GenoMEL Guidelines for the Handling of Biological Samples

SAMPLE HANDLING SHOULD BE PERFORMED IN ACCORDANCE WITH THE HEALTH AND SAFETY DIRECTIVES IN PLACE AT YOUR INSTITUTION.

The following is a list of guidelines which provide the MINIMUM protection for staff and sample quality control. These are in addition to general common sense rules governing general hygiene i.e. hand washing!

GenoMEL advises that sample handling should be performed according to the WHO guidelines on sample handling and microbiology practice detailed in full in the WHO Laboratory Biosafety manual 2003 (http://www.who.int/csr/resources/publications/biosafety/Labbiosafety.pdf)

I. Taking Blood Samples
In general nurses:
- MUST ensure they are immunised against Hepatitis B;
- MUST wear latex/nitrile gloves when taking a blood sample;
- MUST treat all samples as infectious
- SHOULD not take samples from Hepatitis A, B or HIV carriers if carrier status is known at time of sampling;
- SHOULD use single use disposable phlebotomy equipment;
- MUST discard contaminated sharps in a puncture and liquid proof container which is closed, sealed and destroyed using appropriate disposal methods;
- MUST ensure sample tubes are clearly labelled as appropriate;
- MUST ensure blood samples to be sent via mail are correctly packaged in accordance with national and/or international rules and regulations (see below).

II. Sample handling in the Laboratory

Laboratory staff should adhere to the Health and Safety and good laboratory practice guidelines in place at their institution.

In general lab staff:
- MUST ensure they are immunised against Hepatitis B;
- MUST wear a clean lab coat and latex/nitrile gloves when handling any sample either pre- or post-processing;
- MUST ensure that sample tracking systems are in place and are kept up to date, ideally incorporating cross checks at each stage of processing and analysis.

a. Sample handling for processing
Ideally processing of whole blood should be performed in a separate room or designated area of bench or in a fume/tissue culture hood.
- No sharps should be used in sample processing operations;
- Blood spillages to be treated with anti-viral detergent e.g. Virkon;
- Following handling of whole blood, surfaces should be wiped down with 10% w/v Virkon solution;
• Extracted DNA should be stored in DNAse, RNAse free containers with sufficient identification to allow visual cross-checking.
• DNA should be re-suspended into a suitable medium such as DNAse/RNAse free dH2O, Qiagen AE buffer or a 1 in 10 dilution of TE buffer. Undiluted TE should not be used as this may interfere with PCR.
• DNA is not required to be stored at a standard concentration (although more concentrated DNA is less prone to degradation via hydrolysis during long term storage), however for exchange of DNA samples please see section c below.

b, Sample handling for analysis
Ideally separate designated areas should be used for pre- and post- PCR work. If this is not possible then the following precautions should be observed:
• Dedicated pipettes should be used for pre- and post- PCR work;
• Surfaces and pipettes should be regularly swabbed with DNA-Away or equivalent product;
• Aliquots of stock DNA should be used for analysis rather than using the stock DNA directly.

c, Sample handling for exchange of samples
The following procedures should be in operation:
• Samples should be provided in the format and concentration requested by the receiving group where possible;
• Samples should be clearly labelled, preferably with two identifiers e.g. Study No and DOB. Samples must be link-anonymised;
• Samples should be adequately sealed and packaged to meet international transport of biological samples standards. See Part IV;
• Paperwork pertaining to the samples must be included with the samples and ideally also sent to the receiving group in electronic format;
• Groups should ensure that they include the correct documentation required by customs of the receiving country and ideally should send a copy of this documentation to the receiving group, in advance of the sample package.

III. Transportation of samples

Below are the regulations laid down by the International Air Transport Association (IATA) to cover transport of infectious substances. These incorporate those proposed by the United Nations (UN). Please be aware that requirements may differ according to country and/or carrier.

a, Blood samples

IATA made significant changes to the regulations for shipping specimens in the 46th Edition of the Dangerous Goods Regulations (DGR) manual. A new category of shipping was created for shipping patient specimens for which there is minimal likelihood that pathogens are present.

The new regulations cite examples of many routine laboratory tests that can now be transported as Exempt Human Specimens. Examples of those tests are: blood or urine for cholesterol levels, hormone levels, prostate specific antigens (PSA), tests to monitor organ function (heart, liver, kidney), tests conducted for insurance or employment, pregnancy, biopsies for cancer, drug or alcohol presence testing. This category also applies to samples taken for the purposes of DNA testing.
The new Exempt Human Specimen (EHS) category has a specific packing requirement and marking requirement. Specimen shipping packages consigned to couriers and air carriers must have the marking "Exempt Human Specimen", state both the address of the receiver and sender on the outside, and must at a minimum, meet the following package requirements:

- 100mm x 100mm dimension on one side
- leak-proof primary container
- leak-proof secondary container
- absorbent between primary and secondary sufficient to absorb total primary container (s) contents
- outer packaging of adequate strength for its capacity

Samples of known infectious risk are NOT covered by these regulations. Since January 2007 these samples are covered by the IATA regulations as UN3373 BIOLOGICAL SUBSTANCE, CATEGORY B. The regulations are available in full at http://www.iata.org/NR/rdonlyres/C993126E-9AAF-4498-B76E-583B3D774F90/0/DGR_48_PI650.pdf

Packaging meeting the new IATA UN3373 regulations is available from a number of companies.

b, DNA samples

Currently extracted DNA from individuals of no known infectious risk are not covered by IATA regulations. However, GenoMEL recommends that DNA be shipped according to the guidelines for the Exempt Human Specimen category:

- DNA sent in either a sealed 96 well plate or individually labelled, screw-topped Eppendorf – style tubes. Plates should be individually wrapped in Saran-wrap to prevent evaporation and leakage.
- Tubes should be wrapped in sufficient absorbent material to absorb the tube contents and sealed in a plastic bag.
- Plates should be wrapped in sufficient absorbent material to absorb the tube contents, sealed in a plastic bag and packed in a box (e.g. tip box) to prevent warping during transit.
- Outer packaging of adequate strength for its capacity should be used. Envelopes / padded envelopes should NOT be used as outer packaging.
- Be labelled "Exempt Human Specimen"
- All consignments should state both the address of the receiver and sender.

Generally it is not necessary to send DNA samples on ice, or frozen on dry ice. Please be aware that consignments on ice/dry ice are covered by additional shipping regulations.

c, Paraffin Blocks and Slides

Block and slides present little risk of infection and are also not specifically covered by IATA guidelines. However, GenoMEL recommends that they be shipped according to the guidelines for the Exempt Human Specimen category:

- Blocks and slides can be shipped in specially designed mailers available from a number of companies
- Alternatively paraffin blocks can be placed in a small box separated by clean tissue/paper or individually wrapped in clean tissue/paper to cushion and sealed inside a plastic bag. A box
should be used as an outer package rather than a padded envelope to avoid damage during transit.

- Slides should be shipped inside a purpose designed slide box or folder. These should be tightly cushioned inside a box to prevent movement during transit.
- All consignments should be labelled "Exempt Human Specimen" and “Fragile”
- All consignments should state both the address of the receiver and sender.

Before sending any consignments please check the packaging requirements for your carrier and your country of destination.