

Women Prefer Self-Collection of Vaginal Swabs which are as Effective for the Diagnosis of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* as Urine, Cervical Swabs and Clinician-Collected Vaginal Swabs.

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UPDATED ABSTRACT

Background: Recent findings show that vaginal swabs (VS) tested in nucleic acid amplification tests can detect *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC) infections. **Objectives:** The APTIMA Combo 2 Assay (Gen-Probe Incorporated) was evaluated for CT and GC detection in several sample types in a multi-centered study. As part of the study, an ethics review board-approved questionnaire was administered to determine patients' experiences in collecting their own VS. **Methods:** A 5-point Likert Scale was used to determine how easy or difficult it was to follow the instructions provided and use the VS. Other data collected included self-collected VS preference, education level, and experience with STD's and vaginal swabbing. **Results:** The current analysis reflects the opinions of 1,090 patients in a study demonstrating excellent sensitivity, specificity and agreement for self-collected VS to diagnose CT (prev. = 12.5%) and GC (prev. = 5.3%) by the APTIMA Combo 2 Assay. Greater than 90% thought the self-collection procedure was very easy. The majority of women (74.4%) were 16 to 30 years old and had completed high school (40.1%) and some college (21.9%). Most were attending the clinic for a STD screen (58.0%) or an annual exam (23.0%) and were not pregnant (94.7%). Eighty-five percent (84.9%) had been tested for a STD and 49.2% had been infected in the past. Although 87.0% indicated looking at their vagina before, only 16.2% had used a vaginal swab previously for STD investigation. Seventy-six percent (76%) preferred VS over a pelvic examination, 60% preferred VS over urine collection, and 94% indicated that they would test themselves more often if the self-collected VS were available. **Conclusions:** These young, sexually-active women, most of whom had not collected VS previously, found self-collection of VS to be relatively easy and preferred it to a pelvic exam or urine collection.

PURPOSE

To assess female patients' interaction, experience, and preference for the patient-collected APTIMA[®] Vaginal Swab (VS) Specimen Collection Kit (Gen-Probe Incorporated) during a multi-center clinical investigation of the APTIMA Combo 2 Assay for the detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae*.

METHODS

An ethics review board-approved questionnaire was used to survey subjects on how easy or difficult it was to use the patient-collected VS (PVS) by factors such as:

- Clinical Site
- Age
- Education

Other data collected included:

- Preference for self-collection of VS compared to the pelvic exam and urine collection
- Experience with sexually transmitted diseases (STD), tampon use, vaginal swabbing, and pregnancy

METHODS (Con't)

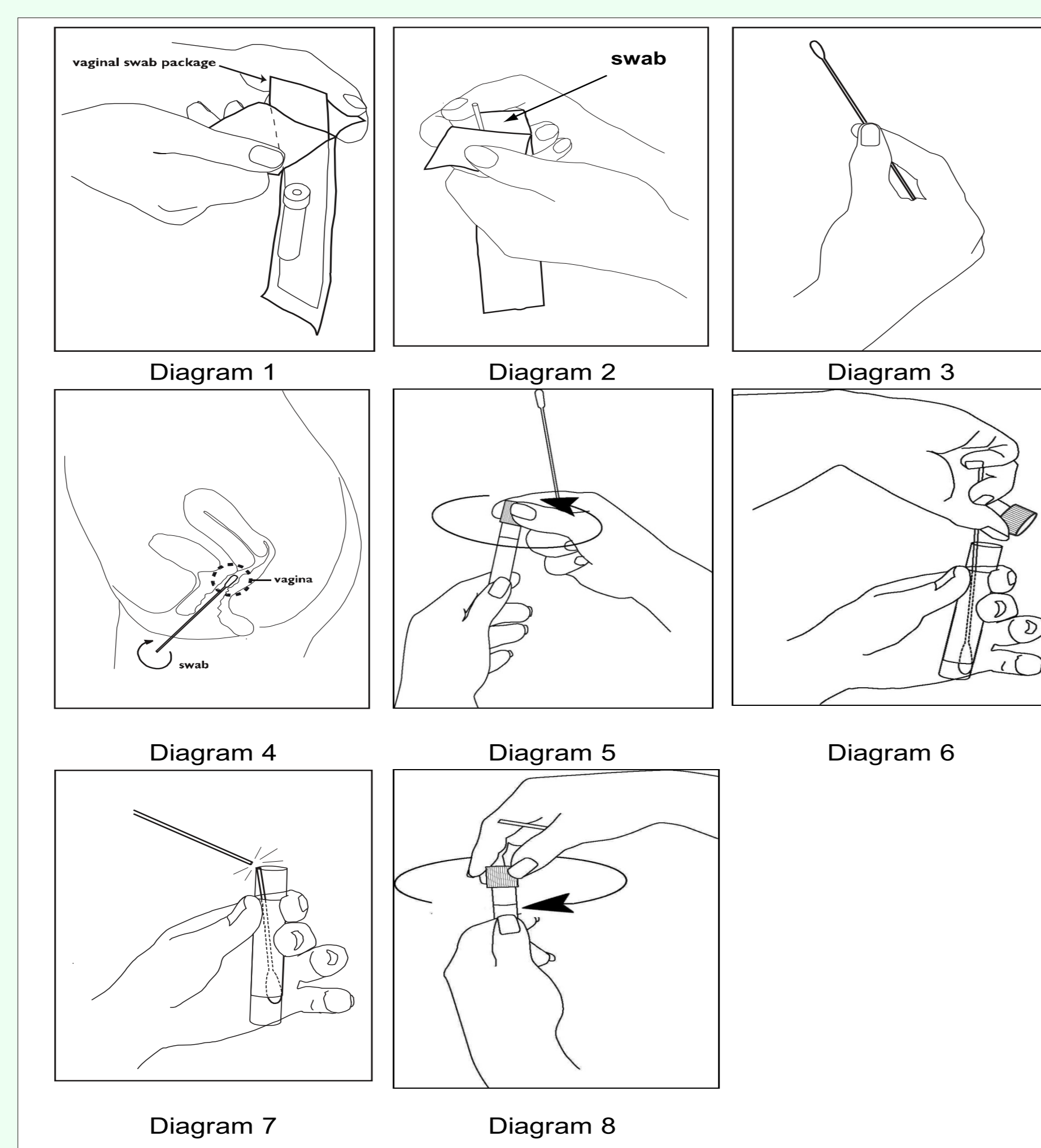
Subject Population

Subjects Surveyed (n)	1330
Responded (%)	82%
Declined (%)	18.1%
Age (mean yrs. ±SD)	26.6 (±7.5)
Age Range (years)	15 - 71
Ethnic Origin (%)	
Black	59.6%
White	25.4%
Hispanic	11.0%
Asian	1.9%
Other/Unknown	2.0%

Patient Instructions

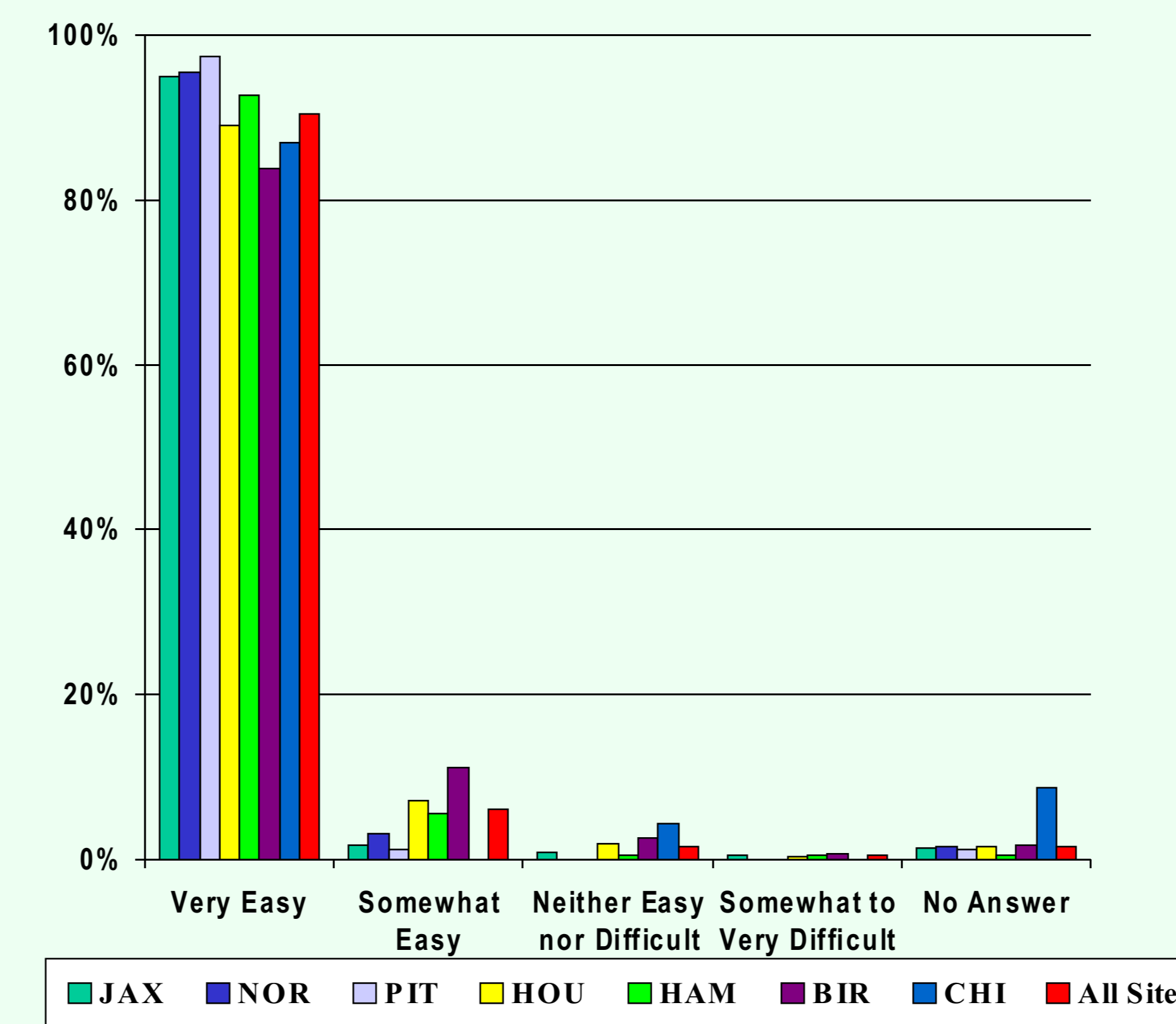
1. Open the vaginal swab collection kit as shown in Diagram 1.
2. Remove tube and the swab package.
3. Open the swab package as shown in Diagram 2.
4. Remove the swab; do not touch the soft tip or lay the swab down.
5. Hold the swab as shown in Diagram 3.
6. Insert the swab into your vagina about two inches as shown in Diagram 4.
7. Gently rotate the swab for 10 to 30 seconds in your vagina.
8. Withdraw the swab without touching the skin.
9. While holding the swab in the same hand, remove the cap from the tube as shown in Diagram 5.
10. Place the swab into the transport tube so that the tip of the swab is visible below the tube label as shown in Diagram 6.
11. Break the swab shaft against the side of the tube as shown in Diagram 7; use care to avoid splashing of the contents.
12. Re-cap the tube tightly as shown in Diagram 8.

NOTE: If you have any questions about this procedure, please ask your doctor or nurse.



RESULTS

PVS Ease of Use by Clinical Site



PVS Ease of Use by Age

Age (Years)	N	Very Easy	Somewhat Easy	Neither Easy nor Difficult	Somewhat to Very Difficult
16-20	212	191 (90.1)	14 (6.6)	3 (1.4)	0 (0)
21-25	401	370 (92.3)	23 (5.7)	5 (1.2)	1 (0.2)
26-30	198	177 (89.4)	14 (7.1)	2 (1.0)	1 (0.5)
31-35	119	105 (88.2)	9 (7.6)	1 (0.8)	2 (1.7)
36-40	98	86 (87.8)	6 (6.1)	3 (3.1)	1 (1.0)
>40	61	55 (90.2)	0 (0)	2 (3.3)	1 (1.6)
Total	1090	984 (89.7)	66 (5.5)	16 (1.8)	6 (0.8)

PVS Ease of Use by Education

Education	N	Very Easy	Somewhat Easy	Neither Easy nor Difficult	Somewhat to Very Difficult
Elementary School	16	14 (87.5)	0 (0)	0 (0)	1 (6.3)
High School	509	457 (89.8)	32 (6.2)	8 (1.8)	4 (0.7)
Technical School	37	37 (100)	0 (0)	0 (0)	0 (0)
College	383	352 (91.9)	25 (6.5)	4 (1.7)	0 (0)
Post-Graduate	22	18 (81.8)	2 (9.1)	1 (4.5)	1 (4.5)
Unknown	123	107 (87.0)	7 (5.7)	3 (2.4)	0 (0)
Total	1090	985 (89.7)	66 (4.6)	16 (1.7)	6 (1.9)

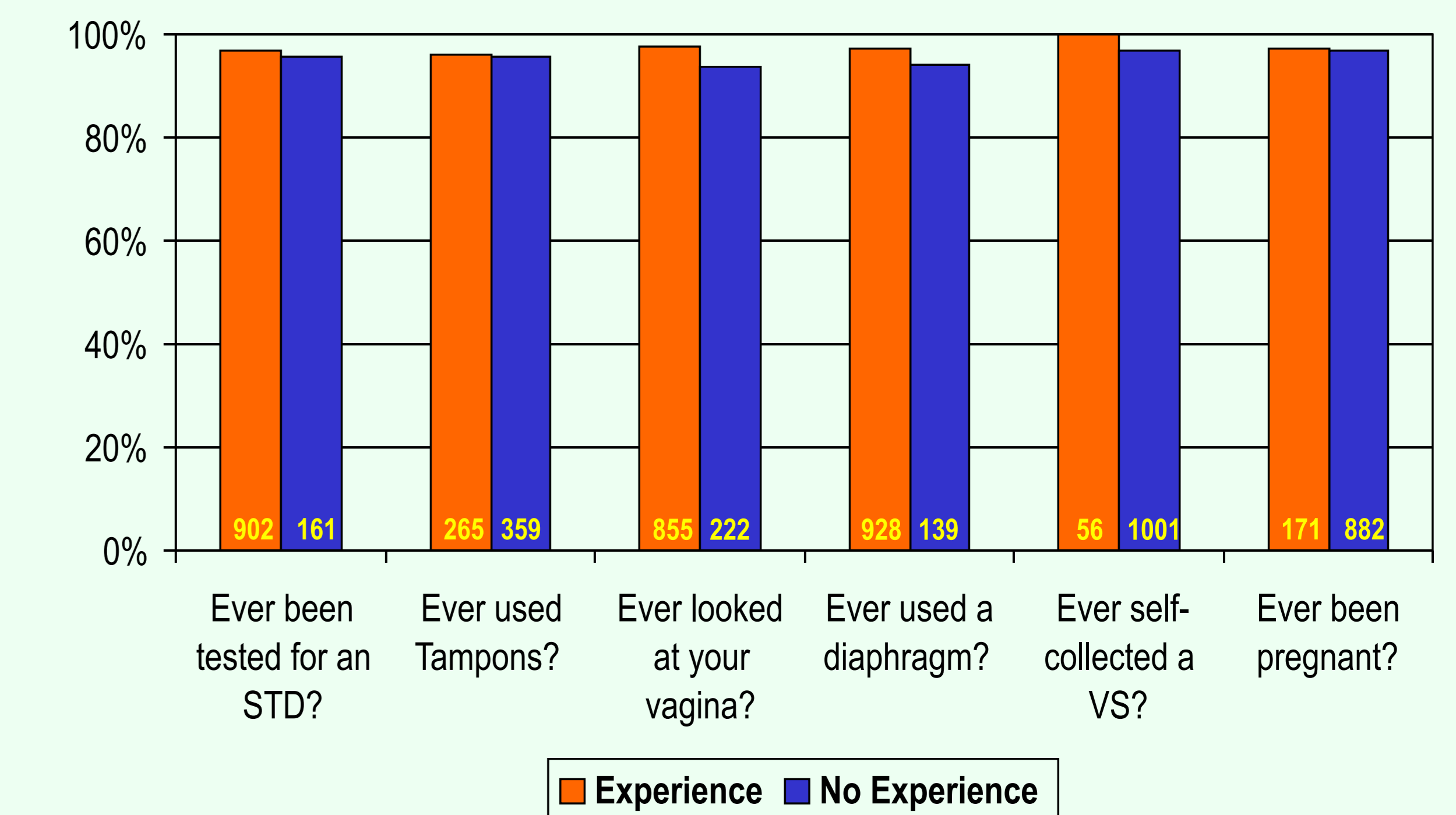
CONCLUSIONS

Sexually-active women of all ages and education levels reported that:

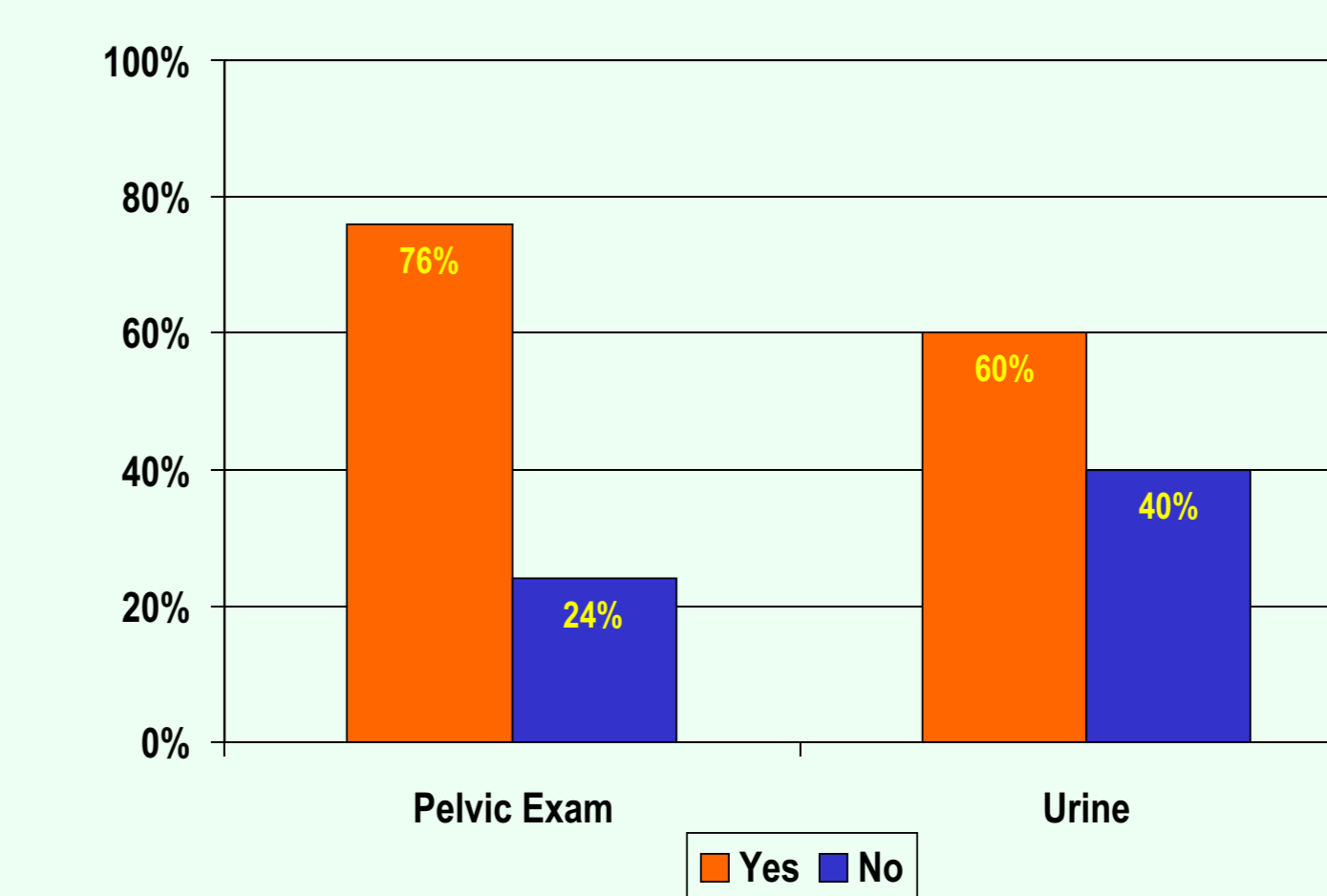
- The patient-collected APTIMA VS Specimen Collection Kit was very easy to use
- They preferred the patient-collected APTIMA VS over a pelvic exam or urine collection
- They would test themselves for STDs more often if the patient-collected APTIMA VS were available for use

PVS Ease of Use by Subject Experience

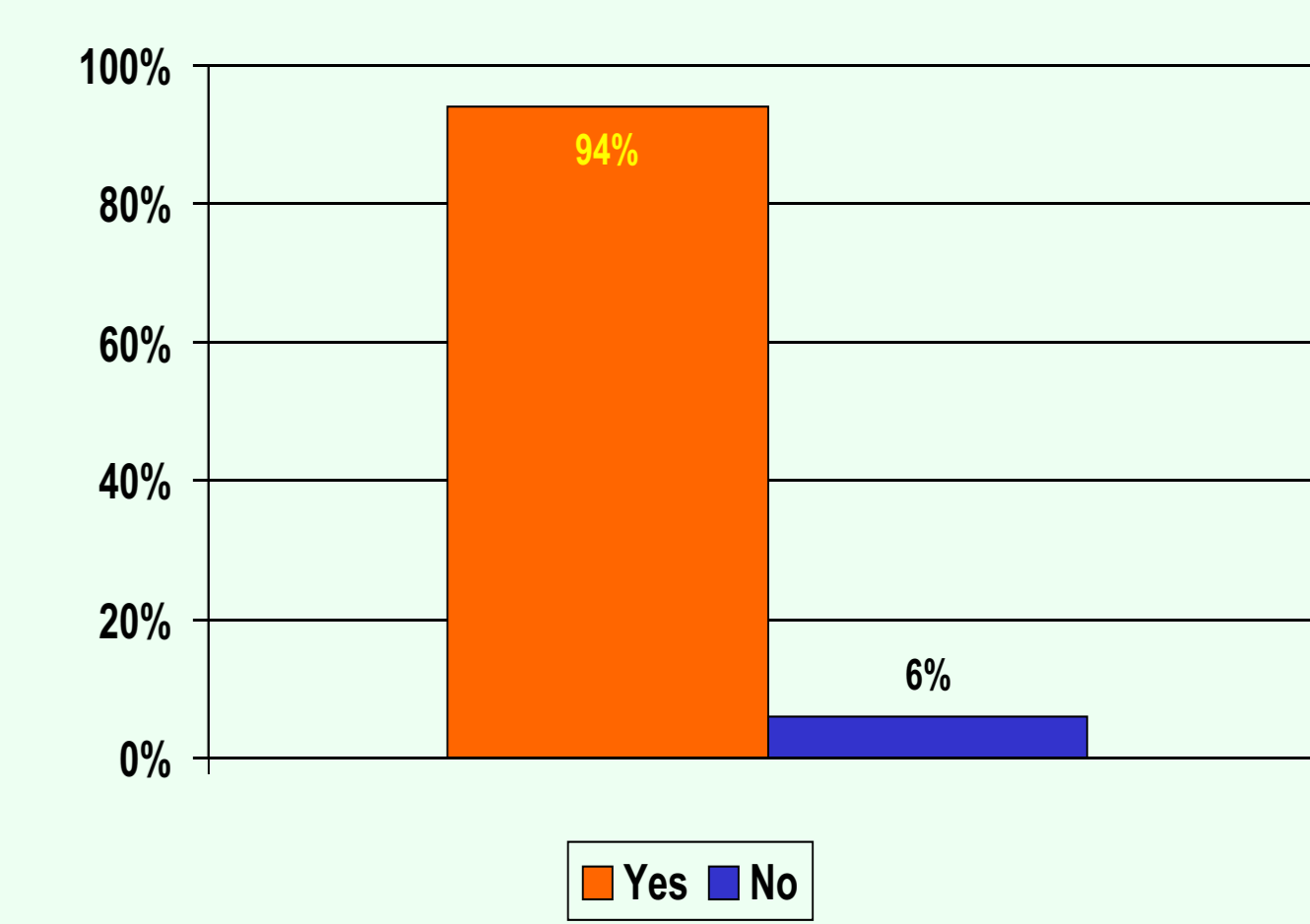
The Questionnaire included questions about women's experiences with STDs, tampon use, vaginal swabbing and pregnancy. Over 96% of respondents with experience and over 93% of respondents with no experience found the PVS easy to use.



Do You Prefer PVS over Pelvic Exam? Over Urine?



Would You Test More Often for STD if PVS were Available?



Ability of APTIMA Combo 2 Assay to Detect CT and GC Infections using PVS versus First Catch Urine (FCU), Endocervical Swabs (CS), and Clinician-Collected Vaginal Swabs (CVS)

Clinical Sample	Infection	
	C. trachomatis (n=180)	N. gonorrhoeae (n=78)
PVS	172 (95.5%)	76 (97.4%)
CVS	174 (96.6%)	75 (96.2%)
FCU	165 (91.6%)	73 (93.6%)
CS	172 (95.5%)	74 (94.9%)

SUMMARY

The survey preference responses, along with the high APTIMA Combo 2 Assay sensitivity (CT: 96.6%, GC: 98.7%) and specificity (CT: 97.8%, GC: 99.6%) of the patient-collected APTIMA VS, indicate that self-collection of VS is an appropriate specimen collection method for use with the APTIMA Combo 2 Assay.