Title: Procedure for UO1 DHS Module Manufacture

Purpose: To manufacture, QC and release 1 unique DHS Module for UO1 clinical site specimen collection.

Procedure:
1. If necessary, prepare 50% Glycerol solution. Finish using current lot of glycerol solution first. If none remains, refer to the Procedure for the Preparation of 50% Glycerol for Use in DHS Kits.

2. Assemble the following materials to manufacture one DHS module:
   - 20 mL of 50% glycerol solution
   - 100 5 mL Dot tubes and yellow caps
   - 1 5 mL Dot tube and red cap
   - 6 microw tubes with red cap insert
   - 9 sheets dry mop
   - 4 Eastern boxes
   - 1 graduated (0.5 mL) pipet, 2 mL
double-sided tape
   - 4 red dot labels
   - 4 blue dot labels
   - shrink wrap
   - 50 disposable plastic collection cups
   - 2 polystyrene collection cups
   - 8 box liner labels (4 numbered 01A-25B; 4 numbered 26A-50B)
   - 2 Sharpie marking pens
   - 1 plastic bag 6 x 8”
   - 1 15 ml vacutainer
   - 2 large plastic bags 10 x 12”
   - 5 sheets of notched urine labels
   - 6 sheets of D red labels
   - 1 sheet of serum endo labels
   - 1 sheet of vacutainer labels
   - 8 sheets of Avery box labels
   - 1 cardboard box/bin labeled with the appropriate module number
   - 5 sheets of the specific Urine Collection Log
   - 1 Kit label for the Urine Collection Log
   - 1 DHS Specimen Collection Log/Record

3. 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.

4. The kit label number must be unique. This 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.

DHS Urine Component:

5. Red dot boxes: Remove cardboard dividers from the 2 eastern boxes. Place 1 sheet of dry mop into bottom and top of each box. Then place a piece of double sided tape in the top and bottom of each box. Take one numbered sheet from 01A-25B and place inside the bottom of the box, pressing down to ensure a smooth surface. Then take an additional numbered sheet from 01A-25B and place into the top of the box. Repeat these steps, this time using two numbered sheets of 26A-50B. Replace cardboard divider and put a 5ml dot tube into each slot.

6. Pipet 0.2 mL (200 µL) of the 50% glycerol solution into each of the 100 5 mL Dot tubes in the red dot boxes using the Digiflex or Eppendorf repeater pipeter (labeled kit use only).

   a. Prime the machine. Pour 30 mL of the glycerol solution for each DHS module into a clean 250 mL Erlenmeyer flask. Put the flask on the stand to the left of the Digiflex while removing the flask of ddL H2O that is normally in this position. Insert the plastic tube into the flask with the glycerol solution and cover with parafilm to avoid evaporation. Make sure that the tubing tip is completely immersed in the solution. Press the sample button. Put a collection container at the bottom of the pipet at the right side of the Digiflex and press prime to get the residual water out of the tubes. Let the machine prime a few times. The collection container is used to accumulate the excess water that was in the system.

   b. Enter the desired volume by pressing the left sample button. Then press the number of µL to be dispensed from the flask (200 µL) and press enter.

file: 2.6 U01 DHS
Created: 5/2/96 TS
Modified: 9/15/05 KG
Approved: 9/22/05 KG
c. Attempt aliquotting a few times by pressing the single button. Press the stop/start button when ready to proceed.

d. If the machine is working properly, press continue and stop/start when ready. This will cause the Digiflex to continuously aliquot 200 µL of the solution at short intervals. Stop the aliquotting by pressing stop/start. Refill the flask with the adequate volume of glycerol solution from time to time during the dispensing process when appropriate.

e. When the dispensing process is complete, put the original flask of ddI H2O on the stand to the left of the Digiflex and repeat the priming procedure using the ddI H2O in place of the glycerol solution. This will clean the Digiflex and refill the tubings with ddI H2O. Dispose of the fluid in the collection container in the sink and wash the container. Cap the tubes tightly with yellow caps after dispensing.

7. Blue dot boxes: Remove cardboard dividers from 2 Eastern boxes. Place 1 piece of dry mop into top and bottom of each box, use 2 strips of double sided tape to tape in top and bottom of each Eastern box. Then place numbered sheet from 01A-25B in bottom of a box. Repeat the same step for the top of box. Replace cardboard divider, by folding it to one side of the box. Count out 25 plastic cups, then lay them into the bottom of the box. Close box and place a blue dot label in the right hand corner. Repeat steps A and B for the other box. This time using numbered sheet from 26A-50B. Replace cardboard divider by folding it to one side of box, then put in 2 polystyrene collection cups and 25 plastic cups into the box. Add 2 sharpie marking pens to the box. Close box and place a blue dot label in the right hand corner.

8. Find Avery laser labels and label each red dot box with the corresponding number. Repeat this for each blue dot box. Then label each box in the left hand corner with the corresponding Avery Laser label. Place a check in the appropriate 01-25 or the 26-50 box.

9. Label each tube with an individually barcoded 5 mL label checking at this time to ensure each tube has glycerol. The labels are numbered 01A-50B. Note that the module number (0-99) is embedded in the tube label; it is the 5th and 6th number in the 8 digit barcode. Place these tubes in box in accordance with the box liner labels.

10. Place the corresponding kit number label onto page one of the Urine Collection Log in the designated box.

11. QC the urine boxes by checking the appropriate tube labels for the first, last and 3 other random tubes in each box to the tube SIDS on the 5 page Urine Collection Log and also that the tubes are positioned according to the box liners. The log sheet should have 5 pages that number from 1A-50B with the kit number embedded in the barcode.
DHS Serum Component:

12. Place the DHS Serum Collection Log/Record, 1 small 6 x 8 bag, the samco pipette and the half sheet of dry mop into a 10 x 12 module bag. Label the module bag on the upper left-hand side with the appropriate module label.

13. Take 6 micrew tubes with red dot inserts in the cap and label each with serum labels D2-7, making certain the red dot on the label is positioned toward the top of the tube. Tape each label with scotch tape. Place the tubes into the appropriately labeled cardboard box/bin.

14. Label the red-capped 5ml dot tube with the notched serum D1 label, making certain the red dot is positioned toward the top of the tube. Place the tube into the appropriately labeled cardboard box/bin.

15. Label the 15 mL red top vacutainer with the appropriate vacutainer label making certain the red dot is positioned towards the bottom of the tube. Place the tube into the appropriately labeled cardboard box/bin.

16. QC all tubes in the cardboard box/bin to ensure all tubes are labeled with the appropriate three-digit module number. If a tube is mislabeled put it aside in another cardboard box/bin labeled with appropriate module number and make certain the corresponding module number has not been released to a clinical site. This is most easily accomplished by performing a find in U01 Kit Database (located on the NAS Server: CLASS Users: CLASS Folder: Kit Databases: U01 Kit Database) for this module number. If this module has been released to a clinical site, notify the Lab Manager immediately. Then find the correct label and apply it to the tube. If all is as it should be, place tubes into the module bag and seal tightly.

17. Stack all 4 boxes together with the red dot boxes (containing the glyceroled tubes) on the bottom and the blue dot boxes on the top. Place a rubberband around the boxes and shrink wrap twice around in each direction. Then place the Urine Collection Log and the serum bag on top of the box and rubber band everything together. Record the serial number of the module, lot numbers of components, special notes, etc. in notebook. The module may be packaged and sent to the site via UPS Ground or DHL depending upon need.

18. When DHS kits are released to clinical sites, please update the U01 Kit Database. Its located on the CLASS NAS Server: CLASS Users: CLASS Folder: Kit Databases: U01 Kit Database. The U01 Kit Database assists in the tracking of urine kits by serial number. Enter the fact that a urine kit is to be released and shipped, the name of contact person to whom the kits are being sent, the number of units sent, the carrier or method of release, the date and the serial numbers of any urine kits that were released.
19. Use the Procedure for Inventory Management to keep track of the supplies used. Subtract the number of supplies used to manufacture kits.

20. Evaluate and restock module supplies. Cap 5 mL Dot tubes with red caps and micrew tubes, etc. as time permits.

21. Sites may inform CLASS of how many DHS 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 upcoming month.