CHAPTER 3

RESULTS

Characteristics of the Study Population

1)   General characteristics of the study population

A total of 256 pregnant women of the first attending of antenatal care at Srinagarind hospital during November, 1994 and February, 1995 were recruited to the study. Most of them attained primary school (53.9%). Their age ranged from 17-39 years old with the mean of 25.9 and median of 25.0 years old (standard deviation = 4.9). The major occupation of both the pregnant women and their husband is farmer (35.7% and 27.9% respectively). All of them are Thai and Buddhist is their religion. Their weight is between 37.8 and 93 kilograms with a mean of 53.9 and a median of 53.0 (standard deviation = 8.6). The height ranged from 140 to 179 centimeters with a mean of 153.9 and a median of 154 (standard deviation = 5.7). See Table 1. for more detail.

Table 1. General characteristics of the study population

Characteristics	number	percent
1. Age (years) (mean $\pm$ SD. = 25.9 $\pm$ 4.9)		
< 20	21	8.2
20-34	225	87.9
> 35	10	3.9
Total	**256**	**100.0**
2. Educational attainment		
primary school	137	53.9
secondary school	44	17.3
high school	37	14.6
graduated	36	14.2
Total	**254**	**100.0**
3. Occupational of the women		
Farmer	91	35.7
Trader	20	7.8
Housewife	53	20.8
Labourer	24	9.4
Government service	25	9.8
General employee	42	16.5
Total	**255**	**100.0**

Table 1. (continued)

Characteristics	number	percent
4. Occupation of the husband		
Farmer	71	27.9
Trader	21	8.3
Labourer	41	16.1
Government service	52	20.5
General employee	69	27.2
Total	**254**	**100.0**
5. Weight (kilograms) (mean $\pm$ SD. = 53.9 $\pm$ 8.6)		
< 40	2	0.8
40 - 60	193	76.2
61 - 80	48	19.0
> 80	10	4.0
Total	**253**	**100.0**
6. Height (centimeters) (mean $\pm$ SD. = 153.9 $\pm$ 5.7)		
< 150	43	16.8
151 - 160	173	67.6
161 - 170	24	9.4
> 170	16	6.2
Total	**256**	**100.0**

2)   Obstetric and Gynecologic Characteristics of the study population

Age at menarche of the study group was between 11 and 19 years old with a mean of 14.6 and a median of 15 (standard deviation = 1.5). Total number of pregnancy ranged from 1 to 5 with a median of 2 and about 80.5% are the first or second pregnancy. Total number of delivery was between 0-3, mostly 0 and 1 with the percentage of 45.3 and 45.7 respectively.

There are 160 women who had previous pregnancy who have never been pregnant before was not included. Among these women who have at least one previous pregnancy, the outcomes are the followings:- 129 (80.6%) were live birth, 9 (5.6%) were stillbirth, 26 (16.3%) were spontaneous abortion, 13 (8.1%) were induced abortion, 9 (5.6%) were unspecified abortion, 1 (0.6%) was ectopic pregnancy, 4 (2.5%) were preterm labour and term delivery, and 2 (1.3%) is preterm delivery. In summary, there are a total of 57 women who experienced at least one of all of the above outcomes except live birth. In other words, 57 out of 160 women (35.6%) have previously faced the complication of pregnancy.

There are 47 (18.4%) pregnant women who reported experiencing vaginal infection. From this figure 38 (80.9%) received treatment from medical doctors, the duration of treatment was mostly a few days (66.7%). There were 13 (5.1%) pregnant women experiencing STD. Again most of them received treatment from medical doctors (75.0%) with the duration of treatment of a few days and a few weeks at the most (83.4%).

There are 15 (5.9%) husbands with STD history, most of them were treated by medical doctors (66.7%). The duration of treatment was mostly a few weeks (46.7%). See more detail in Table 2.

Table 2. Obstetric and gynecological history

Characteristics	number	percent
1. Age at menarche (years) (mean $\pm$ SD. = 14.6 $\pm$ 1.5)		
< 13	27	11.3
13 - 14	77	31.6
15 - 16	108	44.2
> 16	44	12.9
Total	**256**	**100.0**
2. Total number of pregnancy (gravidity)		
1	96	37.5
2	110	43.0
3	38	14.8
4	11	4.3
5	1	0.4
Total	**256**	**100.0**

Table 2. (continued)

Characteristics	number	percent
3. Total number of deliveries (parity)		
0	116	45.3
1	117	45.7
2	22	8.6
3	1	0.4
Total	**256**	**100.0**
4. Outcome of previous pregnancy (n = 160) *		
4.1 Live birth	129	80.6
4.2 Stillbirth	9	5.6
4.3 Spontaneous abortion	26	16.3
4.4 Induced abortion	13	8.1
4.5 Abortion	9	5.6
4.6 Ectopic pregnancy	1	0.6
4.7 Preterm labour and term delivery	4	2.5
4.8 Preterm delivery	2	1.3

Some women had more than one previous pregnancies

Table 2. (continued)

Characteristics	number	percent
5. Previous experience of vaginal infection	**47**	**18.4**
5.1 Seeking for treatment from		
none	5	10.6
medical doctor	38	80.9
others	4	8.5
Total	**47**	**100.0**
5.2 Duration of treatment		
a few days	28	66.7
a few weeks	10	23.8
a few months	3	7.1
> three months	1	2.4
Total	**42**	**100.0**
6. Previous experience of STD	13	5.1
6.1 Seeking for treatment from		
none	9	75.0
medical doctor	3	25.0
Total	**25**	**100.0**

Table 2. (continued)

Characteristics	number	percent
6.2 Duration of treatment		
a few days	5	41.7
a few weeks	5	41.7 .
a few months	2	16.6
Total	**12**	**100.0**
7. Husband's STD history	15	5.9
7.1 Seeking for treatment from		
none	3	20.0
medical doctors	10	66.7
unknown	2	13.3
Total	**15**	**100.0**
7.2 Duration of treatment		
a few days	4	26.7
a few weeks	7	46.7
a few months	1	6.7
unknown	3	20.0
Total	**15**	**100.0**

Characteristics of the current pregnancy

Most of the current pregnancy is the second one (104 pregnancy, 41.6%). The gestational age is from 6-41 weeks with the average of 18.9 ± 9.8 weeks and median of 16 weeks. Most of them are at the 2nd trimester of gestational age (113, 44.1%). All the first visit for antenatal care, 12 (4.7%) of them complain of any obstetrical and gynecological disorders. The complaints include morning sickness, excessive vaginal discharge, vulvovaginal itching with vaginal discharge in 6, 4, 2 cases respectively. More detail is shown in Table 3.

Table 3. Characteristics of the current pregnancy

Characteristics	number	percent
1. Gravidity		
1st	96	38.4
2nd	104	41.6
3rd	38	15.2
4th	11	4.4
5th	1	0.4
Total	**250**	**100.0**

Table 3. (continued)

Characteristics	number	percent
2. Gestational age (weeks) (mean $\pm$ SD. = 18.9 $\pm$ 9.8)		
1st trimester	80	31.3
2nd trimester	113	44.1
3rd trimester	63	24.6
Total	**256**	**100.0**
3. Complaints of any obstetrical or gynecological disorders	12	4.7

Personal characteristics

The prevalence of risk behavior concerning both smoking and alcoholic consumption are 0.8% (2/256). See more detail in Table 4.

Table 4. Personal characteristics of pregnant women being studied.

Characteristics	number	percent
1. Smoking		
Never 246	96.1	
Ex-smoker	8	3.1
Current smoker	2	0.8
Total	**256**	**100.0**
2. Alcoholic consumption		
Never	229	89.4
Ex-consumer	25	9.8
current consumer	2	0.8
Total	**256**	**100.0**

Clinical findings resulting from vaginal examination.

There is only one pregnant women, 0.4%, who has abnormal external genital appearance, it was leukoplakia of vulva. Abnormal vaginal mucosa or discharge was found in 14 (5.5%) women. Such abnormalities include inflamed vaginal mucosa, 1 (7.1%); foamy discharge, 1 (7.1%); mucopurulent discharge, 1 (7.1%); homogeneous

discharge, 1 (7.1%); yellowish discharge, 1 (7.1%); curd like discharge, 5 (35.8%); amine odour, 4 (28.7%). Abnormal cervix is found in 14 (5.5%) women. These are mucopurulent discharge, 1 (7.1%); condyloma like lesion, 1 (7.1%); milky like discharge, 2 (14.3%); cervical erosion, 10 (71.5%). Uterine abnormalities were detected in 15 (6.0%). These abnormalities include uterine size lesser than gestational age, 6 (40.0%); uterine size larger than gestational age, 7 (46.7%); nodular surface of uterus that suspicious of myoma uteri, 2 (13.3%).

All adnexa and cul-de-sac were normal. See more detail in Table 5.

Table 5. Clinical finding from per vaginal examination

Characteristics	number	percent
1. External genital appearance		
normal	254	99.6
abnormal	1	0.4
Total	**255**	**100.0**
2. Vaginal mucosa or discharge		
normal	241	94.5
abnormal	14	5.5
Total	**255**	**100.0**

Table 5. (continued)

Characteristics	number	percent
3. Cervix		
normal	241	94.5
abnormal	14	5.5
Total	**255**	**100.0**
4. Uterus		
normal	239	93.7
abnormal	16	6.3
Total	**255**	**100.0**

Note: *For some characteristics, the total is not equal to 256 which is caused by missing information.*

Microbiological examination

Papanicolaou smear class II (inflammation with or without pathogenic organisms identified) was 37.2% (90/242). There were 1.2% (3/242) women having class III (mild to moderate dysplasia).

The results of cultures were the followings: none for G.C.,3.5% (9/256) for

GBS., 0.8% (2/256) for fungus, and 77.3% (198/256) for bacterial flora, ELISA test

for chlamydia was found to be positive in 7.0% (18/256).

Gram stain of cervical smear was positive (showed inflammatory reaction or

identified the pathogens) in 18.4% (46/250).

Amine odour (Whiff test) was positive in 5.5% (14/254).

Wet mount examination of vaginal secretion positive for at least one criteria

for vaginitis was 21.7% (55/254).

See more detail in Table 6.

Table 6. Results of microbiological examination

Type of Microbiological study	Number	Percent
1. Papanicolaou smear		
class 0 (Unsatisfied)	1	0.4
class I (Normal)	148	61.2
class II (Inflamed)	90	37.2
class III(Dysplasia)	3	1.2
Total	**242**	**100.0**

Table 6. (continued)

Type of Microbiological study	Number	Percent
2. Culture positive		
normal (no growth)	47	18.4
G.C.	0	0.0
GBS.	9	3.5
fungus	2	0.8
bacteria flora	198	77.3
Total	**256**	**100.0**
3. ELISA		
negative	238	93.0
positive	18	7.0
Total	**256**	**100.0**
4. Gram stain of cervical smear		
negative	204	81.6
positive	46	18.4
Total	**250**	**100.0**

Table 6. (continued)

Type of Microbiological study	Number	Percent
5. Amine odour (Whiff test)		
negative	240	94.5
positive	14	5.5
Total	**254**	**100.0**
6. Wet mount examination of vaginal secretion		
negative for pathogenic organism	199	78.4
positive clue cells	32	12.6
positive fungus	11	4.3
positive T.V.	1	0.4
positive G.C.	0	0.0
others	11	4.3
Total	**254**	**100.0**

Prevalence for vaginitis based on selected test results

1) **Prevalence for vaginitis using clinical symptoms and signs**

Among 256 pregnant women, 33 of them were diagnosed as having vaginitis based on clinical symptoms and signs which is used as the routine current practice in this hospital. Thus this yields the prevalence of 12.9%. Note that the clinical

symptoms and signs include complaints of the patient and abnormal vaginal discharge.

2) Prevalence for vaginitis using vaginal fluid pH

Vaginal fluid pH ranged from 3.0 to 5.5 with the median of 4. There are 68 (26.6%) who have pH greater than 4.5 which is the cutoff point for classifying vaginitis. Therefore the prevalence of infectious vaginitis using pH criteria in pregnant women receiving antenatal care at Srinagarind Hospital is 26.6% (95% CI : 21.2 -32.0) (Table 7.).

Table 7. Vaginal fluid pH.

pH	number	percent
3.0	7	2.7
3.5	85	33.2
4.0	52	20.3
4.5	44	17.2
5.0	**22**	**8.6**
5.5	**46**	**18.0**
Total	**256**	**100.0**
pH > 4.5	68	26.6

3)   Prevalence for vaginitis using gold standard test

Among 256 pregnant women, 80 were diagnosed as having vaginitis based on positive for at least one of the gold standard tests. Thus the prevalence of vaginitis was 31.3%. The proportion for each pathogens was shown below (Table 8).

Table 8. Type of vaginitis among 256 pregnant women at the first visit ANC *

Type of vaginitis	N	%
BV[1]	14	5.5
BV[2]	33	12.9
Inflamed[3]	46	18.0
TV	1	0.4
GBS	9	3.5
Fungus	11	4.3
Chlamydia	18	7.0

Note: *1. When gold standard test for BV is three of four clinical criteria.*

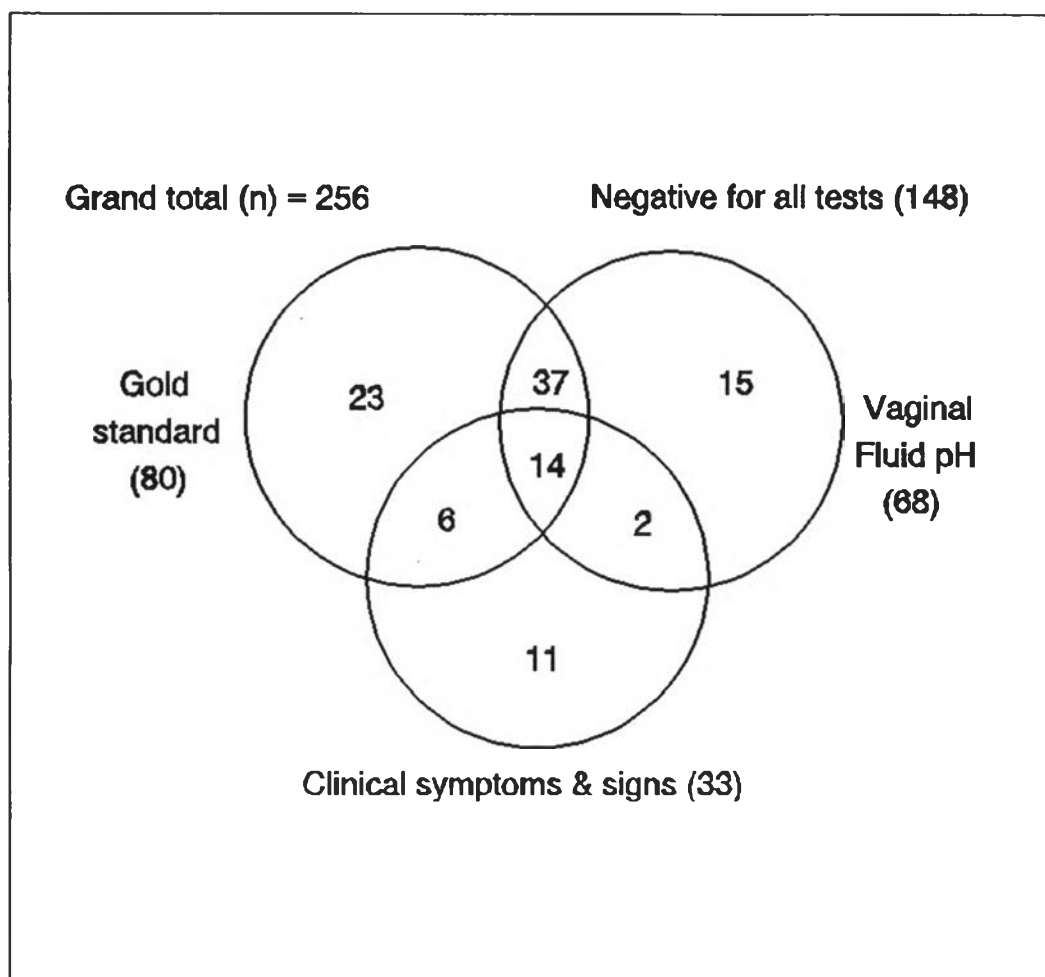*2. When gold standard test for BV is two of four clinical criteria.*

3. Gram stain positive results.

* *Some patients could have more than one positive results of the gold standard tests.*

As mentioned earlier that 33 pregnant women who were presented with clinical symptoms and signs related to vaginitis. From these, 20 cases (60.6%) were confirmed as having vaginitis based on gold standard test results. Again, as mentioned earlier that 80 cases were diagnosed as having vaginitis using the gold standard test. Therefore 60 cases (75.0%) were asymptomatic vaginitis.

From 60 asymptomatic cases, 37 cases (61.7%) can also be detected by vaginal fluid pH. Using the results from vaginal fluid pH test combined with clinical symptoms and signs can detect vaginitis 57 out of 80 cases (71.3%). (Fig. 3)

Fig. 3. The diagram showing the number of pregnant women falling in to each part corresponding to the results of each test.

Grand total (n) = 256

Negative for all tests (148)

Gold standard (80)

23

37

15

14

Vaginal Fluid pH (68)

6

2

11

Clinical symptoms & signs (33)

Diagnostic performance of vaginal fluid pH

1)   Diagnostic performance of vaginal fluid pH using cutoff point of greater than 4.5

Among 256 pregnant women, 80 (31.3%) have vaginitis according to the applied gold standard. From a total of 80 cases, the vaginal fluid pH can correctly detect 51 of them resulting the sensitivity of 63.8%. For a total of 176 who were non vaginitis, the vaginal fluid pH can clarify as so in 159 cases resulting the specificity of 90.3%.

In 68 cases of the positive test (pH > 4.5) have positive gold standard test 51 cases resulting the positive predictive value of 75.0%. And 188 cases of negative test (pH < = 4.5) have negative gold standard test resulting in 84.6% negative predictive value. As the results of the test compare with the gold standard test was shown in Table 9 and the Receiver Operative Characteristics (ROC) curve of the test was shown in Fig.4

Table 9. Diagnostic performance of vaginal fluid pH to detect vaginitis in general

pH test	Gold standard test		Total
	positive	negative	
positive (pH > 4.5)	51 (63.8%)	17	68
negative (pH < =4.5)	29	159 (90.3%)	188
Total	80	176	256

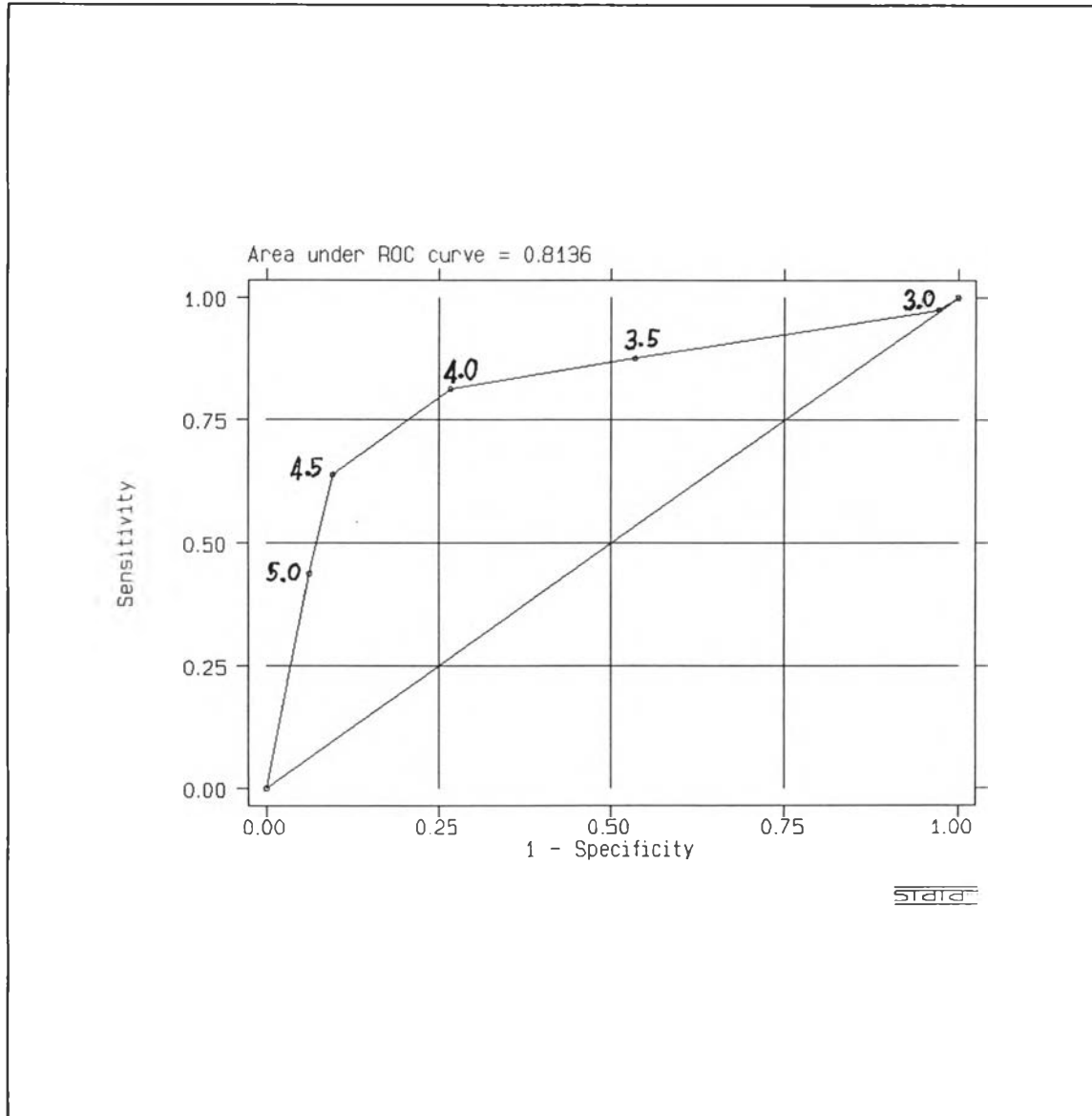Sensitivity   =   63.8%

Specificity   =   90.3%

Positive predictive value   =   75.0%

Negative predictive value   =   84.6%

Accuracy   =   82.0%

Fig.4. The Receiver Operative Characteristic (ROC) curve of the test

2) Diagnostic performance of vaginal fluid pH using cutoff point of greater than 4.0

The vaginal fluid pH give positive predictive results for 112 pregnant women which correctly detect vaginitis of 65 out of 80 cases. Thus sensitivity of the test was 81.3%. Among the negative pH test of 144 cases, there were 129 cases who have no vaginitis resulting in the specificity of the test of 73.3%, the positive and negative predictive value of 58.0% and 89.6% respectively. The accuracy of the test was 75.8%. (Table 10.)

Table 10. Diagnostic performance of vaginal fluid pH to detect vaginitis using cutoff point of 4.0

pH test	Gold standard test		Total
	positive	negative	
positive (pH > 4.0)	65 (81.3%)	47	112
negative (pH < =4.0)	15	129 (73.3%)	144
Total	80	176	256

Sensitivity   =   81.3%

Specificity   =   73.3%

Positive predictive value   =   58.0%

Negative predictive value =   89.6%

Accuracy   =   75.8%

3)   **Comparing the performance and cost-effective of vaginal fluid pH between cutoff point of 4.0 and 4.5**

Comparing the two different cutoff points, we can see that the gain were in sensitivity and negative predictive value when using cutoff point of 4.0 (Table 11.)

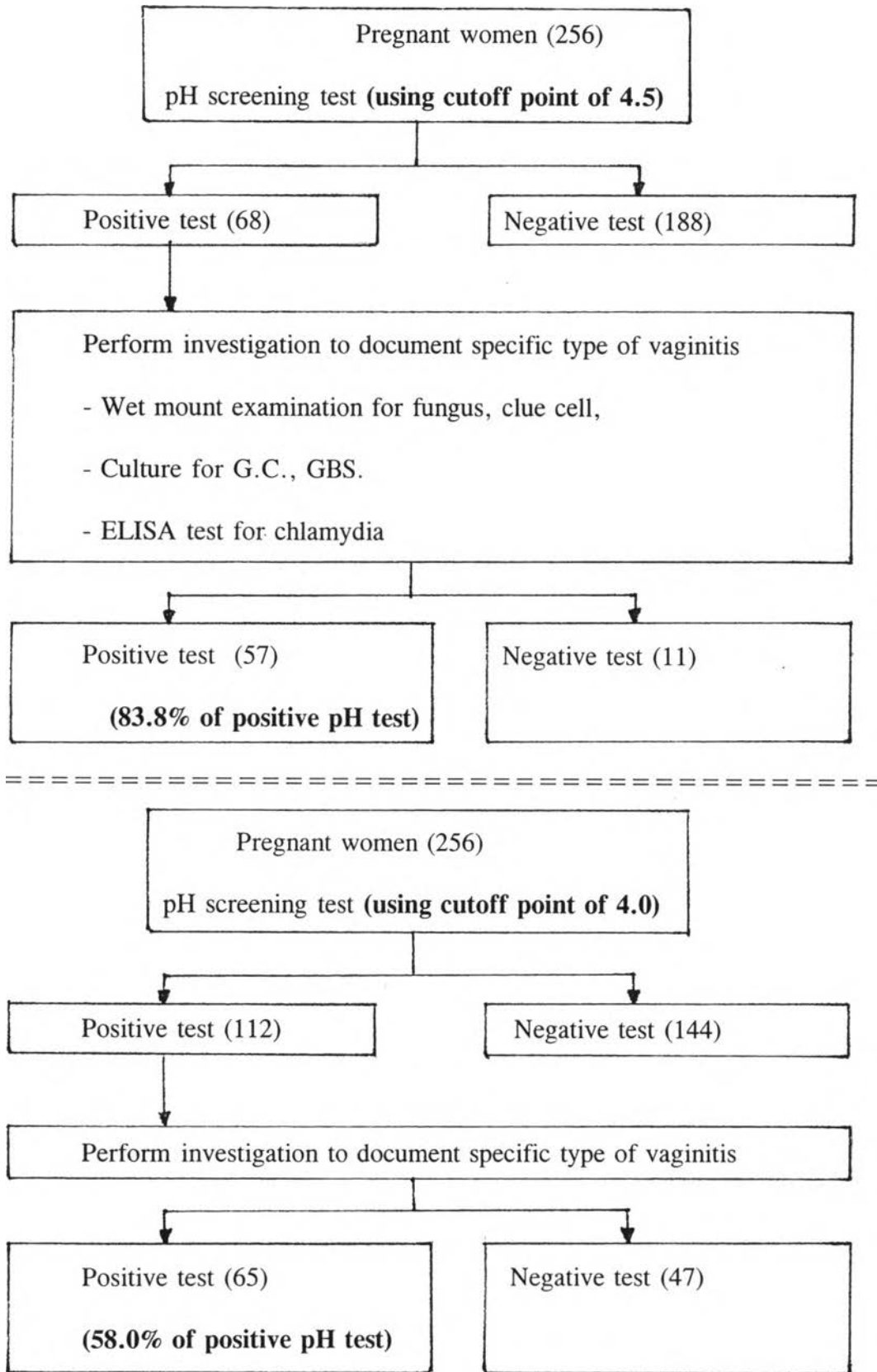**Table 11.** Performance of the test by the two cutoff points

Performance of test	pH 4.0 (%)	pH 4.5 (%)
Sensitivity	81.3	63.8
Specificity	73.3	90.3
PPV	58.0	75.0
NPV	89.6	84.6
Accuracy	75.8	82.0

However the predictive value positive is the appropriate value for selecting the test being compare in this circumstance it is obviously shown that the positive predictive value is higher when using cutoff point of 4.5 (75.0%) than when using cutoff point of 4.0 (58.0%).

When using the cutoff point of 4.0 rather than of 4.5 as initially plan, number of positive result was 44 (112-68= 44) more cases while there was only 8 more cases (65-57=8) were detected. (Fig.5)

Fig.5 Vaginal fluid pH screening comparing between cutoff point of 4.0 and 4.5

Pregnant women (256)

pH screening test **(using cutoff point of 4.5)**

Positive test (68)　　　　　Negative test (188)

Perform investigation to document specific type of vaginitis

- Wet mount examination for fungus, clue cell,

- Culture for G.C., GBS.

- ELISA test for chlamydia

Positive test　(57)

(83.8% of positive pH test)　　　　Negative test (11)

Pregnant women (256)

pH screening test **(using cutoff point of 4.0)**

Positive test (112)　　　　　Negative test (144)

Perform investigation to document specific type of vaginitis

Positive test (65)

(58.0% of positive pH test)　　　　Negative test (47)

Given that the cost of confirmatory test is fixed, denoting X, the cost per case detected are 1.2 X (or 68 X / 57) for the cutoff point of 4.5 and 1.7 X (or 112 X / 65) for the cutoff point of 4.0. In other words, the cost per case detected for the cutoff point of 4.0 is 1.4 times higher than that for the cutoff point of 4.5. Therefore, although we gain higher sensitivity when using cutoff point of 4.0, we also faced the higher cost per case detected.

Diagnostic performance of vaginal fluid pH to detect specific vaginitis

Using the gold standard for each of specific pathogens, the performance of vaginal fluid pH test in detecting vaginitis are shown in Table 12. The results suggested that the low performance of the test, i.e., sensitivity of the test, is found in the non BV pathogens which includes each of the following; chlamydia, fungus, GBS.,TV. On the contrary, high performance of the test was observed in the BV group.

However, the result of the performance of the test for TV., GBS., fungus, chlamydia, separately may not be valid due to small outcomes. The combined results, then, is preferred which is shown in Table 15.

Table 12. Diagnostic performance of vaginal fluid pH to detect vaginitis for specific organisms

Pathogens	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	Accuracy (%)
BV[1]	100.0(14/14)	77.7(188/242)	20.6(14/68)	100.0(188/188)	78.9(188/256)
BV[2]	97.0 (32/33)	83.9(187/223)	47.1(32/68)	99.5 (187/188)	85.5(219/256)
Inflamed[3]	76.1 (35/46)	84.3(177/210)	51.5(35/68)	94.2 (177/188)	82.8(212/256)
TV*	100.0(1/1)	73.7(188/255)	1.5 (1/68)	100.0(188/188)	73.8(189/256)
GBS	66.7 (6/9)	74.9(185/247)	8.8 (6/68)	98.4 (185/188)	74.6(191/256)
Fungus	54.6 (6/11)	74.7(183/245)	8.8 (6/68)	97.3 (183/188)	73.8(189/256)
Chlamydia	38.9 (7/18)	74.4(177/238)	10.3(7/68)	94.2 (177/188)	71.9(184/256)

Note: *1. When gold standard test for BV is three of four clinical criteria.*

2. When gold standard test for BV is two of four clinical criteria.

3. Gram stain positive results.

* The result of TV has to be ignored since the number of cases is small (less than 3 percent of the total number of study population)[33].

Performance of vaginal fluid pH test and Papanicolaou smear combined : The parallel test

Vaginal fluid pH and Papanicolaou smear results were combined as a diagnostic test, that is, pregnant women who have positive result from at least one of the two tests- either vaginal fluid pH of more than 4.5 and/or Papanicolaou smear of class 2 or more, were classified as having vaginitis. Compared the results with those from the gold standard test resulting the sensitivity of 78.8% and the specificity of 60.8%. The positive predictive value (PPV) is 47.7% and the negative predictive value (NPV) is 86.3%. The gain, as compared to when used the vaginal fluid pH result alone is increase of the sensitivity from 63.8% to be 78.8%. But the specificity is decreased from 90.3% to be 60.8%. (Table 13.)

Table 13. Performance of vaginal fluid pH test and Papanicolaou smear combined:the

parallel test

pH test + Pap smear	Gold standard test		Total
	positive	negative	
Positive	63 (78.8%)	132	68
Negative	17	107 (60.8%)	124
Total	80	176	256

Performance of vaginal fluid pH in screening of vaginitis for Bacterial vaginosis

(BV) and non-Bacterial vaginosis (NonBV)

As mentioned in Chapter 2: methodology that BV was diagnosed when three

out of four the following clinical criteria were observed: thin homogeneous discharge,

fishy amine odour, positive clue cells, and vaginal fluid pH greater than 4.5. The

non-BV vaginitis was diagnosed, thus, if there were positive results of one of the

following test : ELISA for chlamydia, culture for GBS, wet smear for fungus and TV. Among 80 cases of vaginitis, there were 14 (5.5%) BV and 37 (14.5%) of non-BV. This suggested that the proportion of non-BV is 2.6 times greater than that of BV. Using the two criteria separately as the gold standard, the performance of vaginal fluid pH test can be determined as follows :

For BV, the sensitivity and the specificity of vaginal fluid pH are 100.0% and 77.7% respectively. The positive predictive value is 20.6% and the negative predictive value is 100.0%. However, this result should have been interpreted with caution since one of the criteria for BV is the diagnostic test being studied. That is, the perfect sensitivity could be due to the role of incorporation bias (Table 14.)

Table 14. Performance of vaginal fluid pH in screening for BV vaginitis

pH test	Gold standard test		Total
	positive	negative	
Positive (pH > 4.5)	14 (100.0%)	54	68
Negative (pH <= 4.5)	0	188 (77.7%)	188
Total	14	242	256

For non-BV, the sensitivity and the specificity are 50.0% and 77.3% respectively. The positive predictive value is 9.6% and the negative predictive value is 90.4%.

(Table 15.)

Table 15. Performance of vaginal fluid pH in screening for non-BV vaginitis

pH test	Gold standard test		Total
	positive	negative	
Positive (pH > 4.5)	19 (51.4%)	49	68
Negative (ph <= 4.5)	18	170 (77.3%)	188
Total	37	219	256