

## **Comparison of self-reported female condom failure and biomarker-confirmed semen exposure**

### **Supplementary Material**

#### **Section 1: Information on study-supplied lubricant**

For the functionality study, subjects were provided with a 2.5 oz. (70.9 g) bottle of Astroglide®, manufactured by BioFilm Inc, Vista, CA. For the NICHD efficacy substudy, participants were provided with one 3 mL packet of a lubricant manufactured by Dahua which was designed to have similar lubricant characteristics to those of Astroglide ®. Both the Dahua lubricant and the Astroglide ® lubricant were found not to interfere with PSA assays conducted using the ARCHITECT System (Abbott, Abbott Park, Illinois, USA) [24].

#### **Section 2: Information on swube specifications**

Falcon Swubes® (Becton Dickinson and Company) [25] consist of a 6-inch (15.2 cm) cotton-tipped swab attached to the screw cap of a 16 x 150 mm clear plastic tube. The cotton-tipped swab measured 5.2 mm in diameter and absorbed a mean of 384 µL of distilled water (SD 106 µL). A desiccant pellet was placed at the bottom of each tube after trimming the shaft of the swab by approximately 1 cm.

#### **Section 3. Subject swab collection**

To minimize the likelihood that the precoital swab would contain PSA deposited from a previous act of intercourse, subjects received instructions to abstain from intercourse for 48 hours before

using a study condom. Subjects collected the precoital vaginal swab immediately before inserting the study condom and the postcoital vaginal swab and condom swab as soon as possible after removing the study condom following intercourse.

To collect a vaginal sample, female subjects inserted the swab until feeling resistance, rotated the swab five times, and removed the swab from the vagina. The swab was then reinserted into the plastic tube and the cap tightened.

Following intercourse, subjects collected a semen sample from inside the condom by inserting the swab to the bottom of the WC interior or into the largest accumulation of semen within the condom. The swab was then reinserted into the plastic tube and the cap tightened.

#### **Section 4: Description of laboratory procedures**

Dried swabs were stored at room temperature, until they were extracted. Each swab was extracted by placing it in a labeled extraction tube containing 450uL of phosphate-buffered saline with 0.05% Tween20 (polysorbate20, a surfactant) for 30 minutes. The tube was then agitated using a Vortex machine. The resulting eluent was frozen at  $-80^{\circ}\text{C}$  until the PSA assay was performed. After thawing, eluents were assayed using the ARCHITECT i2000<sub>SR</sub> system (Abbott Diagnostics, Abbott Park, IL) [22, 26-27]. The ARCHITECT Total PSA assay is a Chemiluminescent Micro-particle Immunoassay (CMIA) for the quantitative determination of total PSA (both free PSA and PSA complexed to alpha-1-antichymotrypsin). This assay has a lower limit of quantification of 0.008 ng/ml [22].

## **Section 5: Definitions of semen exposure and clinical condom failure**

We defined semen exposure as condom uses in which the postcoital vaginal PSA result was at least 22 ng/mL greater than the precoital vaginal PSA result. We chose a difference of 22 ng/mL because, in a previous study where duplicate vaginal samples were collected after inoculation with 1000 mL of semen, 95% of the duplicate samples varied by less than 22 ng/ml [16]. At least two other studies have used this criterion [13, 28].

Clinical female condom failure is defined as condom uses during which, by self-report, one or more of the following occurs: condom breaks during intercourse or withdrawal; condom completely slips out of the vagina during intercourse; misdirection (vaginal penetration whereby the penis is inserted between the condom and the vaginal wall); or invagination (part or entire external ring of the condom is pushed into vagina). This definition conforms to the standard list of terms and definitions developed by a WHO technical review committee in 2006 [5].

## **Section 6: Calculation of sensitivity and specificity**

The calculation of sensitivity and specificity is a means of quantifying the loss of information about semen exposure when relying on reports of condom failure. The sensitivity of self-reported clinical failure is the number of condom uses with semen exposure and self-reported condom failure (breakage, slippage, misdirection, or invagination) divided by the number of uses with semen exposure. The specificity of self-reported clinical failure is the number of condom uses without either semen exposure or clinical failure (breakage, slippage, misdirection, or invagination) divided by the number of uses without semen exposure.

**Section 7: Condom self-report form used in CONRAD Functionality Study**



18. Did the penis ever go between the condom and the vagina? (Check all that apply.)

- 0  No: Skip to Question 19.
- 1  At insertion of the penis: 1  1 time or 2  More than once
- 1  During intercourse: 1  1 time or 2  More than once
- u  Don't know

18a. What did you do when you noticed this problem?

(Check all that apply.)

- 1  Stopped intercourse, reinserted the penis into the condom, and continued
- 1  Continued intercourse without any attempt to adjust condom
- 1  Removed the condom and continued intercourse without it
- 1  Removed the condom and stopped intercourse
- 1  Other, Explain: \_\_\_\_\_

19. Did the outer ring of the condom ever get pushed into the vagina?

- 0  No: Skip to Question 20.
- 1  Yes: 1  1 time or 2  More than once
- u  Don't know

19a. What did you do when you noticed this problem?

(Check all that apply.)

- 1  Stopped intercourse, adjusted the condom, and continued
- 1  Continued intercourse without any attempt to adjust condom
- 1  Removed the condom and continued intercourse without it
- 1  Removed the condom and stopped intercourse
- 1  Other, Explain: \_\_\_\_\_

20. During intercourse, did the condom ever completely SLIP OUT of the vagina?

- 0  No: Skip to Question 21.
- 1  Yes, clung to penis: 1  1 time or 2  More than once
- 1  Yes, did not cling to penis: 1  1 time or 2  More than once
- u  Don't know

20a. What did you do when you noticed this problem?

(Check all that apply.)

- 1  Stopped intercourse, reinserted the condom into the vagina, and continued
- 1  Removed the condom and continued intercourse without it
- 1  Removed the condom and stopped intercourse
- 1  Other, Explain: \_\_\_\_\_

21. During withdrawal of the penis after intercourse, did the condom completely SLIP OUT of the vagina?

- 0  No
- 1  Yes, clung to penis
- 2  Yes, did not cling to penis
- u  Don't know

22. Did the condom ever break?

- 0  No: Skip to Question 23.
- 1  Yes, while opening package
- 2  Yes, after opening package but before inserting it
- 3  Yes, while trying to insert it
- 4  Yes, after inserting it but before intercourse began
- 5  Yes, during intercourse
- 6  Yes, during withdrawal of penis from vagina
- 7  Yes, during removal of condom from vagina
- 8  Don't know when
- 9  Other, Describe: \_\_\_\_\_

22a. Where did the condom break? Check the answer that best applies.

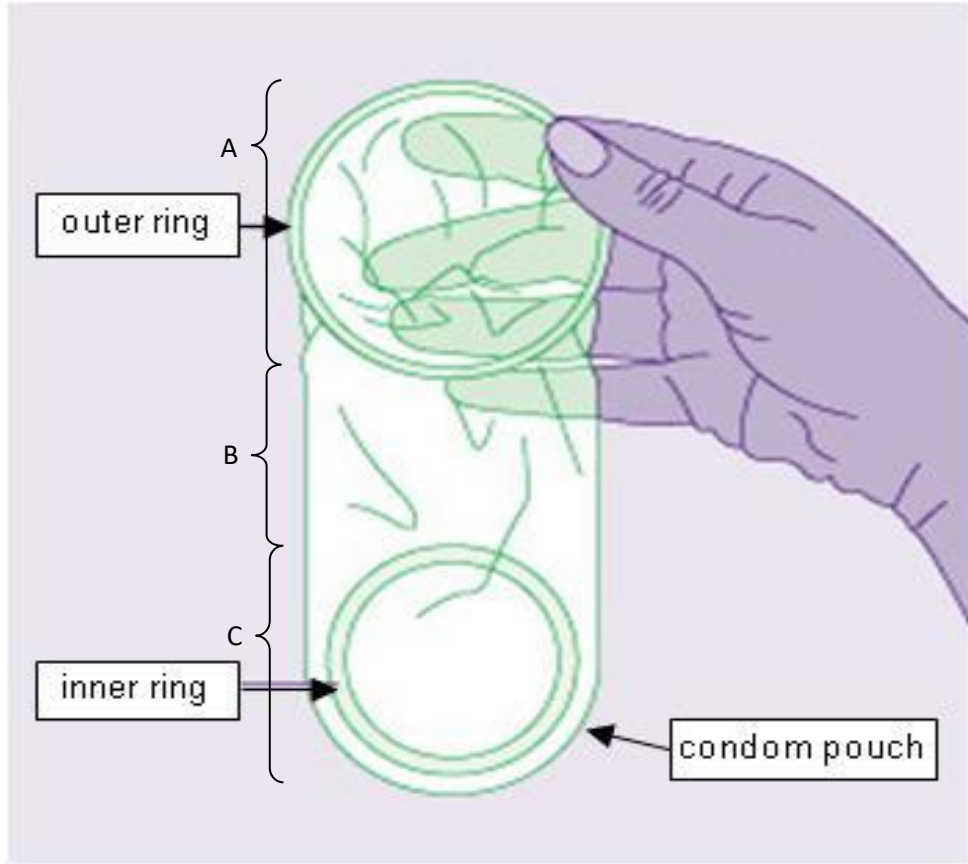
Refer to diagram.

- 1  Near outer ring- see Section A on diagram
- 2  In the middle- see Section B on diagram
- 3  At the tip- see Section C on diagram
- 4  In more than one place

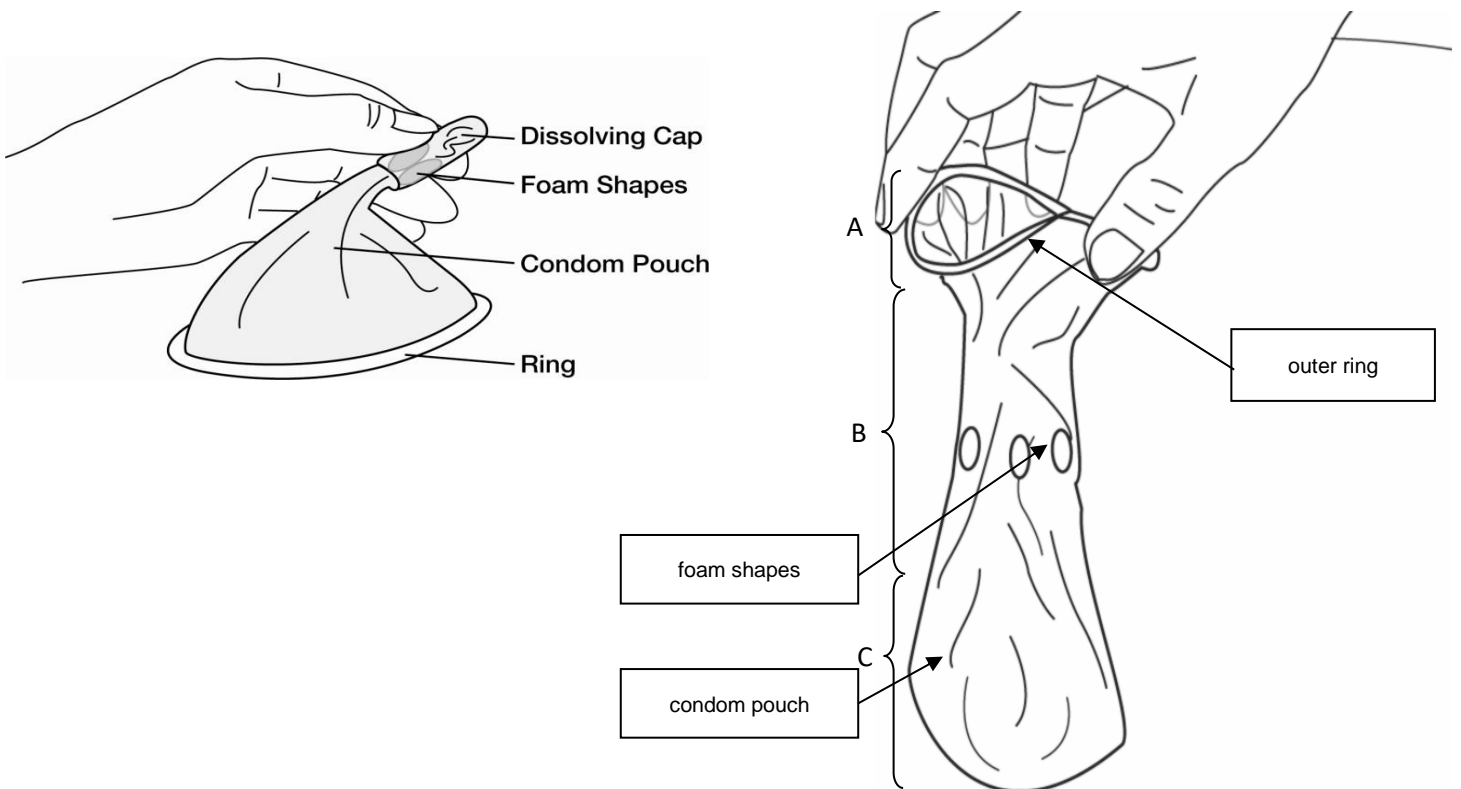
22b. If you just used the Woman's Condom, did the condom break along the seam?

- N  N/A, used the FC2 Female Condom
- 0  No, not along seam
- 1  Yes, along seam
- u  Don't know

### FC2 Female Condom



### Woman's Condom



**The BEFORE Vaginal Swab**

23. Did you collect the "BEFORE" swab from the vagina?

- 1  Yes, before intercourse started
- 2  Yes, but after intercourse started
- 0  No, did not collect the "BEFORE" swab, *Explain* : \_\_\_\_\_
- 3  Other, *Describe* : \_\_\_\_\_

**The AFTER Vaginal Swab**24. Did the male partner ejaculate into the vagina while using this condom?

- 1  Yes, when using the condom
- 2  No, ejaculated into the vagina when not using the condom, *Explain*: \_\_\_\_\_
- 3  No, did not ejaculate into the vagina, *Explain*: \_\_\_\_\_

25. Did you collect the "AFTER" swab from the vagina?

- 1  Yes, before intercourse ended
- 2  Yes, after intercourse ended: How many minutes after: \_\_\_\_\_
- 0  No, didn't take swab, *Explain and Skip to Q28*: \_\_\_\_\_
- \_\_\_\_\_

26. Did ejaculation occur before you took this swab?

- 1  Yes
- 2  No, ejaculated after taking the swab
- N  NA, didn't ejaculate

27. Did you have any unprotected intercourse between the time you collected the "BEFORE" and "AFTER" swabs? (*Check one.*)

- N  NA, only took the "AFTER" swab
- 0  No
- 1  Yes, before the condom was inserted
- 2  Yes, after the condom was removed
- 3  Yes, both before the condom was inserted AND after the condom was removed
- 4  Other, *Describe* : \_\_\_\_\_

**The CONDOM Swab**

28. Did you collect the "CONDOM" swab from the condom after intercourse?

- 1  Yes
- 0  No
- 2  Other, *Describe* : \_\_\_\_\_

**The PREVIOUS Act of Intercourse**

29. Before this act of intercourse, how long ago was your last act of vaginal intercourse (with or without a condom)?

- 1  In last 24 hours (in the last day)
- 2  24-47 hours ago (1-2 days ago)
- 3  48-72 hours ago (2-3 days ago)
- 4  More than 72 hours ago (more than 3 days ago)

30. During that act of intercourse, which of the following occurred? (*Mark the answer that best applies.*)

- 1  Finished intercourse with a condom (study or non-study)
- 2  Finished intercourse without a condom and ejaculated inside of the vagina
- 3  Finished intercourse without a condom and did not ejaculate (or ejaculated outside of the vagina)

31. Additional comments about this condom use: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_



	If YES:				
Did you experience any of the following during or right after condom use?	How bad was the event at its worst?	When did the event begin?	How long after contact with the condom did this event last?	Do you know what might have caused the event?	Did you use any treatment for this problem?
<b>32. Genital pain/discomfort</b> (burning, stinging, pressure) 0 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes $\implies$	1 <input type="checkbox"/> Mild 2 <input type="checkbox"/> Moderate 3 <input type="checkbox"/> Severe	1 <input type="checkbox"/> During condom use 2 <input type="checkbox"/> Right after condom use	1 <input type="checkbox"/> Only while using condom 2 <input type="checkbox"/> 1-10 minutes after 3 <input type="checkbox"/> 11-60 minutes after 4 <input type="checkbox"/> More than 1 hour after	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes, Describe: _____ _____	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes, Specify: _____ _____
<b>33. Genital itching</b> 0 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes $\implies$	1 <input type="checkbox"/> Mild 2 <input type="checkbox"/> Moderate 3 <input type="checkbox"/> Severe	1 <input type="checkbox"/> During condom use 2 <input type="checkbox"/> Right after condom use	1 <input type="checkbox"/> Only while using condom 2 <input type="checkbox"/> 1-10 minutes after 3 <input type="checkbox"/> 11-60 minutes after 4 <input type="checkbox"/> More than 1 hour after	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes, Describe: _____ _____	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes, Specify: _____ _____
<b>34. Genital redness or rash</b> 0 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes $\implies$	1 <input type="checkbox"/> Mild 2 <input type="checkbox"/> Moderate 3 <input type="checkbox"/> Severe	1 <input type="checkbox"/> During condom use 2 <input type="checkbox"/> Right after condom use	1 <input type="checkbox"/> Only while using condom 2 <input type="checkbox"/> 1-10 minutes after 3 <input type="checkbox"/> 11-60 minutes after 4 <input type="checkbox"/> More than 1 hour after	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes, Describe: _____ _____	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes, Specify: _____ _____
<b>35. Urinary pain/discomfort</b> (burning, stinging, pressure) 0 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes $\implies$	1 <input type="checkbox"/> Mild 2 <input type="checkbox"/> Moderate 3 <input type="checkbox"/> Severe	1 <input type="checkbox"/> During condom use 2 <input type="checkbox"/> Right after condom use	1 <input type="checkbox"/> Only while using condom 2 <input type="checkbox"/> 1-10 minutes after 3 <input type="checkbox"/> 11-60 minutes after 4 <input type="checkbox"/> More than 1 hour after	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes, Describe: _____ _____	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes, Specify: _____ _____
<b>36. Pelvic/lower abdominal pain</b> 0 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes $\implies$	1 <input type="checkbox"/> Mild 2 <input type="checkbox"/> Moderate 3 <input type="checkbox"/> Severe	1 <input type="checkbox"/> During condom use 2 <input type="checkbox"/> Right after condom use	1 <input type="checkbox"/> Only while using condom 2 <input type="checkbox"/> 1-10 minutes after 3 <input type="checkbox"/> 11-60 minutes after 4 <input type="checkbox"/> More than 1 hour after	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes, Describe: _____ _____	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes, Specify: _____ _____
<b>37. Vaginal spotting/bleeding</b> (not menstrual period) 0 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes $\implies$	1 <input type="checkbox"/> Mild 2 <input type="checkbox"/> Moderate 3 <input type="checkbox"/> Severe	1 <input type="checkbox"/> During condom use 2 <input type="checkbox"/> Right after condom use	1 <input type="checkbox"/> Only while using condom 2 <input type="checkbox"/> 1-10 minutes after 3 <input type="checkbox"/> 11-60 minutes after 4 <input type="checkbox"/> More than 1 hour after	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes, Describe: _____ _____	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes, Specify: _____ _____
<b>38. Other, Specify:</b> _____ _____ 0 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes $\implies$	1 <input type="checkbox"/> Mild 2 <input type="checkbox"/> Moderate 3 <input type="checkbox"/> Severe	1 <input type="checkbox"/> During condom use 2 <input type="checkbox"/> Right after condom use	1 <input type="checkbox"/> Only while using condom 2 <input type="checkbox"/> 1-10 minutes after 3 <input type="checkbox"/> 11-60 minutes after 4 <input type="checkbox"/> More than 1 hour after	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes, Describe: _____ _____	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes, Specify: _____ _____

Did you experience any of the following during or right after condom use?	How bad was the event at its worst?	When did the event begin?	How long after contact with the condom did this event last?	Do you know what might have caused the event?	Did you use any treatment for this problem?
<b>39. Genital pain/discomfort (burning, stinging, pressure)</b> 0 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes $\implies$	1 <input type="checkbox"/> Mild 2 <input type="checkbox"/> Moderate 3 <input type="checkbox"/> Severe	1 <input type="checkbox"/> During condom use 2 <input type="checkbox"/> Right after condom use	1 <input type="checkbox"/> Only while using condom 2 <input type="checkbox"/> 1-10 minutes after 3 <input type="checkbox"/> 11-60 minutes after 4 <input type="checkbox"/> More than 1 hour after	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes, Describe: _____ _____	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes, Specify: _____ _____
<b>40. Genital itching</b> 0 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes $\implies$	1 <input type="checkbox"/> Mild 2 <input type="checkbox"/> Moderate 3 <input type="checkbox"/> Severe	1 <input type="checkbox"/> During condom use 2 <input type="checkbox"/> Right after condom use	1 <input type="checkbox"/> Only while using condom 2 <input type="checkbox"/> 1-10 minutes after 3 <input type="checkbox"/> 11-60 minutes after 4 <input type="checkbox"/> More than 1 hour after	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes, Describe: _____ _____	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes, Specify: _____ _____
<b>41. Genital redness or rash</b> 0 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes $\implies$	1 <input type="checkbox"/> Mild 2 <input type="checkbox"/> Moderate 3 <input type="checkbox"/> Severe	1 <input type="checkbox"/> During condom use 2 <input type="checkbox"/> Right after condom use	1 <input type="checkbox"/> Only while using condom 2 <input type="checkbox"/> 1-10 minutes after 3 <input type="checkbox"/> 11-60 minutes after 4 <input type="checkbox"/> More than 1 hour after	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes, Describe: _____ _____	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes, Specify: _____ _____
<b>42. Urinary pain/discomfort (burning, stinging, pressure)</b> 0 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes $\implies$	1 <input type="checkbox"/> Mild 2 <input type="checkbox"/> Moderate 3 <input type="checkbox"/> Severe	1 <input type="checkbox"/> During condom use 2 <input type="checkbox"/> Right after condom use	1 <input type="checkbox"/> Only while using condom 2 <input type="checkbox"/> 1-10 minutes after 3 <input type="checkbox"/> 11-60 minutes after 4 <input type="checkbox"/> More than 1 hour after	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes, Describe: _____ _____	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes, Specify: _____ _____
<b>43. Other, Specify: _____</b> _____ 0 <input type="checkbox"/> No    1 <input type="checkbox"/> Yes $\implies$	1 <input type="checkbox"/> Mild 2 <input type="checkbox"/> Moderate 3 <input type="checkbox"/> Severe	1 <input type="checkbox"/> During condom use 2 <input type="checkbox"/> Right after condom use	1 <input type="checkbox"/> Only while using condom 2 <input type="checkbox"/> 1-10 minutes after 3 <input type="checkbox"/> 11-60 minutes after 4 <input type="checkbox"/> More than 1 hour after	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes, Describe: _____ _____	0 <input type="checkbox"/> No 1 <input type="checkbox"/> Yes, Specify: _____ _____

**Section 8: Condom self-report form used in NICHD Efficacy Substudy**

ID

Female Birthdate

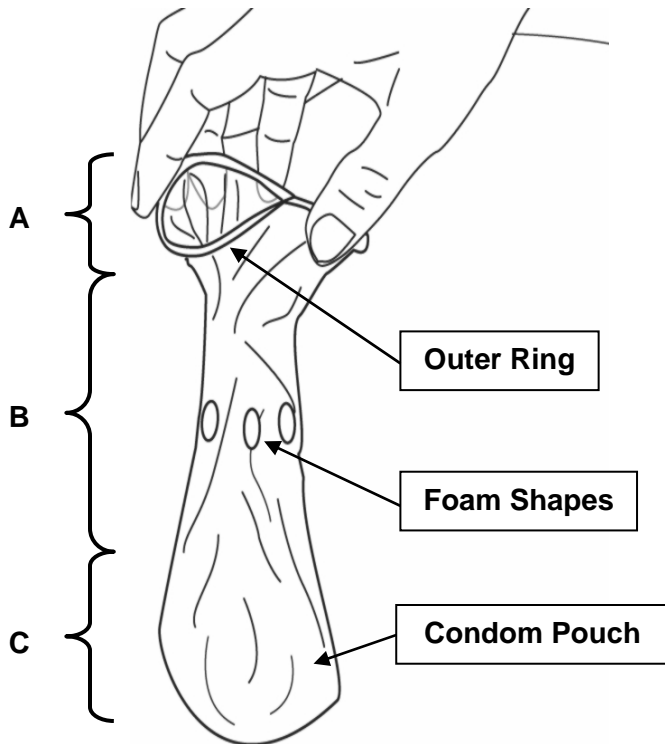
Date Used

**INSTRUCTIONS**

This report should tell us about the study condom you were using when you started intercourse. If a condom is defective or torn when you open the package, do not use that condom and do not record its information here.

If you remove the condom before you finish intercourse, be sure to take the after samples before you continue intercourse (with or without another condom).

**FEMALE CONDOM DIAGRAM**



**INTERCOURSE INFO**

- When was the condom inserted?
  - Before intercourse started: \_\_\_\_ minutes before
  - After intercourse started: \_\_\_\_ minutes after
- Did you use study lubricant during this condom use? (Check all that apply)
  - None added
  - On the penis:
    - Before intercourse and/or  During Intercourse
  - In the vagina:
    - Before intercourse and/or  During intercourse
  - On the inside of the condom:
    - Before intercourse and/or  During intercourse
  - On the outside of the condom:
    - Before intercourse and/or  During intercourse

- Did you add any other, non-study lubricant?
  - No
  - Yes, lubricant with spermicide (N-9 or nonoxynol-9)
  - Yes, Replens lubricant
  - Yes, other lubricant
  - Yes, unsure if lubricant contained spermicide:  
Specify exact name: \_\_\_\_\_
- While wearing this condom, which of the following sexual positions did you use? (Check all that apply)
  - Front entry, man on top
  - Front entry, woman on top
  - Rear entry, woman on knees
  - Rear entry, woman on side or stomach
  - Standing
  - Anal intercourse
  - Other, Explain: \_\_\_\_\_
- How long did you have vaginal intercourse while wearing this condom? \_\_\_\_\_ Minutes

**REMOVING THE CONDOM**

- How did you remove the condom?
  - Twisted the outer ring, and pulled the condom out
  - Pulled the condom straight out (without twisting)
  - Other, Describe: \_\_\_\_\_
- During removal, was there any spillage of semen?
  - No
  - Yes, onto woman's genital area
  - Yes, away from woman's genital area
- When did you remove the condom?
  - Before intercourse ended: \_\_\_\_ minutes before
  - After intercourse ended: \_\_\_\_ minutes after
  - Don't know / Not sure

9. Additional comments about this condom use:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

## PROBLEMS USING THE CONDOM

---

10. Did the penis ever go between the condom and the vagina? (Check all that apply)

- No: Skip to Question 11
- At insertion of penis:
  - 1 time or  More than once
- During intercourse:
  - 1 time or  More than once
- Don't know

10a. What did you do when you noticed this problem? (Check all that apply)

- Stopped intercourse, reinserted the penis into the condom, and continued
- Continued intercourse without any attempt to adjust condom
- Removed the condom
- Other, Explain: \_\_\_\_\_

11. Did the outer ring of the condom ever pushed into the vagina?

- No: Skip to Question 12
- Yes:  1 time or  More than once
- Don't know

11a. What did you do when you noticed this problem? (Check all that apply)

- Stopped intercourse, adjusted the condom and continued
- Continued intercourse without any attempt to adjust condom
- Removed the condom
- Other, Explain: \_\_\_\_\_

12. During intercourse, did the condom ever completely SLIP OUT of the vagina?

- No: Skip to Question 13
- Yes, clung to penis:
  - 1 time or  More than once
- Yes, did not cling to penis:
  - 1 time or  More than once
- Don't know

12a. What did you do when you noticed this problem? (Check all that apply)

- Stopped intercourse, reinserted the condom into the vagina, and continued
- Did not replace the condom and continued without it
- Did not replace the condom and stopped intercourse
- Other, Explain: \_\_\_\_\_

13. During withdrawal of the penis after intercourse, did the condom completely SLIP OUT of the vagina?

- No
- Yes, clung to penis
- Yes, did not cling to penis
- Don't know

14. Did the condom ever break?

- No: Skip to Question 15
- Yes, during intercourse
- Yes, during withdrawal of penis from vagina
- Yes, during removal of condom from vagina
- Don't know when
- Other, Describe: \_\_\_\_\_

14a. Where did the condom break? (Check the answer that best applies. Refer to diagram.)

- Near outer ring – see Section A on diagram
- In the middle – see Section B on diagram
- At the tip – see Section C on diagram
- In more than one place

14b. Did the condom break along the seam?

- No, not along seam
- Yes, along seam
- Don't know

**The BEFORE Vaginal Swab**

15. Did you collect the “BEFORE” swab from the vagina?

- 1  Yes, before intercourse started
- 2  Yes, but after intercourse started
- 0  No, did not collect the “BEFORE” swab: Explain \_\_\_\_\_
- 3  Other, Describe: \_\_\_\_\_

**The AFTER Vaginal Swab**

16. Did the male partner ejaculate into the vagina while using this condom?

- 1  Yes, when using this condom
- 2  No, ejaculated into the vagina when not using this condom, Explain: \_\_\_\_\_
- 3  No, did not ejaculate into the vagina, Explain: \_\_\_\_\_

17. Did you collect the “AFTER” swab from the vagina?

- 1  Yes, before intercourse ended
- 0  Yes, after intercourse ended:  
How many minutes after: \_\_\_\_\_
- 3  No, didn’t take swab,  
Explain and Skip to Q21: \_\_\_\_\_

18. Did ejaculation occur before you took this swab?

- 1  Yes
- 2  No, ejaculated after taking the swab
- N  NA, didn’t ejaculate

19. Did you have any unprotected intercourse between the time you collected the “BEFORE” and “AFTER” swabs?

- N  NA, only took the “AFTER” swab: Skip to Q21
- 0  No
- 1  Yes, before this condom was inserted
- 2  Yes, after this condom was removed
- 3  Yes, both before this condom was inserted AND after this condom was removed
- 4  Other, Describe: \_\_\_\_\_

20. Did you use another study condom or any other method between the time you collected the “BEFORE” and “AFTER” swabs?

- (Check all that apply)
- 0  No
  - 2  Yes, after this condom was removed
  - 4  Other, Describe: \_\_\_\_\_

**The CONDOM Swab**

21. Did you collect the “CONDOM” swab from this condom after intercourse?

- 1  Yes
- 0  No
- 2  Other, Describer: \_\_\_\_\_

**The PREVIOUS Act of Intercourse**

22. Before this act of intercourse, how long ago was your last act of vaginal intercourse (with or without a condom)?

- 1  In last 24 hours (in the last day)
- 2  24-47 hours ago (1-2 days ago)
- 3  48-72 hours ago (2-3 days ago)
- 4  More than 72 hours ago (more than 3 days ago)

23. During that act, which of the following occurred? (Mark the answer that best applies)

- 1  Finished intercourse with a condom (study or non-study)
- 2  Finished intercourse with another barrier method like a diaphragm, cap or spermicide
- 3  Finished intercourse without a method and ejaculated inside the vagina
- 4  Finished intercourse without a method and did not ejaculate (or ejaculated outside of the vagina)