

Web Version Revision 1 1/2013

# Clinical/Biological (Serum or Plasma and Urine) Recommended Collection and Shipping

Notify us prior to shipping!

Electronic versions of the sample manifest/packing list and testing order form must be received by our sample receiving technician (email: samples@crafttechnologies.com) at least 24 hours prior to planned shipment date. This step ensures that your samples will be processed accurately and as quickly as possible.

Craft Technologies, Inc. recommends samples to be shipped *Monday – Wednesday* to allow ample time for the samples to arrive before the close of business on Friday. Our company is not open on Saturday or Sunday.

## **Carriers**

We recommend shipping <u>FedEx Priority Overnight</u> service. If you chose an alternative carrier, please check with them concerning their policies on dry ice shipments. UPS does not accept boxes for shipment with greater than 5 lbs dry ice. We also recommend that you schedule a FedEx pickup for your shipment instead of taking it to a FedEx location.

## **Collection Procedures:**

Cautions: All blood samples should be regarded as potentially infectious and serious pathogens may be transmitted, including HIV and hepatitis B virus among others. Therefore, great care is required when collecting and processing blood samples. Personal protection equipment, such as *safety glasses and rubber gloves* should always be worn when handling blood specimens.

Collection methods and procedures vary depending on matrix (serum, plasma, urine) and species (human or animal). It is recommended that human blood collection *be performed by a qualified phlebotomist*. CTI is only able to provide general collection procedures. The client should establish protocols and set general guidelines representative of the project to ensure consistent results.

Special attention should be taken to label specimens appropriately and permanently. The labels should include all essential identifying information written with indelible ink on labels. Labels should be secured to tubes/vials by a water insoluble adhesive. The identification information should also be recorded on a hard copy and electronic spreadsheet (contact CTI for our "packing list" spreadsheet or link provided under Information Center on our website).

## Human plasma collection.

As a general rule we prefer plasma over serum due to variations in collection and preparation methods. If serum is to be supplied it is essential that the whole blood has had adequate time to coagulate and that it has been centrifuged properly.

Venous blood should be drawn, following aseptic technique, by direct venipuncture, into a sterile 10 or 5 ml green top (BD; sodium heparin as anticoagulant) vacutainer tube and mixed by manual inversion, at least three times.

4344 Frank Price Church Road, Wilson, North Carolina 27893

Telephone: (252) 206-7071 Fax: (252) 206-1305 e-mail: staff@crafttechnologies.com

Webpage: www.crafttechnologies.com

For fractionation of plasma from the cellular blood component, centrifuge for 10 minutes at 4000 - 4500 rpm. Plasma should be immediately removed and transferred into sterile tubes, a minimum aliquot of 170 uL. The tube should be frozen as soon as possible and stored at  $-70^{\circ}$ C until shipment.

### Reference:

Blood separation and centrifugation. www.pal.com/main/Medical/Blood-Separation-and-Centrifugation.com

#### **Urine**:

Sample size preferred is 2 mL's with a minimum of 1 mL. The tube should be frozen as soon as possible and stored at -70°C until shipment.

**Analysis Specific Sample Preparation:** 

Vitamin C Analysis

Urine samples must be stabilized with a 40% metaphosphoric acid solution. The solution is added to freshly collected urine to achieve a 5% final concentration of MPA in the urine. Thus a 2mL sample of urine requires 0.30 mL's of PA. Minimize exposure to light.

## **General Definitions**

## Diagnostic Specimens:

Any human or animal material including, but not limited to, excreta, secreta, blood and its components, tissue and tissue fluids, being transported for diagnostic or investigational purposes, but excluding live infected animals.

# **Biological Product:**

Those products derived from living organisms, that are manufactured and distributed in accordance with the requirements of national governmental authorities which may have special licensing requirements, and are used either for prevention, treatment, or diagnosis of disease in humans or animals, or for development, experimental or investigational purposes related thereto. They include, but are not limited to, finished or unfinished products such as vaccines and diagnostic products.

## Infectious substances or etiologic agents:

Substances known to contain, or reasonably expected to contain, pathogens. Pathogens are microorganisms or recombinant microorganisms that are known or reasonably expected to cause disease in humans or animals.

## **Shipping Recommendations**

Do not write "specimens" or "diagnostic specimens" on the box. Specimens that are potentially infectious to humans or animals are subject to specific packaging requirements and there should not be any misunderstanding about your shipment. If you think your samples are infectious, stop and contact your courier and recipient for instructions. All shipments must comply with all applicable local, state and federal laws governing packing, marking and labeling.

Blood, urine, fluids, and other specimens containing or suspected of containing infectious substances must be shipped according to applicable government, International Air Transport Association (IATA) and International Civil Aviation Organization (ICAO) regulations.

Contact your courier for specific requirements for the packaging and labeling of biological materials.

## **Classification of Shipments**

Human blood, blood by-products, tissues, etc. always require "Universal or Standard Precautions" and may be considered a diagnostic specimen and shipped without the dangerous goods paperwork. (Use packaging instructions for non-infectious substances - see below)

**Shipping Frozen Specimens on Dry Ice** 



## a DOT Class 9 dry ice label.

Most couriers have limitations on the how much dry ice is acceptable per package. Contact your courier for acceptable weight limit. Dry ice should be placed in a Styrofoam box along with the secondary specimen container(s) and then the Styrofoam box is placed in the outer packaging. Interior support (i.e., Styrofoam pieces or paper stuffing) can be used to secure the secondary packaging(s) in the original position and to slow the sublimation rate of dry ice. More dry ice rather than packing material should be provided. The outer packaging must permit the release of carbon dioxide gas. Wet ice or blue ice is not recommended for shipping of biological samples. <a href="http://www.dryiceinfo.com/shipping.htm">http://www.dryiceinfo.com/shipping.htm</a>

## **Packaging Instructions for Non-Infectious Substances**

(Non-hazardous diagnostic specimens and biological products where a low probability exist that infectious substances are present.)

Samples are recommended to be boxed and the top should fit properly to prevent samples from falling out during shipping. Rubber bands to secure box tops on are not recommended, but are acceptable.

Four layers of packaging must be used for securely packing samples: Primary receptacle (Cryovial)
Secondary receptacle (specimen boxes)
Absorbent Material
Outer Packaging

- 1. Primary water tight receptacle(s) (cryovials) with screw-on caps is recommended for sample containment, we do not recommend snap on lids, as these can "pop" open during transport or cataloging. (See Figure 1) Proper labeling for identification should be adhered to each sample, it is recommended to use nylon labels or labels that wrap around vial until touching, (do not obscure identification), or neat hand written identification with a permanent sharpie marker is also acceptable.
- 2. Secondary packaging specimen boxes, either cardboard or plastic, should be used to store the samples. These can be purchased with 81 or 100 count inserts, 2" or 3" boxes. (See Figure 1) Please note front of box. The top should fit properly and be secured to prevent samples from falling out during shipping. Optional: You may secure the specimen boxes in water tight packaging i.e., sealable plastic storage bag or biological bag.





Figure 1 – Specimen box and tube /vial. https://us.vwr.com/store/catalog/product.jsp?catalog\_number=82007-162

Label sample tubes/vials sequentially and place in specimen box (should correspond with packing list).

Absorbent material may be placed between the secondary receptacle and specimen boxes. If multiple secondary receptacles are placed in the same plastic storage or biological bag, these should be individually wrapped to prevent contact between them, this prevents specimen boxes from adhering to each other as well. Enough absorbent material must be used to absorb the entire contents of all the primary receptacles. Acceptable absorbent materials include cellulose wadding, cotton balls, super-absorbent packets and paper towels.

- 3. Please include a letter of request from your company, organization, etc., detailing the analyses you are requesting to be performed and a copy of an approved quote, if obtained. Please include all contact information regarding to whom correspondence, results and invoicing should be submitted.
- 4. Care should be taken to record exact identification information of the samples. Please include an itemized list (request CTI packing list spreadsheet) of contents enclosed between the secondary packaging and the outer packaging. Samples that arrive without a packing list and in disarray may be subject to an administrative fee. If possible, please email the packing list spreadsheet to: samples@crafttechnologies.com
- 5. Sturdy outer packaging (see picture below). Use rigid outer packaging constructed of corrugated fiberboard, wood, metal or plastic, appropriately sized for the contents. Chipboard or paperboard boxes are unacceptable outer packaging. In addition, Styrofoam, plastic bags and paper envelopes are NOT acceptable outer packaging.) Reusing a dry ice box is a good use of resources. If you choose to reuse a box, completely obliterate all unnecessary marking such as hazard labels, addresses, FedEx (or other courier) labels and barcodes. Use caution if reusing a box that has been used to ship infectious material or diagnostic specimens. Only reuse a box if you can personally verify it is not contaminated and its integrity is intact. A box should not be reused if it is torn, cut, stained, or if the insulation is cracked or broken.



## http://www.uline.com

- 6. Shipments must also have "Perishable" designated on the outer packaging.
- 7. For International shipments: Each box should contain the following on the outer packaging: all paperwork should be in *triplicate*. This should include a Statement of Intent on company letterhead from the collecting/shipping organization or Department of Health indicating the sample(s) are "non-pathogenic"; a Biological Statement letter on Craft Technologies letterhead, indicating our expectation and tests to be performed (optional contact if needed). Please provide additional copies inside of shipment on the top of the insulated lid, just under the flaps of the outer container. Most couriers will provide additional shipment information on their websites.

<u>Domestic shipments</u>: Each box should contain the following on the <u>outer</u> packaging: courier labeling, including any required documents by courier, a statement on your company letterhead (if available) detailing your expectations and test to be preformed, and a packing list of the contents. Please note that shipment is "<u>Perishable</u>" on the side of the box using a permanent black marker if not provided on the container. Please provide additional copies inside of shipment on the top of the insulated lid, just under the flaps of the outer container.

- 8. If a shipment contains dry ice, refer to the previous section on shipping frozen specimens. In addition, a Class 9 dry ice label must be placed on the <u>outer packaging</u>.
- 9. A Shipper's Declaration for Dangerous Goods is not required.

- 10. Craft Technologies, Inc. recommends samples to be shipped Monday Wednesday to allow ample time for the samples to arrive before the close of business on Friday. Our company is not open on Saturday or Sunday.
- 11. Seasonal considerations should be taken in account when shipping sample(s), such as holidays and weather (summer months please ensure ample dry ice is included in the shipment).
- 12. Please use the courier track number to follow your sample(s) until they arrive safely at Craft Technologies, Inc. This information is imperative, as this will alert you to any potential problems along the way. Should customs hold your sample(s) for a period of time for any reason, you should contact your courier and request storage of the shipment to be located in a freezer until resolved. In most cases such sample(s) are irreplaceable and extreme care should be stressed.
- 13. Please email sample receiving upon sending your shipment and provide the courier tracking number. Please attach an electronic copy of your packing list. (samples@crafttechnologies.com)

## Infectious substances or etiologic agents:

Substances known to contain, or reasonably expected to contain, pathogens. Pathogens are microorganisms or recombinant microorganisms that are known or reasonably expected to cause disease in humans or animals. (Some couriers will find these types of shipments unacceptable for carriage. Contact your courier and Craft **Technologies, Inc. to verify acceptance of shipment.)** 

If human blood is known to be infected with an infectious substance, or if it is being transported for the purpose of initial confirmatory testing for the presence of a pathogen, it must be packaged and shipped as such and requires the dangerous goods paperwork. (Use packaging instructions for infectious substances - see below) **Packaging Instructions for Infectious Substances** 

(Including hazardous diagnostic specimens)Please *contact* Craft Technologies, Inc. to discuss specific analysis request, shipping, packing, marking and labeling requirements regarding infectious substances. A Shipper's Declaration for Dangerous Goods is required. All shipments of infectious blood samples, blood by-products,

tissues, etc. requires a "BIOHAZARD" label in a prominent position on the outer packaging.

All shipments should be sent to the following address:

Sample Receiving Craft Technologies, Inc. 4344 Frank Price Church Rd. Wilson, NC, 27893 USA samples@crafttechnologies.com

Phone: (252) 206-7071 Fax: (252) 206-1305

This document was prepared by CTI to assist you in shipping clinical/biological samples to our laboratory. It is not for dissemination. There are many sources other than this document. We encourage you to obtain information relevant to your project before shipping. We are not responsible for returned, lost or held samples by a courier or any government agency due to improper packing or documentation.

General content is based upon our experience in receiving and handling of biological matrices. The following websites were used to provide additional information and some source content is referenced.

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http://www.ncsu.edu/ehs/dot/Bio\_shipping.pdf

http://www.safety.duke.edu/SafetyManuals/Lab/Section 1Biological Safety/Chapt%2013%20 PACKAGING%20 AND%20 SHIPPING%20 BIOLOGICAL%20 MATERIALS.pdf

http://www.ups.com/content/us/en/resources/ship/hazardous/biological\_substances.html

http://www.ors.od.nih.gov/sr/dohs/BioSafety/shipbio/Pages/shipping\_biological\_material.aspx

http://images.fedex.com/downloads/shared/packagingtips/pointers.pdf

http://www.oehs.wayne.edu/training/shippingbiologicalsubstances\_dryice.pdf

www.cdc.gov/nceh/.../biological\_substances\_shipping\_detailed.doc

http://www.cdc.gov/od/eaipp/faq.htm

http://www.unh.edu/research/sites/unh.edu.research/files/docs/EHS/Chem-safety/UNH-Shipment-of-Biological-Materials-Manual.pdf

http://www.uline.com

 $\underline{https://us.vwr.com/store/catalog/product.jsp?catalog\_number=82007-162}$ 

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