Title: Procedure for J. Douglas Kit Manufacture

Purpose: To assemble and manufacture Julie Douglas kits for clinical site specimen collection.

Procedure:
1. Assemble the following materials. They may be found in Room A120A at CLASS.

   1 pre-printed Label Sheet, laser label stock, white
   1 8 1/2 x 11 inch Log Sheet
   1 Large Kit bag, 10 x 12”
   2 Small Kit bags, 6 x 8”
   3 50 mL blue-capped conical tubes
   2 Red-Capped Dot 5 mL tubes
   10 red-capped Microcentrifuge tubes, 1.5 mL, for serum aliquots
   5 yellow-capped Microcentrifuge tubes, 1.5 mL for urine aliquots
   3 2mL Samco pipets
   1 Dry Mop, full sheet
   1 4 oz polypro urine cup, white cap and label

Note: 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.

2. The kit label number must be unique. This number is to be checked in the J. Douglas Kit Database to ensure that duplicate label sets will not be manufactured nor distributed to sites. The J. Douglas Kit Database is located on the NAS Server: CLASS Users: CLASS Folder: Kit Databases: J. Douglas Kit Database. Simply go to “select” and then “find” and enter the series number that was just printed and type “find.” If this kit number has been used, inform the Lab Manager and the IT Group responsible for the production of labels. Any duplicate kit labels should be destroyed immediately. 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 Procedural Worksheet in the J. Douglas Kit Notebook.

3. Assemble the kit.
a. Place the appropriate label onto the bag/tube according to the log sheet. Tape all microcentrifuge tube labels with scotch tape in order to ensure the label will continue to adhere to the tube through collection, processing and storage. It is not necessary to tape the wrap-around labels on the 5 mL Dot tube.

b. Place the 10 labeled microcentrifuge tubes with red caps and the 2 labeled 5 mL dot tubes with red caps into small baggie #1.

c. Place the 5 labeled microcentrifuge tubes with yellow caps into small baggie #2.

d. The small baggies, dry mop, 3 samco pipets, urine cup and 3 labeled 50 mL blue conical tubes are to be placed into the large kit bag with the log sheet.

4. Each kit must be checked as part of the CLASS quality control program. The bar-coded labels on the kit bag, the small draw bags, and all the tubes inside the large bag should match with the log sheet. Additionally check to make sure the correct number of dry mop sheets are in the large bag.

5. Record the serial numbers of the kit or kits being released in your lab notebook and in the Douglas Kit Database. Also record the date released, method of shipment and other lot-specific supply information in the comments field. Place the necessary number of kits in a box/bag, such as those that can be found in Room A122. Remove any distinguishing marks from a box that could lead to an error in shipping. Label the bag/box with the number of kits and their serial numbers. Notify the CLASS Manager that the kits are ready to be released.

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

7. Restock kit supplies as needed.