

Evaluation of a scientific papers used to support claims made about Maybe Baby - Mini-Microscope (MB) for ovulation cycle observation

MB is a precision instrument (optical system: magnification 52 ± 2 times) used to examine a crystallized salts in the dry saliva sample, which under illumination from a LED light source, can be seen as "fern leaves". The design of MB has been based on the following

Reference papers:

1. C. Andreoli & M. Della Porta (1957): "*Ricerche sulla cristallizzazione salivare durante il ciclo mestruale*" Clinica Ostetrica Ginecologica dell'Universita di Torino
2. J. M. B. Casals (1968): "*Nuevo test de ovulacion*", Medicina Clinica, Organo De La Facultad De Medicina, Hospitales Y Sociedades Medicas De Barcelona
3. G. Galati, et al (1994): "*A new test for human female ovulation diagnosis*" Reprint Vol:6-No1, 1994 www.ecobrand.co.uk (DONNA is marketed as calista^{MB} Saliva Ovulation Test in the UK).
4. T.Pal & K.Bhattacharyya (1989): "*Cyclic changes in salivary lactate dehydrogenase, peroxidase and leucine aminopeptidase during menstrual cycle*", Indian Journal of Experimental Biology Vol. 27 August 1989, pp. 695-698
5. R. Ganovic, et al (1994): "*Determination of fertile and infertile days of the menstrual cycle of women by using the saliva crystallization test*", Clinic of Gyneacology and Obstetrics "Narodni Front" Clinical Centre of Serbia.

Principle is based on the so-called "fern-phenomenon" that was discovered by Italian doctors **C. Andreoli & M. Della Porta (1957)** at the University of Torino. These physicians discovered that the level of the sex hormone estrogen could be detected through visual observation of a dried saliva sample on a microscope slide. At high levels such as those present during ovulation, the crystallized estrogen exhibits a pattern resembling fern leaves. When estrogen is present, a fern leaf pattern is observed with the use of MB.

Casals (1968) also concludes that on the basis of saliva, it is possible to detect fertile and infertile days during the menstrual cycle of a woman. Other usefulness of Casals work is the aim to address problem that face women with irregular menstrual cycle. Author does not only put emphasis on the importance of the ovulation detection and precise time but simplicity of use of the method. Many well known methods for ovulation detection involve unavoidable help from clinics. Casals compares saliva test method with other known methods and differentiate saliva test on the basis of use simplicity. This requirement for simplicity of use had especially been taken into account when MB design is concerned.

Galati, et al (1994) with his research conclusions joins other authors who claim that the saliva fertility tester can be used to determine the fertile period and also can be used

easily by any woman. They also claim the reliability of the method close to 98% and recommend the method to be used for pregnancy prevention (see summary).

Pal & Bhattacharyya (1989), also find that due to the increased contents of estrogen hormones during the fertile days, the quantity of salts in saliva rises. Pal & Bhattacharyya (1989) also draw a very useful conclusions that saliva test may be affected by several factors such as oral cavity, immunization, allergies and infection and such conditions may not produce reliable results. These have been taken into account and listed in the IFU.

Ganovic et al (1994) adds to Casals (1968) discussions claiming that vast number of ovulation detection methods cannot be carried out in a simple way. Authors go further by picking the remaining simple method based on basal body temperature and then emphasizing that although simple, such method cannot precisely in advance determine ovulation. This is especially important for differentiation of MB over other methods (*"MB shows a higher tendency towards positivism 4-5 days before the ovulation and 2-3 days after the ovulation."*). Ganovic et al (1994) find that MB test is as valid and sensitive as FERN test, come up to reliability of 86% and concludes that MB, with instructions, may be easily used by any woman.

Summary

The above mentioned authors' and their works provided important basis for the design of MB and almost all remarks have been taken into account. There are some minor issues that have not been adopted. These have nothing to do with the method but issues such as reliability (98%) and the idea of using MB for pregnancy prevention purposes (Galati et al (1994)). Former is specifically based on Galati et al (1994) research. MB could only be linked to the research carried out by Ganovic et al (1994) specifically for the MB device. That is why MB claims 86% reliability. Later claim is decided to be too complex issue which includes length of life of the sperm etc., to have it marketed.

The production of MB is well established since 1994, and a number of gynecologists and lay users helped in production of current version of IFU. Current IFU version contains sections such as 'Conditions for use and storage' and 'Disclaimer' which include remarks not originally present in the above scientific works. Nevertheless, former findings were result of a long time experience and risk analysis for which the most prominent medical experts and engineers were consulted. Additionally, MB contains other useful features that have not been mentioned in the scientific works such as pre-set dioptry with $\pm 4D$ and a locker which 'forces' the lay user to easily achieve required focus.