

**PROGRESS REPORT INTERNATIONAL REVIEW OF MEDICAL SCIENCES**

**A NEW TEST FOR HUMAN FEMALE OVULATION DIAGNOSIS**

Abstract Material and Method Results References Conclusions

REPRINT Vol: 6 - No 1, 1994 Edizioni Universitarie Romane DONNA *Saliva Fertility Tester*. (DONNA is marketed as **calista™ Saliva Ovulation Test** in the UK)

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**Abstract:**

The Authors performed the saliva test on 328 women using the Saliva Tester. In 48 cases the test results revealed a fern-like crystallized structures as illustrated in "Figure 3" below. In 20 cases they performed a Transvaginal Ultrasonography (T.V.U.S.). In 16 cases (80%) they found an ovarian follicle greater than 2 cm.

**Key words:**

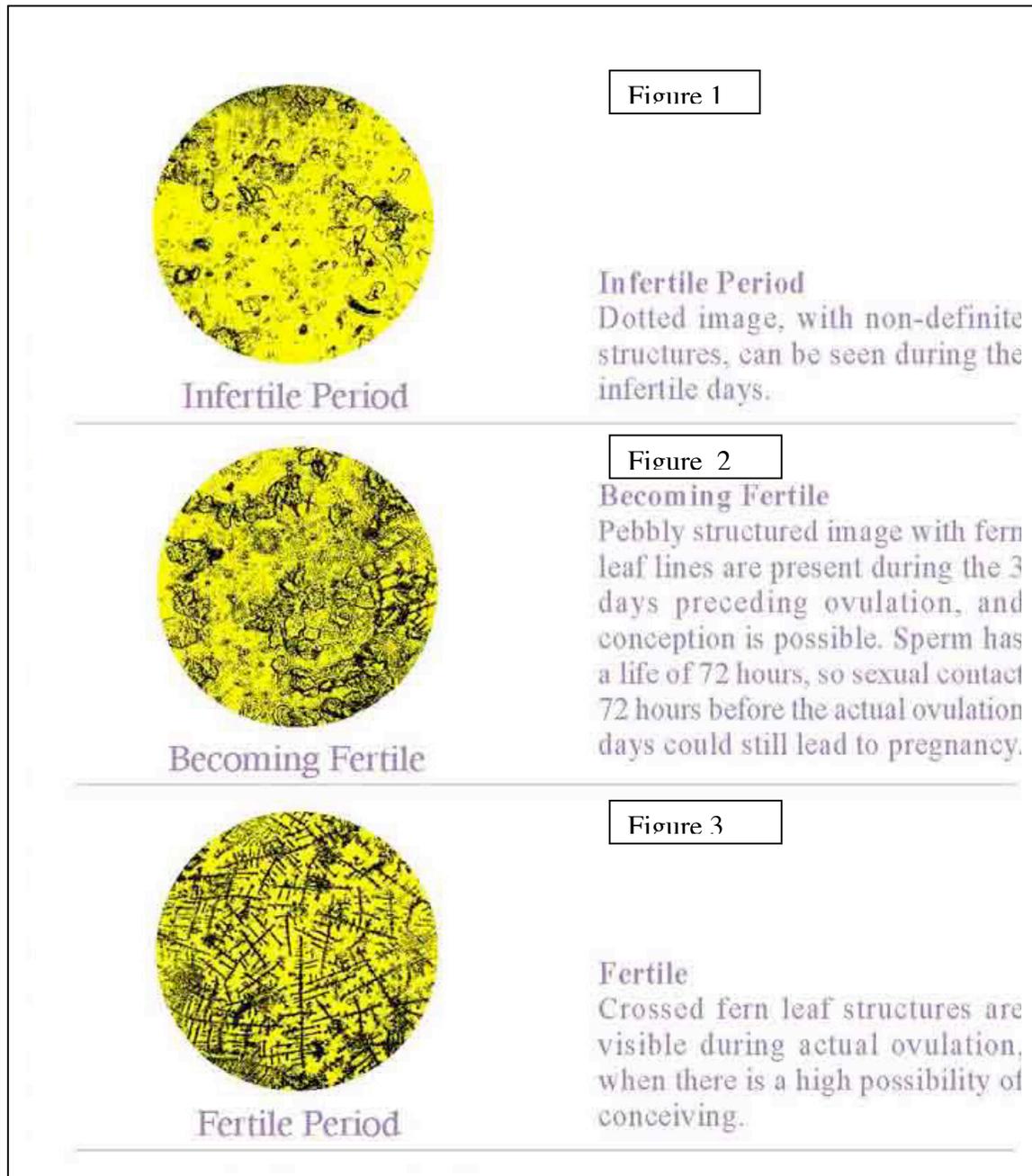
- Fertility tester, saliva, fertile period, Transvaginal Ultrasonography.
- To know the days of their menstrual cycle when fecundation is possible has always been a demand felt by women and this both in the case when they want to avoid it (1).
- Many methodologies exist that enable us to verify or not the presence of a mature ovarian follicle or its happened explosion.
- A very simple methodology was reached with observation and testing of the Saliva Tester; results that may be easily and directly realized by any woman, at any moment of the day, anywhere.
- The prospective advantages that descend as to the knowledge of the useful days for a fecundation are such that they led us to directly and correctly try this new test.

**Material and Method**

It has been considered the use of a mini-microscope, or "Saliva Microscope", made up of a small cylindrical body or eyepiece where we note an optical part with an opposite small slide where a sample of saliva is placed. As soon as the sample of saliva has dried, the small eyepiece body is put into a cylindrical container, that leads down to a lighting system. By focusing the lens, a fern-like

characteristic crystallization is pointed out, in a very near correlation with the ovulation period (Figure 3).

Out of the fertile days there are no fern-like crystallization structures seen, as pictures named "Figure 1" (during the non-fertile period) and "Figure 2" (during the intermediate period) indicate. We have taken into consideration 328 women between 15 and 50 years old, not using OCP who were placed under our observation at the out-patients' departments of the Institute of Obstetrics and Gynecology of the University "La Sapienza" in Rome.



No selective principle has been adopted. We have only invited the patient to leave a sample of saliva on the slide of the mini-microscope, and afterwards age, day of the cycle in which the patient was and length of her cycle were noted. 48 women, whose sample of saliva gave the fern-like characteristically stratification were invited to undergo an ultrasonography with transvaginal sound for the control of the ovary and of the presence or not of the pertinent follicle. 20 women accepted our request, 28 women kindly refused. Figure 1 (Infertile) Figure 2 (Intermediate) Figure 3 (Fertile)

**Results:**

Results are reported by Tables 1,2 and 3. In Table 1 we see 448 women of 328 who, as far as anamnesis is concerned, are in the ovulation period; 40 of these women gave us the picture "Figure 3" type after test, 40 gave us the picture "Figure 2" and 248 the picture "Figure 1" type (Table 2). At the anamnesis, 36 women were in the intermediate period; in all 36 cases of this group, we have noted a picture "Figure 2" type. At the anamnesis, 244 women were in the non-fertile period and we have noted a picture "Figure 1" type in all the 244 cases. In the Table 3, are pointed out the 20 cases who, at the saliva test, showed a picture "Figure 3" type and have accepted to undergo sonographic control by means of transvaginal sound.

**Table 1** - Number of women undergoing the saliva test, correlated to the supposed fertile or non-fertile period of the cycle.

<b>Day of the cycle</b>	<b>No. of women undergoing test</b>
Non-fertile period	244
Intermediate period	36
Fertile period	48
Total	328

**Table 2** - Picture stressed by means of the saliva test.

<b>Stressed picture</b>	<b>N° cases</b>
Table 1	248
Table 2	40
Table 3	40
Total	328

**Table 3** - Echographic control of 20 women by means of picture Figure 3 type of the saliva test

<b>Ovary Echographic Control</b>	<b>N° cases</b>
Follicle Absence	0
Follicle < 1 cm	4
Follicle > 2 cm	16

stressed.

## **Conclusion**

The Fertility Tester can be used to look for a pregnancy: the fertile moments will be identified with a continuous use, cycle after cycle.

The Tester will also allow, by repeating every month the tests, to obtain some significant indications about the monthly cycle behaviour and the hormonal situation of the woman.

The comparison of the figures given in Tables 1 and 2 indicate the following:

- at the anamnesis No: 244 women were in the non-fertile period and we have noted a picture "Figure 1" type in all 244 cases.
  - at the anamnesis No: 36 women were in the intermediate period; in all 36 cases of this group, we have noted a picture "Figure 2" type.

In both cases we had a PERFECT COINCIDENCE between supposed fertile or infertile days of the cycle and test executed with "Donna (CALISTA) Fertility Tester".

- at the anamnesis 48 women were in the fertile period; in 40 of them we have noted a picture "Figure 3" type. Such difference is due to the fact that 4 of them had a meal one hour before testing, thus invalidating the result, and the other 4 may have not correctly performed the test.

Therefore, even if we assume that all these 8 women were in fact fertile (very unlikely), the final result of such test is that only 8 women out a panel of 328, i.e. less than 3%, resulted false negative (in fact fertile) at the saliva testing.

## **THE AUTHORS CONCLUDE STATING THE FOLLOWING: \***

**"To our knowledge the saliva microscope can be significantly helpful in providing an additional aid to women wanting to identify their likely fertile period during the menstrual cycle. The outcome is that its accuracy, in determining fertile moments of the monthly cycle, is close to 98%, higher than other contraceptive devices like condom, spyral, diaphragm, not to mention billings and ogino-knaus methods, placed at the lower end of this scale. To prevent a pregnancy only the contraceptive pill has a higher rate**

**(99%) ; at the same time everybody today is aware of bad secondary effects of the use of the pill. This tester is not invasive and there is no need of reagents or other evidence system. \* Any woman can easily do the test. She can perform it anytime and anywhere."**

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