Title: Procedure for Clinical Sites to Perform a Quality Control Check on U01 Follow-up and DHS Modules

**Purpose:** To assist clinical site staff in performing Quality Control on U01 Follow-up and Daily Hormone Study modules received from CLASS.

**Procedure:**
1. Upon receipt of a batch of modules, inspect the shipping container or any contained module for rough handling; i.e., torn packages or broken vacutainers. Should any damage exist, please contact the shipping carrier and report the damage. Also send an e-mail notification to Kimberly Gonzalez (gonzaleb@umich.edu) and copy Annie Kolar (KolarA@edc.pitt.edu) at the Coordinating Center. If broken vacutainers are found, do not under any circumstances open the baggie but rather proceed to step #4.

2. QC individual modules prior to use and only one at a time in order to avoid mixing components between modules by the following:
   a. Check to ensure the correct number of components are present in the appropriate module according to the modules’s specimen collection log or the Manual of Operations. An additional list of module components is included below as well.
   b. Check to ensure all tubes have the appropriate three-digit number corresponding to the kit number which is located on the outside of the module bag or on the specimen collection log. In the case of 2 mL tubes or microtubes the three-digit number is located at the top of the label next to the colored dot or in the case of the 5 mL tube, the number is located in between the notched portions of the label.
   c. In regards to DHS modules, please check the serum bag as indicated in step #2a and 2b and additionally check whether glycerol may have spilled from loose/ajar caps on the 5 mL tubes prior to giving the module to the participant. If glycerol has spilled, please follow the directions outlined in step #4. Also QC the first and last tube in each box by comparing the full barcode (SID) located underneath the barcode on the label or at the top of the label underneath the black line with the corresponding barcode on the urine collection log as the three-digit number on the urine tubes refers to the tube pair and thereby the position of the tube in the box rather than the kit number.

**Follow-up kits** contain the following:
1 generic specimen collection record and on the reverse side of the paper, the specific specimen collection log containing the unique barcoded sample identifications (SID).

1 Draw kit containing:
file: 2.11 sites QCing kits
Created: 11/4/97 KG,RM
Modified: 10/13/03 KG
Approved: 10/13/03 KG
2 10 mL red top vacutainer tubes
1 7 mL purple top vacutainer tube
2 4.5 blue top vacutainer tubes
1 vacutainer needle

1 Aliquot kit containing:
2 5 mL tubes (S1 and S2)
8-12 2 mL tubes (S3,S6-S8 red capped vials; P2-P5 blue capped vials; U2-U5 yellow-capped vials, if urine is collected at the site)
1 blue, 1 yellow, 2 red and 3 green-capped MRL tubes
1 urine cup, if the site is collecting urine

DHS kits contain the following urine components:
2 boxes labeled with a blue dot- 1 is checked 1-25 on the outside label. It should contain 2 labels on the inside of the box-one on the lid and one on the bottom of the box, indicating the tube positions (01A-25B) where the subject should place the tubes. This box should also contain one divider and 25 plastic cups. The second box (26A-50B) should contain the appropriate labels inside of the box, 25 plastic cups and 2 polypropylene cups and 2 sharpies.

2 boxes labeled with a red dot-1 is again 01A-25B and the other is 26A-50B with corresponding tubes containing 200 µL of glycerol.

1 5 page urine collection log with a kit label attached to the first page listing the appropriate barcodes for that kit. The kit # is also represented in the barcode for each tube listed; it is the 5th and 6th number in the barcode. For example, tube #36862162 belongs in kit # 21.

DHS kits contain the following serum components:
1 generic specimen collection record and on the reverse side of the sheet, a specific specimen collection log with the unique barcodes.
2 half sheets of dry mop
1 transfer pipette
1 5 mL tube (D1)
6 2 mL microtubes (D2-D7)
1 15 mL red top vacutainer

4. If any components are missing, broken or one or more components has the wrong three-digit number, please proceed with the following:

a. With a piece of paper and tape label the kit with a message something akin to “do not use” with a brief explanation of the occurrence. This will ensure others at the clinical site do not inadvertently use the kit and then set it aside.
b. As soon as possible send an e-mail notification to Kimberly Gonzalez with a copy to Annie Kolar with a complete description of the occurrence including the full kit number, not simply the three-digit number as these numbers repeat in each group of 100 kits. Also, if possible, include the date the kit was received in the e-mail; this will assist CLASS in tracking the kit information. It is important that this step be completed in a timely manner because if for example tubes were switched between kits, the other kit or kits must be tracked, potentially another site contacted, the kit in question located and the situation resolved.

c. RSP in turn will indicate instructions if an action may be completed at the site or issue shipping instructions and an account number to return the kits identified above. Kits may then be shipped as requested.

5. If a kit has been used and then found at the time of shipment to have inappropriate tubes; i.e., one or more tubes with the wrong three-digit code, the occurrence should be documented at the site and the tube SIDs which were actually used should be recorded on the specimen collection log and recorded in the DMS. Additionally an e-mail notification is still to be sent to CLASS and the Coordinating Center so that the corresponding kit with inappropriate tubes may be tracked and the occurrence resolved preferably prior to use. CLASS has taken the additional step in its Sample Check-in Procedure of checking the three-digit code of tubes received in each baggie and, if notified of such an occurrence in advance of receiving the shipment as well as the specifics as to when the shipment containing these samples will arrive, CLASS will be on the lookout for the specified tubes, proceed with sample check-in and not bother site personnel with a problem already resolved.