DATES	14
7.4	REPORTING INCIDENTS DURING TRANSPORTATION THAT MAY AFFECT THE QUALITY OF THE SPECIMEN OR THE SAFETY OF PERSONNEL	14
7.5	PROCEDURES IN THE EVENT OF A SPILLAGE	15
7.5.1	<i>Spillage or Leakage in the PTTS</i>	<i>15</i>
7.5.2	<i>Spillage or Leakage of Specimens being transported by Blood Porters</i>	<i>15</i>
8.	APPENDICES.....	16

SJH CENTRE for LABORATORY MEDICINE & MOLECULAR PATHOLOGY			
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1. SCOPE

This procedure is to be followed when transporting specimens to, from, and within St. James's Hospital. The procedure is available to those who are responsible for specimen transportation to and within St James's Hospital.

2. RESPONSIBILITIES

It is the responsibility of laboratory management in conjunction with hospital management to ensure that this procedure is adequate and adhered to at all times.

3. REFERENCES

'Understanding Accreditation in Laboratory Medicine' by David Burnett 1996
'A Practical Guide to Accreditation in Laboratory Medicine' by David Burnett 2002
'A Practical Guide to ISO 15189 in Laboratory Medicine' by David Burnett 2013
Health Services Advisory Committee: Safety in Health Service Laboratories, Safer Working and the Prevention of Infection in Clinical Laboratories
Safe Transport of Infectious Substances by Air - Central Public Health Laboratory
St. James's Hospital Risk Occurrence Form
St. James's Hospital Health & Safety Policies
REF-GEN-0007 Safety, Health & Welfare at Work Act 2005
REF-GEN-0008 SHAWW Biological Agents Regulations 2013
REF-GEN-0022 Carriage of Dangerous Goods by Road (ADR Regulations) 2023
REF-GEN-0178 Guidance on Regulations for the Transport of Infectious Substances 2021-2022
REF-GEN-0211 Biosafety guidance for diagnostic laboratories handling specimens from individuals with possible or confirmed infection with SARS-CoV-2
REF-GEN-0075: HPSC: Monkeypox: Laboratory transportation plan for hospital-based settings
REF-GEN-0263 HSE Guidelines for the Preparation for Transport of Patient Specimens and other Biological Materials

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4. DEFINITIONS

ADR: Agreement Dangereux Routier (UN/ECE European Agreement Concerning the International Carriage of Dangerous Goods by Road)

Patient specimens: Human material including but are not limited to, excreta, secreta, blood and its components, tissue and tissue fluid swabs, and body parts being carried for purposes such as research, diagnosis, investigational activities, disease treatment and prevention.

Cultures: The result of a process by which pathogens are intentionally propagated.

IATA: International Air Transport Association

Infectious Substance: Category A: An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals. See Appendix No. 5 Category A
Category B: An infectious substance which does not meet the criteria for inclusion in Category A. See Appendix 6 Category B

LIS: Laboratory Information System

CHI: Children's Health Ireland

PTTS: Pneumatic Tube Transport System

UN: United Nations

5. DOCUMENTATION

SJH:CORP042 Policy on the Prevention of Sharps Injuries Policy

MP-GEN-0007 Staff Health and Safety Manual

MP-GEN-0008 Management of Health & Safety

LP-GEN-0004 Specimen Referral and Dispatch

LP-GEN-0007 LabMed User Guide (On-line)

LP-GEN-0016 Use of RFID Technology to Track Precious Specimen Transport to the Laboratory

QP-GEN-0005 Management of Non-conformances in the LabMed Directorate

SJH:LABMED(P)006 Policy on the Provision of Pathology Laboratory Services to General Practitioners

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SJH:LABMED(P)007 Policy on Provision of Pathology Laboratory Services to External Agencies

6. GENERAL

The specimen transportation system ensures the timely arrival of specimens at laboratory reception, in optimal condition, at the correct destination, in a manner that does not pose a threat to the health and safety of anyone coming in contact with the sample and is in compliance with regulations.

7. PROCEDURE

This procedure is in place to ensure specimen integrity and the safety of all those coming in contact with the specimen during transportation. It takes account of ADR Regulations 2017, the Safety, Health & Welfare at Work Act 2005, SHAWW Biological Agents Regulations 2013 and all other relevant health & safety regulations.

7.1 Transport of Specimens

Specimens are transported to and from the LabMed Directorate as follows:

1. To the LabMed Directorate by:
 - Authorised hospital staff
 - General Practitioners
 - Patients
 - Courier
 - Taxi
 - Pneumatic Tube Transport System

2. From the LabMed Directorate by:
 - Courier
 - Taxi
 - Hospital Porters (CHI Crumlin)

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7.1.1 Procedure for Packaging, Labelling and Dispatch of Laboratory Specimens

All laboratory specimens have the potential to contain substances that are infectious. Sometimes this potential is unknown but equally there are times when it may be known. The main principle of safety in this regard is to package and label all specimens in such a manner so that they present no threat to those sending, transporting or receiving them. However, when it is known that a specimen contains a serious hazard in the form of an infectious agent then it is prudent that a higher than normal standard of packaging, labelling and transport be applied. For these reasons specimens are categorised as belong to one of two categories, with each category having its own labelling and packaging instructions.

CATEGORY A: An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in humans or animals. An exposure occurs when an infectious substance is released outside of the protective packaging, resulting in physical contact with humans or animals. An indicative list of infectious agents in Category A is given in Appendix No. 3. Contact the laboratory or refer to Appendix 3 if transporting specimens thought to contain agents in Category A. A full description of Category A is given in Appendix No. 5.

CATEGORY B: An infectious substance that does not meet the criteria for inclusion in Category A. A full description of Category B is given in Appendix No. 6.

The majority of laboratory specimens fit into Category B.

Specimens suspected or confirmed of containing SARS-CoV-2 / Monkeypox can safely be shipped as UN3373 biological substance, Category B.

Ref: REF-GEN-0211 Biosafety guidance for diagnostic laboratories handling specimens from individuals with possible or confirmed infection with SARS-CoV-2

REF-GEN-0075: HPSC: Monkeypox: Laboratory transportation plan for hospital-based settings

Ref.: Appendix No. 3: Indicative Examples of Infectious Substances (Category A)

Ref.: Appendix No. 5: Category A

Ref.: Appendix No. 6: Category B

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7.1.1.1 Transport and Packaging of Specimens to the Laboratory from within the Hospital.

These regulations are in place to ensure the safety of all those coming in contact with pathology specimens during transportation. All patient specimens should be treated as potentially hazardous and handled accordingly. Should there be a suspicion that a specimen contains a Category A infectious substance, please contact the laboratory for information on packing instructions or refer to Appendix No. 2.

Specimens are transported to the laboratory via the pneumatic transport system or are brought directly to the laboratory by members of the hospital staff. Samples from patients with suspect COVID 19 should be double bagged. They can be hand delivered or arrive through the PTTS.

All samples taken from patient(s) with ?Monkeypox virus (MPX) and for ?Monkeypox investigation will be individually labelled with a hazard label (supplied by Microbiology),



bagged individually, then placed in a second bag. This bag will be hand-delivered to the lab by hospital staff, (GUIDE/A&E/Occ Health) who must inform Central Reception staff of the MPX hazard when delivering the samples. Specimen Reception staff should place the unopened bag into the COVID / Monkeypox bucket, where it will be collected by Microbiology staff. If the bag contains samples for other departments, Microbiology will forward on samples to other labs as required.

If samples taken for routine analysis for departments other than Microbiology, Samples can be either be stored for analysis when MPX status is known or processed if results are required urgently.

For samples taken from the same patient but for investigations carried out in different departments, where possible separate samples should be taken and samples should be packaged separately (e.g. CSF sample for Microbiology and for Cytology).

For precious specimens (currently for the histology department) Radio Frequency Identification (RFID) is a technology used to monitor the location and movement of designated precious samples from clinical areas to the laboratory. It uses scanning

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equipment (RFID antennae) installed at key locations to detect and record RFID tags attached to precious clinical specimens. Primary specimen containers, e.g. blood collection tube or an MSU container, must be placed in an appropriate biohazard plastic bag with the request form (if any).

1. For Histopathology specimens, where specimens are being submitted from two or more patients, each patient's specimen must be bagged separately prior to submission to the laboratory
2. For PTTS transport the bagged specimen is placed inside the carrier pod and sent to the required destination in the laboratory. Specimens excluded from transport via the PTTS are listed in Appendix No. 7
3. Those specimens brought to the laboratory should be packed and transported in a carrier bag in such a way as to avoid damage in transit (see section 7.4 for further details).
4. The carrier bag must be capable of retaining any liquid in the event of sample leakage.
5. If a specimen leaks or is damaged in transit the porter or other staff member should contact the appropriate person(s) as detailed in section 7.4 below.
6. All tissue (excluding bone marrow) from a patient with known or suspected CJD or any TSE must be packaged according to Packaging instruction P650, Appendix No. 1, and brought directly to the histopathology department. The Histopathology Department must be notified in advance of any such tissue being sampled.

Ref.: MP-GEN-0007 Staff Health & Safety Manual.

Ref: LP-GEN-0016 Use of RFID Technology to Track Precious Specimen Transport to the Laboratory

Ref.: Appendix No. 1: Packaging Instruction P650

Ref.: Appendix No. 2: Packaging Instruction P620

Ref.: Appendix No. 3: Indicative Examples of Infectious Substances (Category A)

Ref.: Appendix No. 7: Specimens Excluded from Transport via the PTTS

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7.1.1.2 Packaging of Specimens and Infectious Substances Going to the Laboratory from Outside the Hospital and from the Laboratory to Other Agencies

It is the responsibility of all persons sending samples to and from the laboratory to adhere to this policy and to national regulations and to ensure that specimens sent to the laboratory do not present a risk to anyone coming in contact with it during transportation or on receipt in the laboratory.

Instructions to Person Packaging Specimens

All patient specimens should be treated as potentially hazardous and handled accordingly.

External transportation containers must comply with ADR Regulations 2023.

The vast majority of specimens fall into Category B and require packaging regulation P650, Appendix No. 1. Exemptions to category B are outlined in Appendix No. 6.

Instruction:

- (1) The packaging must be of good quality, strong enough to withstand the shocks and loadings normally encountered during carriage
- (2) The packaging must consist of at least three components:
 - (a) A leak-proof primary receptacle, e.g. blood collection tube, MSU container.
 - (b) A secondary sealable package to enclose and protect the primary container(s) e.g. plastic specimen bag. Several primary containers may be placed in one secondary package. Sufficient absorbent material must be used.
NB: Urine containers must be individually packaged to absorb the entire contents of the primary receptacle.
 - (c) Outer Package: The secondary package is placed in an outer transport container with suitable cushioning that protects it and its contents from external influences such as physical damage and water while in transit. This must conform to P650 of ADR 2017. **NB:** Stationary envelopes and padded envelopes are not considered suitable outer packaging.
- (3) For carriage, the mark illustrated below shall be displayed on the external surface of the outer package.

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The proper shipping name "BIOLOGICAL SUBSTANCE, CATEGORY B" must be marked on the outer packaging adjacent to the diamond-shaped mark.

Figure 1: Example of 3 Layer Packaging System

Minimum 3 Layer Packaging System

Primary Packaging

- Leakproof

Secondary packaging

- Leakproof
- Contain absorbent material sufficient for all liquid present

Outer Packaging

- Robust construction
- Minimum one surface dimension 100 x 100mm

Either primary or secondary packaging to withstand internal pressure of 95kPa

Either secondary or outer packaging must be rigid

Completed package capable of withstanding a 1.2 m drop test

Outer packaging markings

Packaging must

- Display **UN3373 Mark**
(Diamond minimum dimension 50 x 50 mm)
- Display the wording '**Biological Substances Category B'**
(Characters ≥ 6mm High)

Example of Packaging systems

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Ref.: HSE Guidelines for the Preparation for Transport of Patient Specimens and other Biological Materials

Biological substances that have been correctly classified as UN No. 3373 which are packaged and marked in accordance with packaging instruction P650, Appendix No. 1, are not subject to any other requirements of ADR.

This implies that provided the correct packaging is used, there is no requirement for any ADR documentation or for the requirement to have specially marked and equipped vehicles or trained drivers.

In summary, any method of transportation can be used to transport patient specimens once properly packaged and labelled.

Packaging of Specimens Assigned to Category A

Specimens assigned to category A are packaged and labelled in accordance with packaging instruction P620. Refer to Appendix 1 Packaging Instruction P620.

Contact the laboratory or refer to Appendix No.3 Indicative Examples of Infectious Substances (Category A)

7.1.1.3 Transport of Infectious Substances to and from the hospital.

1. Infectious substances are frequently conveyed from one hospital to another, or to other outside institutions, because of the centralisation of laboratory services or for specialised testing. On some occasions hospital transport is used, on others the use of courier services may be required.
2. Infectious substances are subject to detailed transport guidelines **and legislation**, directed towards ensuring that these goods are carried under optimum conditions for the safety of persons, property and environment.
3. Transport legislation follows in principle the UN Recommendations and Model Regulations, whose principle of identifying each hazardous substance with a UN Number for specifying for each their principle and subsidiary hazard classes and packing groups has been adopted for all modes of transport, road, rail, air, sea and inland waterways.

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- Biological substances that have been correctly classified as UN No. 3373 which are packaged and marked in accordance with packaging instruction P650, Appendix No. 1, are not subject to any other requirements of ADR.

This implies that provided the correct packaging is used, there is no requirement for any ADR document or for the requirement to have specially marked and equipped vehicles or trained drivers.

- Upon receipt, inspect the package for any signs of leakage or other damage. Give consideration to opening the package in a Biological Safety Cabinet.
- The transport arrangements UN2814 Category A are different and these must be packaged and marked in accordance with packing instruction P620, Appendix No. 2, and only approved couriers may transport UN2814 'Category A' goods.
- Carriage of goods by road is carried out under the European Agreement Concerning the International Carriage of Dangerous Goods by Road (ADR) Regulations (2023 Edition).
- Transport of pathology specimens by air must comply with the International Air Transport Association (IATA) Restricted Articles Regulations, and any additional requirements of the individual carriers. Documentation required by IATA includes a Shipper's Certificate for Restricted Articles, which requires content, nature and quantity of infectious material to be disclosed. Refer to Appendix No. 4.
- Exemptions

Under the EU BA directive, when cultures of *Mycobacterium tuberculosis*, *Shigella dysenteriae* type 1 and *Escherichia coli*, verotoxigenic, are transported for diagnostic or clinical purposes, they may be classified as infectious substances of Category B. This means they can be packaged as P650 and are not subject to any other requirements of ADR. As of 2007, this same exemption does not apply to IATA or maritime regulations, and if these cultures require transport by air or sea they must be transported by approved couriers as UN2814.

Upon receipt, inspect the package for any signs of leakage or other damage; Give consideration to opening the package in a Biological Safety Cabinet.

Ref.: Appendix No. 1: Packaging Instruction P650

Ref.: Appendix No. 2: Packaging Instruction P620

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Ref.: Appendix No. 3: Indicative Examples of Infectious Substances (Category A)

Ref.: Appendix No. 4: Sample Transport Dangerous Goods Note

Ref.: Appendix No. 5: Category A

Ref.: Appendix No. 6: Category B

Ref.: LP-GEN-0004 Specimen Referral and Dispatch

Ref.: MP-GEN-0007 Staff Health and Safety Manual.

7.2 Protection of the Specimens from Deterioration

All specimens should be dispatched/transported to the laboratory as soon as possible. Specimens should not be stored in ward or clinic areas for longer than is necessary to organise transport to the laboratory.

Specimens from the community (i.e. external sources e.g. GPs) should be dispatched within a few hours of specimen collection. Overnight storage of blood samples before dispatch to the laboratory is not recommended. Please ensure that specimens are collected and transported to the laboratory to meet the specimen reception cut-off times.

Ref.: SJH:LABMED(P)006 Policy on the Provision of Pathology Laboratory Services to General Practitioners

Ref.: SJH:LABMED(P)007 Policy on Provision of Pathology Laboratory Services to External Agencies

Specimens should never be stored in a transport vehicle overnight.

Some samples require special handling e.g. transport within a specific temperature interval, require protection from light, require immediate freezing, transport within a time frame appropriate to the nature of the examination, etc. If in doubt, regarding the specimen container required or the special requirements when taking / transporting the specimen please refer to the relevant test/profile in the LabMed User Guide (LP-GEN-0007), or contact the laboratory for advice.

Ref.: LP-GEN-0007 LabMed User Guide

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Where specific transport/storage conditions are not specified, ambient temperature is applicable. Ensure that specimens are not exposed to extremes of temperature e.g. placed in direct sunlight, near a heat source (e.g. radiator) or allowed to chill or freeze.

Standard transport requirements definitions are as follows:

- Refrigerated: +2° to +8°C
- Frozen: -15° to -25°C
- Ambient: > +8° to +25°C

Note: Failure to transport specimens to the laboratory in a timely manner or under the required conditions may result in deterioration of the specimen and the sample being unsuitable for some/all of the analyses requested.

7.3 Recording of Dispatch Dates

Dispatch dates are recorded in the LIS, and/or in a spread sheet or other paper record stored in the relevant department.

Ref.: LP-GEN-0004 Specimen Referral & Dispatch (and the departmental SOPs references therein)

7.4 Reporting Incidents During Transportation that May Affect the Quality of the Specimen or the Safety of Personnel.

Specimens are labelled in the relevant department and logged into the LIS. This includes the date and time of collection and receipt by the laboratory and this allows flagging of any undue delays which may affect the results. Where there is a health risk posed as a result of the incident, the personnel/organisation responsible for the transportation of the sample will be notified immediately and action will be taken to reduce the risk and prevent recurrence. All relevant incidents are reported to St. James's Hospital Risk Management via the online Adverse Incident Reporting system on Datix. Where appropriate, a non-conformance should be raised in Q-Pulse as described in QP-GEN-0005.

Ref.: MP-GEN-0008 Management of Health and Safety

Ref.: QP-GEN-0005 Management of Non-conformances in the LabMed Directorate

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7.5 Procedures in the event of a Spillage

All leakages or spillages should be dealt with by staff that are trained in the use of Biological Spill Kits.

Ref.: MP-GEN-0007 Staff Health and Safety Manual

7.5.1 Spillage or Leakage in the PTTS

Spillages that occur in PTTS pods are handled by Specimen reception personnel. Liaise with scientists in the destination department to determine whether or not the specimen can be repeated, or if an attempt needs to be made to salvage the remaining specimen (refer to MP-GEN-0007 Staff Health & Safety Manual, section 14.7.12).

Generally, the leaking specimen will have contaminated all others in the same bag. The ward / location that sent the specimens is contacted and a list of the patients on whom fresh specimens are required is given to ward staff.

If the leaking specimen is loose in a PTTS pod, after removal of the contaminated specimens, the pod is steeped in Virkon for 24 hours before re-use.

7.5.2 Spillage or Leakage of Specimens being transported by Blood Porters

Blood porters are trained in Specimen Transportation by the hospital's DGSA. The action to be taken by the porters in the event of a spillage depends on where the incident occurs.

7.5.2.1 Spillage or Leakage in Ward / Clinic Areas

In this instance the procedure is that the blood porter contacts the ward manager / senior nursing staff in the relevant ward or clinic. Procedures to be followed are as outlined in section 5.4 of SJH:COR(P): 042 Sharps and Blood-Borne Pathogens Safe Working Practices Policy.

7.5.2.2 Spillage or Leakage in Corridors or Concourse

In this instance the procedure is that the blood porter contacts the outpatient phlebotomy department (Senior Phlebotomist Bleep 738) where there is a Biological Spill Kit available.

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7.5.2.3 *Spillage or Leakage in the Hospital Grounds*

In this instance the procedure is that the blood porter contacts staff in the LabMed reception area (ext. 2929 or 4862) where there is a Biological Spill Kit available. If the incident occurs outside of normal working hours, the contacts are the on-call scientists (Haematology / Blood Transfusion Bleep 671, Biochemistry Bleep 310 and Microbiology Bleep 194).

8. APPENDICES

1. Appendix No. 1: Packaging Instruction P650
2. Appendix No. 2: Packaging Instruction P620
3. Appendix No. 3: Indicative Examples of Infectious Substances (Category A)
4. Appendix No. 4: Sample Transport Dangerous Goods Note
5. Appendix No. 5: Category A
6. Appendix No. 6: Category B
7. Appendix No. 7: Specimens Excluded from Transport via the PPTS

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Appendix No. 1: Packaging Instruction P650

This packaging instruction applies to infectious substances in Category B and designated UN No. 3373

(1) The packaging shall be of good quality, strong enough to withstand the shocks and loadings normally encountered during carriage, including transshipment between vehicles or containers and between vehicles or containers and warehouses as well as any removal from a pallet or over-pack for subsequent manual or mechanical handling. Packaging shall be constructed and closed to prevent any loss of contents that might be caused under normal conditions of carriage by vibration or by changes in temperature, humidity or pressure.

(2) The packaging shall consist of at least three components:

- (a) a primary receptacle;
- (b) a secondary packaging; and
- (c) an outer packaging of which either the secondary or the outer packaging shall be rigid. **NB:** Stationary envelopes and padded envelopes are not considered suitable outer packaging.

(3) Primary receptacles shall be packed in secondary packaging in such a way that, under normal conditions of carriage, they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packaging shall be secured in outer packaging with suitable cushioning material. Any leakage of the contents shall not compromise the integrity of the cushioning material or of the outer packaging.

(4) For carriage, the mark illustrated below shall be displayed on the external surface of the outer packaging on a background of a contrasting colour and shall be clearly visible and legible. The mark shall be in the form of a square set at an angle of 45° (diamond-shaped) with minimum dimensions of 50 mm by 50 mm; the width of the line shall be at least 2 mm and the letters and numbers shall be at least 6 mm high.



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The proper shipping name "BIOLOGICAL SUBSTANCE, CATEGORY B" in letters at least 6 mm high shall be marked on the outer packaging adjacent to the diamond-shaped mark.

(5) At least one surface of the outer packaging shall have a minimum dimension of 100 mm × 100 mm.

(6) The completed package shall be capable of successfully passing the drop test in 6.3.2.5 as specified in 6.3.2.2 to 6.3.2.4 at a height of 1.2 m. Following the appropriate drop sequence, there shall be no leakage from the primary receptacle(s) which shall remain protected by absorbent material, when required, in the secondary packaging.

(7) For liquid substances:

(a) The primary receptacle(s) shall be leak-proof and must not contain more than 1 litre;

(b) The secondary packaging shall be leak-proof;

(c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them;

(d) Absorbent material shall be placed between the primary receptacle(s) and the secondary packaging. The absorbent material shall be in quantity sufficient to absorb the entire contents of the primary receptacle(s) so that any release of the liquid substance will not compromise the integrity of the cushioning material or of the outer packaging;

(e) The primary receptacle or the secondary packaging shall be capable of withstanding, without leakage, an internal pressure of 95 kPa (0.95 bar) and in the temperature range of -40°C to +55°C

(f) The outer package must not contain more than 4 litres. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold.

(8) For solid substances:

(a) The primary receptacle(s) shall be sift-proof and must not exceed the outer packaging mass limit;

(b) The secondary packaging shall be sift-proof;

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Authorised By	Fiona Kearney	Date: 24th July 2024	7th August 2024

(c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them

(d) Except for packages containing body parts, organs or whole bodies, the outer package must not contain more than 4 kg. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold;

(e) If there is any doubt as to whether or not residual liquid may be present in the primary receptacle during carriage then a packaging suitable for liquids, including absorbent materials, shall be used.

(9) Refrigerated or frozen specimens: Ice, dry ice and liquid nitrogen:

(a) When dry ice or liquid nitrogen is used to keep specimens cold, all applicable requirements of ADR shall be met. When used, ice or dry ice shall be placed outside the secondary packaging or in the outer packaging or an over-pack. Interior supports shall be provided to secure the secondary packaging in the original position after the ice or dry ice has dissipated. If ice is used, the outside packaging or over-pack shall be leak-proof. If carbon dioxide, solid (dry ice) is used, the packaging shall be designed and constructed to permit the release of carbon dioxide gas to prevent a build-up of pressure that could rupture the packaging and the package (the outer packaging or the over-pack) shall be marked "Carbon dioxide, solid" or "Dry ice".

(b) The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used as well as the temperatures and the pressures which could result if refrigeration were lost.

(10) When packages are placed in an over-pack, the package markings required by this packing instruction shall either be clearly visible or be reproduced on the outside of the over-pack.

(11) Infectious substances assigned to UN No. 3373 which are packed and packages which are marked in accordance with this packing instruction are not subject to any other requirement in ADR except for the following:

(a) the name and address of the shipper and the receiver (consignee) must be provided on each package

SJH CENTRE for LABORATORY MEDICINE & MOLECULAR PATHOLOGY			
Edition No.:	05	Laboratory Procedure	Doc No: LP-GEN-0002
Author	Christina Ryan	Date: 13th May 2024	Date of issue:
Authorised By	Fiona Kearney	Date: 24th July 2024	7th August 2024

(b) the name and telephone number of a person responsible must be provided on a written document (such as an air waybill) or on the package

(c) passengers and crew members are prohibited from transporting infectious substances either as, or in, carry-on baggage or checked baggage or on their person.

(12) Clear instructions on filling and closing such packages shall be provided by packaging manufacturers and subsequent distributors to the consignor or to the person who prepares the package (e.g. patient) to enable the package to be correctly prepared for carriage.

(13) Other dangerous goods shall not be packed in the same packaging as Class 6.2 infectious substances unless they are necessary for maintaining the viability, stabilizing or preventing degradation or neutralizing the hazards of the infectious substances. A quantity of 30 ml or less of dangerous goods included in Classes 3, 8 or 9 may be packed in each primary receptacle containing infectious substances. When these small quantities of dangerous goods are packed with infectious substances in accordance with this packing instruction no other requirements of ADR need be met.

(14) If any substance has leaked and has been spilled in a vehicle or container, it may not be reused until after it has been thoroughly cleaned and, if necessary, disinfected or decontaminated. Any other goods and articles carried in the same vehicle or container shall be examined for possible contamination.

SJH CENTRE for LABORATORY MEDICINE & MOLECULAR PATHOLOGY			
Edition No.:	05	Laboratory Procedure	Doc No: LP-GEN-0002
Author	Christina Ryan	Date: 13 th May 2024	Date of issue:
Authorised By	Fiona Kearney	Date: 24 th July 2024	7 th August 2024

Appendix No. 2: Packaging Instruction P620

This packaging instructions applies to infectious substances in Category A and designated UN Nos. 2814 and 2900.

The following packagings are authorized provided the special packing provisions set out below are met:

Packagings approved accordingly consisting of:

(a) Inner packagings comprising:

- (i) leak-proof primary receptacle(s);
- (ii) a leak-proof secondary packaging;
- (iii) other than for solid infectious substances, an absorbent material in sufficient quantity to absorb the entire contents placed between the primary receptacle(s) and the secondary packaging; if multiple primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated so as to prevent contact between them;

(b) A rigid outer packaging of adequate strength for its capacity, mass and intended use.

The smallest external dimension shall be not less than 100 mm.

- c The package must be taken directly to its intended delivery site; no stops are to be made along the way.
- d Upon receipt, inspect the package for any signs of leakage or other damage;
- e Open give consideration to opening the package in a Biological Safety Cabinet.

Special packing provisions for infectious substances (Class 6.2)

- a Consignors of infectious substances shall ensure that packages are prepared in such a manner that they arrive at their destination in good condition and present no hazard to persons or animals during carriage.
- b For UN No. 2814 and UN No. 2900, an itemized list of contents shall be enclosed between the secondary packaging and the outer packaging. When the infectious substances to be carried are unknown, but suspected of meeting the criteria for inclusion in Category A and assignment to UN Nos 2814 or 2900, the words "suspected Category A infectious substance" shall be shown, in parenthesis, following the proper shipping name on the document inside the outer packaging.

SJH CENTRE for LABORATORY MEDICINE & MOLECULAR PATHOLOGY			
Edition No.:	05	Laboratory Procedure	Doc No: LP-GEN-0002
Author	Christina Ryan	Date: 13 th May 2024	Date of issue:
Authorised By	Fiona Kearney	Date: 24 th July 2024	7 th August 2024

- c Before an empty packaging is returned to the consignor, or sent elsewhere, it shall be thoroughly disinfected or sterilized and any label or marking indicating that it had contained an infectious substance shall be removed or obliterated.
- d The provisions of this section do not apply to UN No. 3373 Biological substance, Category B (see packing instruction P650).

Additional requirements:

1. Inner packaging containing infectious substances shall not be consolidated with inner packaging containing unrelated types of goods.
2. Other than for exceptional consignments, e.g. whole organs which require special packaging, the following additional requirements shall apply:
 - (a) Substances consigned at ambient temperatures or at a higher temperature: Primary receptacles shall be of glass, metal or plastics. Positive means of ensuring a leak-proof seal shall be provided, e.g. a heat seal, a skirted stopper or a metal crimp seal. If screw caps are used, they shall be secured by positive means, e.g., tape, paraffin sealing tape or manufactured locking closure;
 - (b) Substances consigned refrigerated or frozen: Ice, dry ice or other refrigerant shall be placed around the secondary packaging(s) or alternatively in an over-pack with one or more complete packages marked in accordance with 6.3.1.1. Interior supports shall be provided to secure secondary packaging(s) or packages in position after the ice or dry ice has dissipated. If ice is used, the outer packaging or over-pack shall be leak-proof. If dry ice is used, the outer packaging or over-pack shall permit the release of carbon dioxide gas. The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the refrigerant used;
 - (c) Substances consigned in liquid nitrogen: Plastics primary receptacles capable of withstanding very low temperature shall be used. The secondary packaging shall also be capable of withstanding very low temperatures, and in most cases will need to be fitted over the primary receptacle individually. Provisions for the consignment of liquid nitrogen shall also be fulfilled. The primary receptacle and the secondary packaging shall maintain their integrity at the temperature of the liquid nitrogen;

SJH CENTRE for LABORATORY MEDICINE & MOLECULAR PATHOLOGY			
Edition No.:	05	Laboratory Procedure	Doc No: LP-GEN-0002
Author	Christina Ryan	Date: 13th May 2024	Date of issue:
Authorised By	Fiona Kearney	Date: 24th July 2024	7th August 2024

(d) Lyophilised substances may also be carried in primary receptacles that are flame-sealed glass ampoules or rubber-stoppered glass vials fitted with metal seals.

Whatever the intended temperature of the consignment, the primary receptacle or the secondary packaging shall be capable of withstanding without leakage an internal pressure producing a pressure differential of not less than 95 kPa and temperatures in the range -40 °C to +55 °C.

SJH CENTRE for LABORATORY MEDICINE & MOLECULAR PATHOLOGY			
Edition No.:	05	Laboratory Procedure	Doc No: LP-GEN-0002
Author	Christina Ryan	Date: 13 th May 2024	Date of issue:
Authorised By	Fiona Kearney	Date: 24 th July 2024	7 th August 2024

Appendix No. 3: Indicative Examples of Infectious Substances (Category A)

UN2814, Infectious substance affecting humans.	<p><i>Bacillus anthracis</i> (cultures only)</p> <p><i>Brucella abortus</i> (cultures only)</p> <p><i>Brucella melitensis</i> (cultures only)</p> <p><i>Brucella suis</i> (cultures only)</p> <p><i>Burkholderia mallei</i>–<i>Pseudomonas mallei</i>–<i>Glanders</i> (cultures only)</p> <p><i>Burkholderia pseudomallei</i>–<i>Pseudomonas pseudomallei</i> (cultures only)</p> <p><i>Chlamydia psittaci</i>–avian strains (cultures only)</p> <p><i>Clostridium botulinum</i> (cultures only)</p> <p><i>Coccidioides immitis</i> (cultures only)</p> <p><i>Coxiella burnetii</i> (cultures only)</p> <p>Crimean-Congo hemorrhagic fever virus</p> <p>Dengue virus (cultures only)</p> <p>Eastern equine encephalitis virus (cultures only)</p> <p><i>Escherichia coli</i>, verotoxigenic (cultures only)</p> <p>Ebola virus</p> <p>Flexal virus</p> <p><i>Francisella tularensis</i> (cultures only)</p> <p>Guanarito virus</p> <p>Hantaan virus</p> <p>Hantavirus causing hemorrhagic fever with renal syndrome</p> <p>Hendra virus</p> <p>Hepatitis B virus (cultures only)</p> <p>Herpes B virus (cultures only)</p> <p>Human immunodeficiency virus (cultures only)</p> <p>Highly pathogenic avian influenza virus (cultures only)</p> <p>Japanese Encephalitis virus (cultures only)</p> <p>Junin virus</p> <p>Kyasanur Forest disease virus</p> <p>Lassa virus</p> <p>Machupo virus</p> <p>Marburg virus</p> <p>Monkeypox virus</p> <p><i>Mycobacterium tuberculosis</i> (cultures only)</p> <p>Nipah virus</p> <p>Omsk hemorrhagic fever virus</p> <p>Poliovirus (cultures only)</p> <p>Rabies virus (cultures only)</p> <p><i>Rickettsia prowazekii</i> (cultures only)</p> <p><i>Rickettsia rickettsii</i> (cultures only)</p> <p>Rift Valley fever virus (cultures only)</p> <p>Russian spring-summer encephalitis virus (cultures only)</p> <p>Sabia virus</p> <p><i>Shigella dysenteriae</i> type 1 (cultures only)</p> <p>Tick-borne encephalitis virus (cultures only)</p>
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SJH CENTRE for LABORATORY MEDICINE & MOLECULAR PATHOLOGY

Edition No.:	05	Laboratory Procedure	Doc No:	LP-GEN-0002
Author	Christina Ryan	Date:	13th May 2024	
Authorised By	Fiona Kearney	Date:	24th July 2024	
			Date of issue:	7th August 2024

	<p>Variola virus Venezuelan equine encephalitis virus (cultures only) West Nile virus (cultures only) Yellow fever virus (cultures only) <i>Yersinia pestis</i> (cultures only)</p>
UN2900, Infectious substances affecting animals	<p>African swine fever virus (cultures only) Avian paramyxovirus Type 1–Velogenic Newcastle disease virus (cultures only) Classical swine fever virus (cultures only) Foot and mouth disease virus (cultures only) Lumpy skin disease virus (cultures only) <i>Mycoplasma mycoides</i>–Contagious bovine pleuropneumonia (cultures only) Peste des petits ruminants virus (cultures only) Rinderpest virus (cultures only) Sheep-pox virus (cultures only) Goatpox virus (cultures only) Swine vesicular disease virus (cultures only) Vesicular stomatitis virus (cultures only)</p>
NOTE:	The microorganisms written in italics are bacteria, mycoplasma, rickettsia or fungi.

Ref: Guidance on regulations for the Transport of Infectious Substances 2019-2020

SJH CENTRE for LABORATORY MEDICINE & MOLECULAR PATHOLOGY			
Edition No.:	05	Laboratory Procedure	Doc No: LP-GEN-0002
Author	Christina Ryan	Date: 13 th May 2024	Date of issue:
Authorised By	Fiona Kearney	Date: 24 th July 2024	7 th August 2024

Appendix No. 4: Sample Transport Dangerous Goods Note

(Only applies to the transport of Infectious Substances)

Example: Consignor Details:

Name: Pat McCarthy

Institution: Our Lady's Hospital

Address: New Road, Portlaoise, Co Laois

Tel. No. (082) 223344

Signature: _____

Date: _____

Consignee Details:

Name:

Institution: Virus Laboratory

Address: Special Institute, Dublin 30

Tel. No. (01) 987654

UN No. UN 2814

Proper Shipping Name: Infectious Substance Affecting Humans [Ebola]

No. of packages: 2

SJH CENTRE for LABORATORY MEDICINE & MOLECULAR PATHOLOGY			
Edition No.:	05	Laboratory Procedure	Doc No: LP-GEN-0002
Author	Christina Ryan	Date: 13 th May 2024	Date of issue:
Authorised By	Fiona Kearney	Date: 24 th July 2024	7 th August 2024

Appendix No. 5: Category A

Under ADR regulations “Infectious substances” are divided into the following categories

1. **CATEGORY A:** An infectious substance which is transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in humans or animals.

An exposure occurs when an infectious substance is released outside of the protective packaging, resulting in physical contact with humans or animals.

Infectious substances meeting these criteria which cause disease in humans or in both humans and animals shall be assigned to **UN 2814**.

Assignment to UN 2814 shall be based on the known medical history and symptoms of the source human or animal, endemic local conditions, or professional judgement concerning individual circumstances of the source human or animal.

The proper shipping name for UN No. 2814 is *"INFECTIOUS SUBSTANCE, AFFECTING HUMANS"*.

The indicative list of infectious substance in Category A is given in Appendix 3 is not exhaustive. Infectious substances, including new or emerging pathogens, which do not appear in the table but which meet the same criteria shall be assigned to Category A. In addition, if there is doubt as to whether or not a substance meets the criteria it shall be included in Category A.

Infectious substances classified as UN2814 must be packaged and marked according to packaging instruction P620, Appendix 2, and transported by approved couriers trained in handling UN2814 material.

SJH CENTRE for LABORATORY MEDICINE & MOLECULAR PATHOLOGY			
Edition No.:	05	Laboratory Procedure	Doc No: LP-GEN-0002
Author Christina Ryan		Date: 13th May 2024	Date of issue:
Authorised By Fiona Kearney		Date: 24th July 2024	7th August 2024

Packages received in the CPL marked with UN2814 should only be opened inside a microbiological safety cabinet.

SJH CENTRE for LABORATORY MEDICINE & MOLECULAR PATHOLOGY			
Edition No.:	05	Laboratory Procedure	Doc No: LP-GEN-0002
Author	Christina Ryan	Date: 13 th May 2024	Date of issue:
Authorised By	Fiona Kearney	Date: 24 th July 2024	7 th August 2024

Appendix No. 6: Category B

CATEGORY B: An infectious substance that does not meet the criteria for inclusion in Category A.

Infectious substances in Category B shall be assigned to **UN 3373**.

The proper shipping name for UN 3373 is. "*BIOLOGICAL SUBSTANCE, CATEGORY B* "

Exemptions

- a Substances which do not contain infectious substances or substances which are unlikely to cause disease in humans or animals are not subject to the provisions of ADR unless they meet the criteria for inclusion in another class.
- b Substances containing microorganisms which are non-pathogenic to humans or animals are not subject to ADR unless they meet the criteria for inclusion in another class.
- c Substances in a form that any present pathogens have been neutralized or inactivated such that they no longer pose a health risk are not subject to ADR unless they meet the criteria for inclusion in another class.
- d Substances where the concentration of pathogens is at a level naturally encountered (including foodstuff and water samples) and which are not considered to pose a significant risk of infection are not subject to ADR unless they meet the criteria for inclusion in another class.
- e Dried blood spots, collected by applying a drop of blood onto absorbent material, or faecal occult blood screening tests and blood or blood components which have been collected for the purposes of transfusion or for the preparation of blood products to be used for transfusion or transplantation and any tissues or organs intended for use in transplantation are not subject to the provisions of ADR.
- f Human or animal specimens for which there is minimal likelihood that pathogens are present are not subject to ADR if the specimen is carried in a packaging which will prevent any leakage and which is marked with the words "Exempt human specimen" or "Exempt animal specimen", as appropriate.

The packaging is deemed to comply with the above requirements if it meets the following conditions:

SJH CENTRE for LABORATORY MEDICINE & MOLECULAR PATHOLOGY			
Edition No.:	05	Laboratory Procedure	Doc No: LP-GEN-0002
Author	Christina Ryan	Date: 13 th May 2024	Date of issue:
Authorised By	Fiona Kearney	Date: 24 th July 2024	7 th August 2024

- (a) The packaging consists of three components:
- (i) a leak-proof primary receptacle(s);
 - (ii) a leak-proof secondary packaging; and
 - (iii) an outer packaging of adequate strength for its capacity, mass and intended use, and with at least one surface having minimum dimensions of 100 mm × 100 mm.
- (b) For liquids, absorbent material in sufficient quantity to absorb the entire contents is be placed between the primary receptacle(s) and the secondary packaging so that, during carriage, any release or leak of a liquid substance will not reach the outer packaging and will not compromise the integrity of the cushioning material;
- (c) When multiple fragile primary receptacles are placed in a single secondary packaging, they are either individually wrapped or separated to prevent contact between them.

NOTE: An element of professional judgment is required to determine if a substance is exempt under this paragraph. That judgment should be based on the known medical history, symptoms and individual circumstances of the source, human or animal, and endemic local conditions. Examples of specimens which may be carried under this paragraph include the blood or urine tests to monitor cholesterol levels, blood glucose levels, hormone levels, or prostate specific antibodies (PSA); those required to monitor organ function such as heart, liver or kidney function for humans or animals with non-infectious diseases, or for therapeutic drug monitoring; those conducted for insurance or employment purposes and are intended to determine the presence of drugs or alcohol; pregnancy test; biopsies to detect cancer; and antibody detection in humans or animals

SJH CENTRE for LABORATORY MEDICINE & MOLECULAR PATHOLOGY			
Edition No.:	05	Laboratory Procedure	Doc No: LP-GEN-0002
Author	Christina Ryan	Date: 13th May 2024	Date of issue:
Authorised By	Fiona Kearney	Date: 24th July 2024	7th August 2024

Appendix No. 7: Specimens Excluded from Transport via the PTTS

Arterial Blood Gas Specimens

Blood Packs

Cryoglobulins

CSF Specimens

Histology Specimens

Labile Specimens

Skin Biopsies

Coagulation samples for platelet aggregation studies

Immunology specimens for Lymphocyte proliferation, Oxidative burst and Leucocyte

Adhesion molecules

Samples from patients ? Monkeypox investigation

Any other specimen which is not easily repeatable for example:

- Tissue specimens,
- Blood culture for TB (glass bottle),
- BAL for TB.