Title: Procedure for U01 Follow-up 2 Module Manufacture

Purpose: To manufacture, QC and release 100 unique Follow-up 2 Serum Modules for U01 clinical site specimen collection.

Procedure:
1. Assemble the following materials which are located in Room A120A at CLASS.
   - 66 regular label sheets
   - 5 Die cut notched serum endo labels
   - 200 Sheets 70 lb paper with Specimen Collection Record side already printed
   - 100 10ml Red Top Vacutainers
   - 200 Kit bags
   - 100 Red Capped Dot 5 mL Tubes
   - 100 Simport 2 mL Tubes
   - 100 Red Simport caps
   - 800 Yellow dot inserts
   - 300 Blue dot inserts
   - 300 Sheets Dry Mop
   - 100 100 Red top vacutainers 7ml.
   - 100 Module Bags
   - 100 MRL Follow-up kits
   - 100 4 oz. capped, labeled BMC Specimen Collection Cups
   - 1700 red dot inserts
   - 2800 micrew tubes

   This set of 66 regular label sheets should consist of:
   - 2 Module Sheets
   - 6 Blue-dotted Plasma labels
   - 34 Red-dotted Serum labels
   - 16 Yellow-dotted Urine labels
   - 2 Aliquot Kit labels
   - 2 Draw Kit labels
   - 4 Red-dotted Vacutainer labels

2. Current label stock may not be used in any of the RSP printers as it destroys the output assembly. Label materials are routinely printed by the U of M Copy Center, located at Auxiliary Services. The Database Administrator produces the label files for printing. Advance Print and Graphics of Ann Arbor may serve as a backup printing facility if necessary.

3. All numbers between 000-099 should be represented and the series number must be unique. This series number is to be checked in the U01 Kit Database to ensure that duplicate label sets will not be manufactured nor distributed to sites. The U01 Kit Database is located on the NAS Server: CLASS Users: CLASS Folder: Kit Databases: U01 Kit Database. Simply go to “select” and then “find” and enter the series number
that was just printed and type “find.” If that series number has been used, contact either the Lab Manager or the Manager of Information Technology. Also Procedural Worksheets for Checking Label Sets may be accessed for the last label series; these worksheets are located in the SWAN Label Notebook located in Room A120A. If other inconsistencies with the labels arise such as label or log sheets missing, labels sheets are not properly aligned, etc., record the occurrence on a Procedural Worksheet for Checking Label Sets; these worksheets may be printed by accessing the SOPs located on the NAS Server: CLASS Users: CLASS Folder: SOPs. Immediately notify the Lab Manager for corrective action. File this Procedural Worksheet in the SWAN Label Notebook.

4. Begin module assembly. It is most efficient if modules are made in sets of 10 at a time. The reason for this will become apparent due to the space involved in assembly at the time of dismantling and redistributing of the Follow-up MRL kit.

   a. The Draw Kit: Each draw kit consists of 1 labeled 10 mL and 1 7 mL red-top vacutainer, 1 unlabeled 10 mL red-top vacutainer, 1 unlabeled 7 mL purple-top vacutainer, 1 unlabeled 5 mL blue-top vacutainer, and 1 vacutainer needle. The labeled 10 mL and 7 mL red top vacutainers are supplied by CLASS; others are supplied by MRL.

   b. The Aliquot Kit: Each aliquot kit consists of 1 labeled (red insert in cap) 2 mL simport tube, 3 plasma (blue insert in cap) micrew tubes, 17 serum (red insert in cap) micrew tubes and 8 urine (yellow insert in cap) micrew tubes. 1 red-capped 5 mL Dot tube, 3 green-capped MRL tubes, 2 red-capped MRL tubes, 1 blue-capped MRL tube, and 1 yellow-capped MRL tube.

   *Note: Two sites, Chicago and New Jersey, do not collect urine and therefore, urine tubes (yellow-capped) and the specimen collection cup are not included in their follow-up modules. If using a follow-up MRL kit, simply remove the yellow-capped MRL tube and store.

   c. Kit Assembly and QC:

   In order to manufacture 10 modules, place 20 kit baggies on the workstation. Label one row of 10 baggies on the upper left hand corner with corresponding Aliquot Kit labels, and the other row with Draw Kit labels.

   Preliminary Aliquot Kit. Label 3 plasma micrew tubes, 17 serum micrew tubes and 8 urine micrew tubes per Aliquot bag with the label numbers for that corresponding Kit number, and place in storage bins labeled with the corresponding three-digit number. Repeat this procedure for 1 Serum simport tube per Aliquot bag. Label 1 red-capped, 5 mL Dot tube per Aliquot Kit. Perform a Quality Control check to ensure all the tubes are correctly labeled with the appropriate three-digit in the storage bin. Then place the tubes in the corresponding aliquot kit baggie.
Preliminary Draw Kit: Label both 10 mL and 7ml red top vacutainers with the corresponding vacutainer labels and place in the corresponding draw kit baggie.

MRL Distribution: For each module, gather one current lot MRL follow-up kit. Opening one MRL kit at a time, remove the three transfer pipets from the bag and store at CLASS. Place the following unlabeled vacutainers into a draw kit baggie: 1 10 mL red-topped vacutainer, 1 5mL blue topped vacutainer, 1 purple-topped, 7 mL vacutainer, and 1 needle. The extra 5mL blue topped vacutainer is to be stored at CLASS. Place the remaining contents of the MRL kit :i.e., the 7 colored MRL tubes, into the aliquot kit baggie.

The Aliquot Kit and Draw Kit baggies now contain all the required components and may be sealed.

Module Assembly: Label the module bags in the upper left corner with the three-digit module label corresponding to the aliquot and draw kits. Place 3 whole sheets of Dry Mop, 1 labeled BMC Specimen Collection Cup, the two corresponding specimen collection log sheets, and the corresponding aliquot and draw kits into the module bag and seal. Repeat this step for each module being produced.

5. Sites may inform CLASS of how many follow-up 2 modules they require during the coming weeks. More often, the Lab Manager, based on interaction with the sites, determines the number of modules to be sent per month. Check the module board on the wall in the office area to keep informed on which site requires a specified number of kits during the up coming month. After a certain number is manufactured to be sent for a site, carefully record all the pertinent GMP information into your notebook and finally into the U01 Kit Database (CLASS NAS Server: CLASS Users: CLASS Folder: Kit Databases: U01 Kit Database). Pertinent GMP information includes the following information: lot number and expiration dates (if applicable) of all components (tubes, vacutainers, dry mop, etc.) used; serial numbers of the modules assembled; the clinical site receiving the shipment; the date; method of shipping (refer to step four for further instructions); anything extraordinary in the comments field, etc.

6. Place the modules into an appropriate box and add one copy of the follow-up 2 instruction sheet to each shipment. Remove any stickers or other distinguishing marks from the box. A sharpie may be used to cross out any writing on the box.

If the Modules need to arrive within one or two days, tape the package securely with any type of packing tape available. Fill out a DHL Airbill, located on the shelves in room A120A. Models of previous Airbills can be found in the U01 Module Shipping Records Binder in Room A120A. Packages to be delivered by DHL may be phoned in for pick-up by calling 1-800-225-5345. Please refer to the U01 Address Sheet which is the first page located in the current U01 Module Shipping Records Notebook located on the shelves of Room A120A.
If the Modules need to arrive between a three and five day span, tape the package with clear tape. Take the appropriate pre-printed address sheet located on the shelves in room A120A and/ A124 and add the following information: UPS Ground, Mail Services, the number of boxes, the account number, your initials and the date. Make a copy of this for administrative purposes and place it in the front pocket of the current U01 Module Shipping Records Notebook. Add a barcode label found on the shelves in A120A to the package; these are provided by Mail Services. Also fill out and add a green shipping label to the package; these are also provided by Mail Services.

7. Use the Procedure for Inventory Management to keep track of the supplies used. Subtract the number of supplies used to manufacture kits.

8. Update the Module Board in Room A120B by listing the number of kits sent and the date they were sent to the site.

9. Evaluate and restock module supplies. Cap and label BMC Specimen Collection Cups and/or cap 5 mL Dot tubes with red caps, micrew tubes, etc. as time permits.