**Clinic Instructions and Record for Measuring Coital Simulation Device Gel Dose**

**PTID:** 

1. Materials to be weighed in a gallon-sized Ziploc bag:
2. One (1) large blue paper underpad
3. Two (2) latex-free gloves
4. One (1) individually-wrapped castile soap towelette
5. Five (5) gauze pads, 4”x4” (not individually wrapped)
6. One (1) coital simulation device (CSD), removed from packaging (just prior to weighing)
7. One (1) weighing dish
8. Four (4) dapivirine gel applicators (removed from overwrap pouches, but capped and with plungers)
9. Weigh the bag containing items 1a-1g: **\_\_\_\_\_\_\_\_\_ grams** (record value to 1 decimal place).
10. Materials needed to provide up to 10 g dose of dapivirine gel for coital simulation:
    1. One (1) weighing dish
    2. Four (4) dapivirine gel applicators
11. Place plunger into applicator barrel.
12. Remove the cap from the applicator barrel.
13. Push plunger to dispense the gel into weighing dish.
14. Complete steps 4-6 for the remaining three gel applicators.
15. Give the participant the weighing dish with the gel and the Ziploc bag of other items.
16. Provide explanation of contents of bag and application of gel to coital simulation device and/or body (anus).
17. Instruct the participant to place all items back into the bag after use/clean up.
18. Allow the participant to ‘lube up’ and use the device for approximately five (5) minutes.
    1. Start the timer directly after the participant has lubricated CSD and/or anus with gel and has inserted the CSD into rectum.

**Start Time: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Stop Time: \_\_\_\_\_\_\_\_\_\_\_\_\_\_**

* 1. Enter these times onto the Dose Administration CRF.

1. After the time has passed:
   1. Collect Ziploc bag containing the items and record weight: **\_\_\_\_\_\_\_\_ grams** (record value to 1 decimal place).
   2. For ease of placement of items back into the bag, either hold the bag open for the participant or place the bag in such a way that remains open.
2. Total estimated amount of gel inserted:

\_\_\_\_\_\_\_\_\_\_\_ grams - \_\_\_\_\_\_\_\_\_\_ grams = **\_\_\_\_\_\_\_\_\_\_ grams**

Weight from Step 2 - Weight from Step 12a = **ESTIMATED AMOUNT OF GEL**

**INSERTED**

1. Enter the ‘ESTIMATED AMOUNT OF GEL INSERTED’ from Step 13 onto the Dose Administration CRF.
2. Discard the Ziploc bag containing the items in a biohazard container.
3. Did participant report having a bowel movement after use of gel/dildo?

**Yes\_\_\_\_\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_\_\_**

If Yes, did participant report seeing gel with BM or in commode?

**Yes\_\_\_\_\_\_\_\_\_\_\_\_ No\_\_\_\_\_\_\_\_\_\_**

1. Enter the information from Step 16 onto the Dose Administration CRF.

Clinic Staff Name (please print): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Clinic Staff Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date:

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