STANDARD OPERATING PROCEDURE

Sheffield Clinical Research Facility

Processing and Aliquoting Blood Specimens

SOP CRF.L101 Version 1.3
Processing and Aliquoting blood specimens
01/11/2010
Page 1 of 3
This SOP has been written to give general guidance to study personnel on processing and aliquoting blood specimens. There are no GLP guidelines on how to process and aliquot blood specimens.

Background
It is important that all staff working in the Clinical Research Facility use the same procedure when processing and aliquoting blood specimens. This will ensure that there is continuity and consistency when processing and aliquoting blood samples.

Definition
Aliquoting is the removal of serum plasma from the whole blood product.

Procedure
The investigator or delegated person should follow protocol specific guidelines for processing and aliquoting blood specimens or follow the procedure outlined below.

1. The investigator is responsible for ensuring that blood specimens are processed and aliquoted according to the study protocol. This duty can be delegated to other appropriately qualified members of the research team as recorded on the project delegation log.

2. When working in the laboratory the investigator or delegated person must wear protective clothing when performing blood smears. This may be in the form of a uniform, a laboratory coat or a disposable apron. Laboratory coats are available in the Clinical Research Facility Laboratory. Aprons can be found in the investigation suite, laboratory, dirty utility, bedrooms 1 & 2, 4 bed bay, treatment room and phlebotomy room.

3. The investigator or delegated person should wash their hands before handling blood samples according to STH hand hygiene policy.

4. The investigator or delegated person should wear disposable gloves when there is a risk of contamination. Gloves should always be worn when aliquoting. There is a supply of disposable gloves in various sizes in the Clinical Research Facility Laboratory.

5. When the whole blood has been spun in the centrifuge (refer to SOP CRF.L103 Use of the Centrifuge) the investigator or delegated person must remove the blood from the centrifuge and place in to a storage rack that can be found next to the centrifuge in the Clinical Research Laboratory. There are racks in the Clinical Research Facility in a variety of sizes.

6. The investigator or delegated person must ensure that the collection tubes for the serum plasma are labelled correctly and are placed in the rack ready for aliquoting.

7. The investigator or delegated person must unscrew the top off the separated blood tube ensuring that it is not tipped. If tipped this may result in the serum plasma and blood mixing together again.

8. The investigator or delegated person must pipette out the serum plasma from the blood cells. The blood tube can be tilted slightly to make pipetting easier. The investigator or delegated person must squeeze the pipette together at the
CONTROLLED DOCUMENT- DO NOT COPY

top. This will enable a suction effect and will avoid any air bubbles in the plasma. The investigator or delegated person will be provided with pipettes, and collection tubes from the study sponsor. These can be stored within the clinical research facility laboratory, if this has been agreed by the operational group.

9. The investigator or delegated person can then place the serum plasma in to the labelled collection tube. They then must ensure that the cap or lid or the tube is securely closed to avoid any leakage or spillage.

10. The whole blood tube and pipette must then be discarded in to a yellow clinical waste bin which can be found in the laboratory in the Clinical Research Facility.

11. The investigator or delegated person must send the samples for shipment to the laboratory as described in the study protocol. If the samples are to be sent by courier to the laboratory the investigator or delegated person must inform the receptionist at the Clinical Research Facility who will complete the courier log held on reception.

12. If the samples are to be stored in the Clinical Research Facility freezers they must inform the link nurse for the study and follow the SOP for freezer storage (refer to SOP CRF.L104 Storage of Samples in the -80°C Freezer & SOP CRF.L106 Storage of Samples in the -20°C Freezer). The link nurse will complete the freezer storage log that is held in the laboratory in the Clinical Research Facility.

13. After the samples have been processed the laboratory work surface should be decontaminated using the appropriate cleaning products. The investigator or delegated person should refer to the STHFT Policy for the Decontamination of Hospital Equipment & Medical Devices.

14. The investigator or delegated person should remove gloves and dispose of them in a clinical waste bin if they are soiled or household waste if not soiled. Coats and gowns should be removed before leaving the laboratory. Coats and gowns should be left close to the exit. Laboratory coats should not be placed in personal lockers.

15. The investigator or delegated person should wash their hands after handling blood samples according to STH Hand Hygiene policy.

**Related Documentation**

<table>
<thead>
<tr>
<th>Document Name</th>
<th>Author</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sheffield Infection Control Guidelines</td>
<td>STH Infection Control Team</td>
</tr>
<tr>
<td>STHFT Policy for the Decontamination of Hospital Equipment &amp; Medical Devices</td>
<td>STH Foundation Trust</td>
</tr>
<tr>
<td>STH Hand Hygiene Policy</td>
<td>STH Infection Control Team</td>
</tr>
<tr>
<td>Project Delegation Log</td>
<td>CRF</td>
</tr>
<tr>
<td>Sheffield Waste Strategy &amp; Policy</td>
<td>J Watts &amp; M Mahon</td>
</tr>
</tbody>
</table>

1 The location(s) of any related document(s) are listed in the CRF SOP Referenced Documents Directory.

The CRF SOP Referenced Document Directory and any Related SOPs, listed on page 1 of this SOP, can be accessed electronically at http://www.crf.dept.shef.ac.uk/downloads/sops.html or can be requested by contacting Sheffield Clinical Research Facility, O Floor, Royal Hallamshire Hospital, Glossop Road, Sheffield, S10 2JF, 0114 2713339.