## GENERAL GUIDELINES FOR SPECIMEN COLLECTION

### COLLECTION AND PROCESSING OF SPECIMENS

Each visit-specific kit has specific testing allocated to it. The detail of the testing is described on the requisition form. A guide to testing is also included in the study documentation.

**2 identifiers must be clearly stated on the specimen to match the information on the requisition form of the patient. This will allow us to positively link the specimen back to the patient.**

**PLEASE ENSURE A SEPARATE PIPETTE IS USED PER DRAW TUBE FOR SERUM AND PLASMA, AND A SEPARATE PIPETTE IS USED PER URINE TRANSFER TUBE WHERE APPLICABLE.**

Remember to follow the instructions regarding storage and shipping of the samples after they have been collected. When centrifuging gel serum separation (SST) gold-top tube(s) for chemistry analysis, it is essential that the gel moves up from the bottom of the tube to separate the red cells from the serum before shipping to $Q^2$ Solutions. Inadequately centrifuged samples will not be analysed by $Q^2$ Solutions. See examples in diagram below:

| Correct ✓ | Incorrect ✗ | Incorrect ✗ |
|---|---|---|
|  |  (Unspun) |  (Partially Spun) |
| The serum (yellow/orange in colour) can be seen above the gel barrier. | The gel barrier has not risen in the tube; only red blood cells are visible. | Full separation has not occurred and serum is contaminated. |

Tubes must be centrifuged at a minimum speed of 1500-2000g. Please check that your centrifuge is set to achieve an rpm to generate the required relative centrifugal force (“g”). Instructions are provided on the following page alongside a conversion chart to determine the correct rpm setting for your centrifuge.

**Note:**
**If the gel has not formed a clear separation layer within 15 min at the setting you are using, it is too slow, and the speed should be increased.**
**If the centrifuge is already at maximum rpm, try spinning for an extra 10 min.**

# Recommended Order of Draw

| Order of Draw | Container/Top | Color | Additive |
|---|---|---|---|
| First | Culture Bottles | Multiple | See Bottle Label |
| |  | Light Blue | Citrate |
| |  | Red/Black, Gold | Gel, SST, Serum |
| |  | Red | No Gel, Serum |
| |  | Light Green, Green/Gray | Heparin |
| |  | Lavender, Pink | K2 EDTA, K3 EDTA |
| |  | Gray | Sodium Fluoride |
| | Tubes with other Additives | | |
| Last |  | Light Yellow | Citrate ACD |

*** When using a "butterfly" blood collection set for venipuncture and a coagulation (citrate) tube is the first specimen tube to be drawn, a discard tube should be drawn first. The discard tube must be used to fill the blood collection set tubing's "dead space" with blood but the discard tube does not need to be completely filled. This important step will ensure proper blood-to-additive ratio. The discard tube should be a non-additive or coagulation tube.***

**Source: BD Vacutainer® Order of Draw for Multiple Tube Collections. (Reflects change in CLSI recommended Order of Draw (H3-A5, Vol 23, No 32, 8.10.2)**

# General Instructions

- **Blood collection:** All blood samples have to be taken from the arm opposite from the infusion (in i.v. dosing) by either direct venipuncture or an indwelling catheter inserted in a forearm vein.
- **Tube inversion:** Immediately after collection, gently invert all tubes to ensure content mixing and prevent clotting. Avoid prolonged sample contact with the rubber stopper. Do not shake the tubes.
- **Clotting or Incubation**: always keep tubes positioned upright
- **Centrifugation:** always centrifuge in a balanced manner: be sure to use a balance tube of the same size with an equivalent volume of water.
- If applicable, ensure the centrifuge is turned on ahead of time to allow cooled centrifugation at 4° C.
- At the end of centrifugation, let the centrifuge come to a complete stop (do not stop it with your hand or abruptly brake). Remove tubes from the centrifuge carefully without disturbing the red cell pellet at the bottom. Prolonged centrifugation may cause hemolysis.
- **Centrifugation of serum samples**: a gel layer will form between the supernatant and the cell pellet; this is normal and meant to allow a better separation
- **Aliquoting:** do not disturb the gel/cell layer or allow any cells into the pipette. Ensure that tube caps are closed and that tubes are correctly labeled.
- If applicable, place mixing tube(s) in wet ice for pre-chilling.
- If transport tubes with samples cannot be put into the freezer immediately after completing the processing, place them on wet ice.
- **Storage**: transfer the vials to a freezer in an upright position for storage in a cardboard box/rack (not Styrofoam).
- **Shipping**: for dry ice shipments: make sure that samples are frozen before shipping
- **CRF:** Record the actual sample collection date and time (using a 24-hour clock) on the collection summary page of the CRFs for the appropriate Subject ID. Sampling problems should be noted in the Notes field of the CRF.

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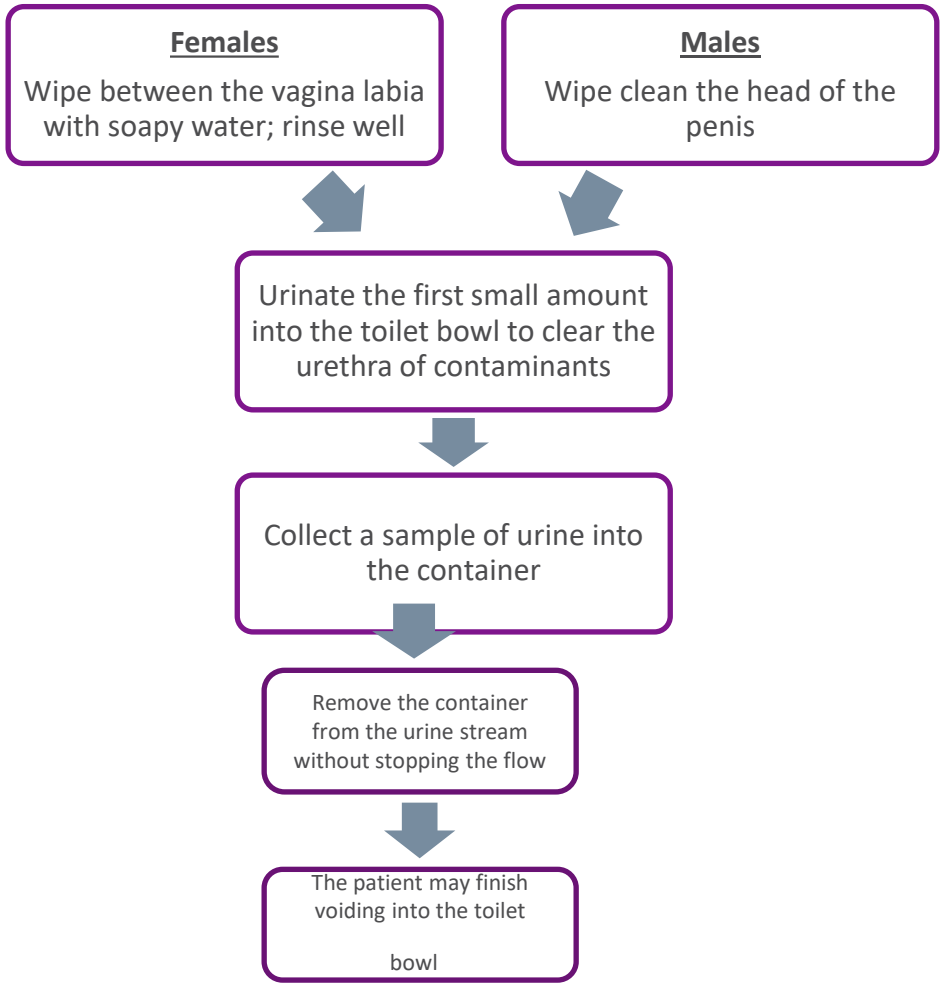
### CLEAN-CATCH INSTRUCTIONS FOR URINE CULTURE SAMPLES *(if applicable to your study)*




**Do not use antiseptics as they may prevent the growth of bacteria during the culture.**

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## BULK SUPPLY

$Q^2$ Solutions will send each site an INITIAL SHIPMENT of lab supplies at the start of the trial. This first shipment contains lab kits (in sponsor-determined quantities) and ancillary materials, including the study specific documentation and a BULK SUPPLY BOX (shown below).


The bulk supply box will include extra tubes and needles.
Each white visit kit contains extra labels detailing the bar-coded accession number. This means that if a tube is lost or damaged, a replacement can be taken from the bulk supply box and an appropriate label from the visit kit attached.


**The bar-code accession number on both the Tube and Requisition Form must match.**