Clinical Process Instruction Manual

Packaging and Offering for Transport: Blood Specimens Process Instruction

Policy:

In order to evaluate the safety of organs for transplantation, Trillium Gift of Life Network (TGLN) performs infectious disease testing for all potential organ & tissue donors. TGLN also facilitates the transport of blood specimens from donor hospitals to specialized labs within Ontario for testing. TGLN coordinators who are packaging and offering patient blood specimens for transport are required by the *Transportation of Dangerous Goods Acts & Regulations* to have certification in the transport of dangerous goods.

TGLN coordinators who handle donor blood specimens will classify, identify, package, and mark the appropriate labels according to *Transportation of Dangerous Goods Regulations* before offering the specimen for transport. All patient blood specimens offered for transport by TGLN coordinators will be packaged as Category B Infectious Substances.

Category A Infectious Substances cannot be packaged and transported without the designated packaging requirements outlined by the *Transportation of Dangerous Goods Act & Regulations*. If a TGLN coordinator has sufficient reason to believe that the patient specimen may contain an infectious specimen that can only be transported as a Category A Infectious Substance (see Appendix 1), it is the responsibility of the TGLN coordinator to contact the Manager-On-Call (MOC) for further direction. The MOC may consult the Transplant Support Physician – Infectious Disease or Chief Medical Officer-Transplant in order to determine if the blood specimen should be appropriately shipped.

For the purposes of this document, an exposure occurs when the infectious substance inside the package leaks to the outer packaging, or contaminates the outside of the package. Any leaks contained within the secondary leak proof packaging would not be considered exposure. A dangerous goods incident occurs when, during transport, exposure of infectious substance cause minor property or environmental damage, which are not fatal or do not cause serious injury. A dangerous goods accident occurs when, during transport, exposure of infectious substances may cause serious injury or fatality to a person.

The TGLN coordinator may be an Organ and Tissue Donation Coordinator (OTDC), Clinical Responder (CR), Clinical Services Coordinator (CSC) and/or Surgical Recovery Coordinator (SRC).

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Process:

Prior to Packaging

1. The TGLN coordinator will review the patient's known medical and social history and current clinical data to identify if there is a risk of potential infectious diseases that may be present in the donor blood samples.

2. If there is sufficient reason to believe that the sample may contain substances which need to be shipped as Category A, the TGLN coordinator will contact the MOC for further direction on transport process. Otherwise, all other specimens will be transported as Category B Infectious Substances.

Packaging

3. When packaging the blood specimens for transport, the TGLN coordinator will use packaging that is Category B compliant and will read and follow the manufacturer's instructions for the package being used. See Exhibit 1.

   3.1 Ensure all packaging is in good condition and free from external contamination.

   3.2 Ensure blood tubes are leak proof and sealed securely. Individually separate and wrap each glass blood tube.

   3.3 Ensure an absorbent pad or foam, sufficient to absorb the contents of the blood tubes is placed around the blood tubes.

   3.4 Place the separated blood tubes and absorbent materials in the hard body canister. Ensure the canister is sealed securely.

   3.5 Place the hard body canister securely in the third layer, the outer package.

   3.6 Place the *Itemized List of Contents* between the canister and the outer bag. See Exhibit 2.

Marking and Labelling

4. When completing the *Marking and Labelling Checklist* for a package for transport, the TGLN coordinator will ensure the package has the following labels. See Exhibit 3 and Exhibit 4:

   - Diamond with the text UN 3373 in the mark
   - Proper shipping name

- 24-hour emergency contact
- Name and phone number for the most responsible person (CSC)
- Shippers address
- Receivers address

5. In the case where a waybill is requested by the person transporting the bloods, when completing a waybill, the TGLN coordinator will enter “UN 3373 Biological Substances, Category B” and the number of packages in the “handling” or “special instruction” section.

6. When transporting a package without infectious substances, the TGLN coordinator will ensure labels that indicate the package contains infectious substances (diamond mark, UN number, and proper shipping name) are not visible (i.e. flipped over to backside).

Re-using infectious substance Packages

7. If a package which contained infectious substances is being re-used, the TGLN coordinator using the bag will properly disinfect it with a disinfectant wipe to remove any soil.

8. Prior to re-using the packaging, the TGLN coordinator will ensure all labels indicating the package contains an infectious substance are removed.

Emergency Response for accidents and/or incidents during transport of blood

9. Any package containing infectious substances known to have damage, or leakage from, must be handled only while wearing protective equipment (i.e. gloves).

10. The CSC is considered the most responsible person for all patient specimen packages during transport. All accidents or incidents during transport of the blood specimens will be reported to the CSC.

11. When a CSC is informed of an incident/accident during transport of a patient’s specimen, the CSC gathers relevant information reported. This may include
    - Name and address of the person making the report,
    - Phone number where the reporter can be contacted,
    - Date, time and location of the event,
    - Level of exposure/quantity of infectious substance involved,

- Extent of injuries,
- Number of people affected, a description of the condition of the packaging, and
- Any emergency actions taken on scene of event if applicable.

12. The CSC will immediately convey the above information to:
    - TGLN Manager On-Call (MOC)
    - Employer of the person who was transporting the bloods
    - TGLN coordinator that shipped the bloods
    - Local police in the region in which the event occurred
    - Canadian Transport Emergency Centre (CANUTEC) (1-888-CAN-UTEC)

13. The MOC will immediately notify the Quality Director or designate of a non-conformance related to transport of blood specimens.

14. The Quality Director or designate carries out the Corrective and Preventative Action Plan as per *Corrective and Preventative Action Procedure, QSP-14-1* on the next business day.

15. The TGLN coordinator who shipped the bloods will provide response personnel, any persons listed in section 12, and the Quality Director or designate with all relevant details which may be related to, but not limited to, classification, identification, and packaging.

16. The Corrective and Preventative Action Plan will be verified within a year from the date of the incident/accident if the event included any of the following:
    - The event resulted in death or injury
    - There was an incorrect identification or classification of the blood specimen
    - Additional damage, loss, or related cost was incurred and not known at the time of the event

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Records:

Record Name	Form No. (if applicable)	Record Holder	Record Location	Record Retention Time (as a minimum)
Corrective Preventative Action Report	QSF-14-1	Director Quality	Quality Assurance Department	16 years

References:

- Corrective and Preventative Action Procedure QSP-14-1
- Transport Canada. 2015. Transportation of Dangerous Goods Bulletin, available at: https://www.tc.gc.ca/media/documents/tdg-eng/TDG_BULLETIN___SHIPPING_INFECTIOUS_SUBSTANCES.pdf
- Transport Canada. Consolidated Transportation of Dangerous Goods, available at: https://www.tc.gc.ca/eng/tdg/clear-tofc-211.htm

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Appendix 1

List of Category A Substances **Not** Approved for Transport by TGLN

a) **Crimean-Congo Hemorrhagic fever virus;**
b) **Ebola virus;**
c) **Flexal virus;**
d) **Guanarito virus;**
e) **Hantaviruses causing hemorrhagic fever with renal syndrome;**
f) **Hantaviruses causing pulmonary syndrome;**
g) **Hendra virus;**
h) **Herpes B virus (Cercopithecine Herpesvirus-1);**
i) **Junin virus;**
j) **Kyasanur Forest virus;**
k) **Lassa virus;**
l) **Machupo virus;**
m) **Marburg virus;**
n) **Monkeypox virus;**
o) **Nipah virus;**
p) **Omsk hemorrhagic fever virus;**
q) **Russian Spring – Summer encephalitis virus;**
r) **Sabia virus; and**
s) **Variola (smallpox virus)**

Adapted from:
Transport Canada. 2015. Transportation of Dangerous Goods Bulletin: https://www.tc.gc.ca/media/documents/tdg-eng/TDG_BULLETIN_SHIPPING_INFECTIOUS_SUBSTANCES.pdf

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Exhibit 1: Manufacturer's Instructions

CSF-9-131

MARSYS NOTICE

THIS MARSYS Clinical Specimen Carrier/Transporter has been designed and fabricated with care by MARSYS in recognition of the fragile nature of the items for which it is intended to transport. However, because of the fragile nature of those items and because MARSYS has no control over the way that Carrier/Transporter will be assembled, filled or handled, MARSYS will not be responsible to any party for the loss of its contents or for any damage to persons or property resulting from the use or misuse of the Clinical Specimen Carrier/Transporter.

INSTRUCTIONS

1. Secure carrier/transporter in upright position, as per label/arrow direction.
2. Insert hard body or ziplock waterproof secondary inner liner into transporter.
3. Insert appropriate inserts for the protective packaging and/or absorbent requirements of the sample specimens or contents intended for shipment.
4. Place specimens into insert openings, as may apply.
5. Insert applicable documentation into document pouch, if provided, and place in unit.
6. Close carrier/transporter lid and secure lid closure mechanism, seal as required.
7. Insert all other shipping/labeling documentation into document pouch, exterior, if provided, as may be required through regulation, law and/or company policy.

IT IS A REQUIREMENT OF THE MARSYS CLINICAL SPECIMEN CARRIER/TRANSPORTER SYSTEM THAT ALL VOIDS WITHIN THE CARRIER/TRANSPORTER BE FILLED WITH INSERTS, SEE BELOW. THIS ENSURES THE SAFE AND SECURE TRANSPORTATION OF THE CONTENTS.

THE MARSYS CLINICAL SPECIMEN CARRIER/TRANSPORTER MODELS/SYSTEMS ARE DESIGNED TO TRANSPORT/SHIP TRANSPORT CANADA TYPE TC125-1B PACKAGINGS ONLY.

MISUSE SHALL AT THE SOLE RISK OF THE SHIPPER.

INSERTS

The following MARSYS inserts are available. ANY COMBINATION of these inserts may be used to meet the above stated requirement.

1. **VACUTAINER INSERT - Model MVB/21-SN Will hold 21 vacutainers, 3.5-10ml.**
2. **URINE/OTHER INSERT - Model MU2-SN Will hold containers, 40 - 90ml.**
3. **HOLLOW HOLDER INSERT - Model MHH34-SN.**

Hollow Holder Inserts will also hold ice packs when specimen integrity is required.

NOTICE

MARSYS SN SERIES UNITS ARE NOT DESIGNED FOR USE WITH ICE CUBES - USE ONLY ICE PACKS OR DRY ICE.

CLEANING

HAND WIPE ONLY AND/OR IN ACCORDANCE WITH USER SAFETY/TECHNICAL INSTRUCTIONS FOR SAME.

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Exhibit 2: Itemized List of Contents

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Itemized List of Contents

Please place between the secondary receptacle and the outer packaging

in accordance with IATA Packing Instruction 650

Item	Please check if present
Diagnostic Specimens (Human, no Animal matter)	
Glass and/or Plastic Tubes	
Glass Slides	
Secondary Container/Canister	
Absorbent Pad (s)	
Requisition	
Instruction Sheet	
Transport Media or Preservative	
Gel Pack/ Refrigerant	

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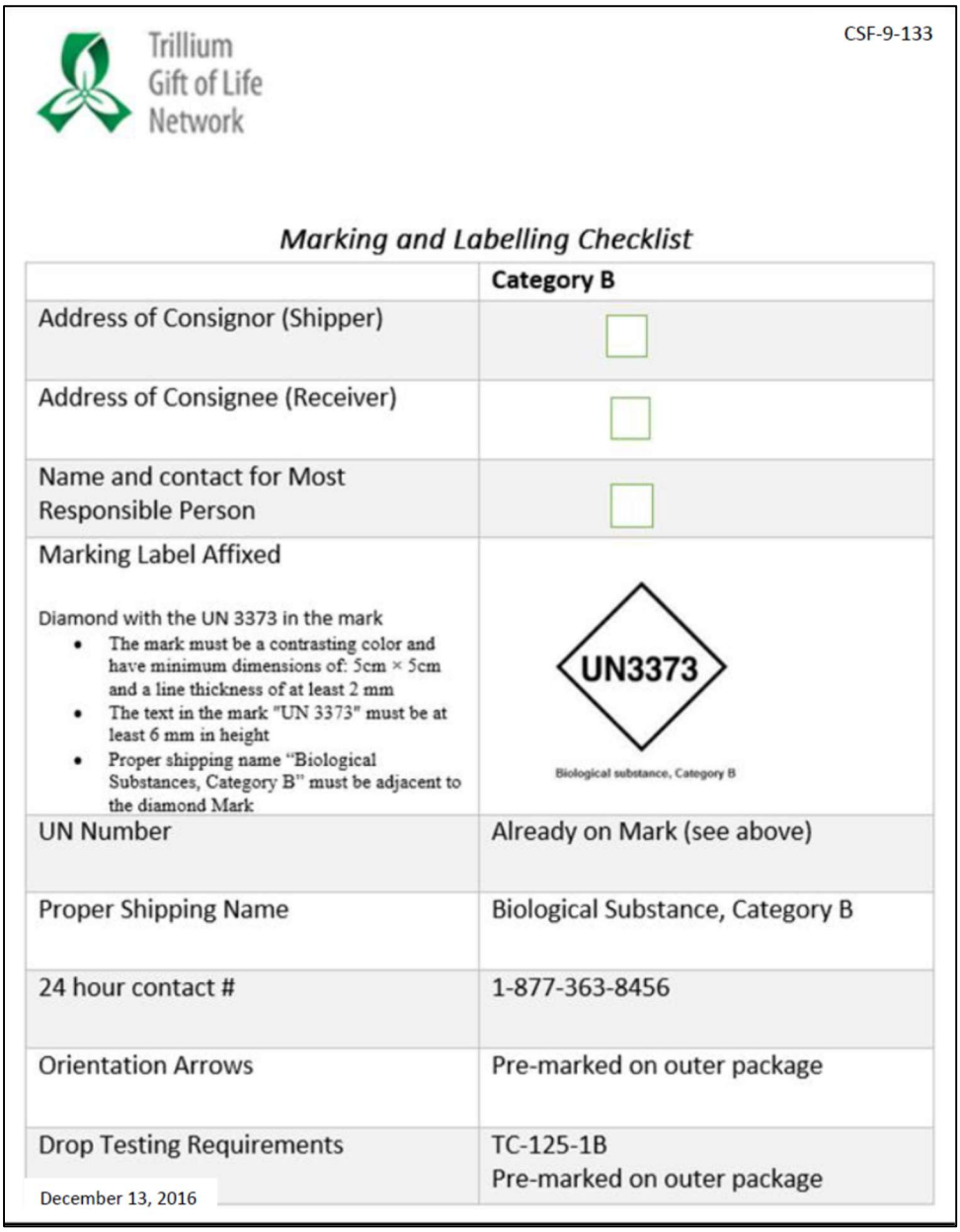
Exhibit 3: Marking and Labelling Checklist



Trillium Gift of Life Network

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Marking and Labelling Checklist

	Category B
Address of Consignor (Shipper)	☐
Address of Consignee (Receiver)	☐
Name and contact for Most Responsible Person	☐
Marking Label Affixed Diamond with the UN 3373 in the mark • The mark must be a contrasting color and have minimum dimensions of: 5cm × 5cm and a line thickness of at least 2 mm • The text in the mark "UN 3373" must be at least 6 mm in height • Proper shipping name "Biological Substances, Category B" must be adjacent to the diamond Mark	UN3373 Biological substance, Category B
UN Number	Already on Mark (see above)
Proper Shipping Name	Biological Substance, Category B
24 hour contact #	1-877-363-8456
Orientation Arrows	Pre-marked on outer package
Drop Testing Requirements	TC-125-1B Pre-marked on outer package

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Exhibit 4: Shipping Label

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