



Comparison of the OvaCue[®] Fertility Monitor and Clearplan Easy[®]

The following provides a brief comparison of Zetek's Electrolyte Method[™] embodied in the OvaCue[®] Fertility Monitor, with the Unipath Clearplan Easy[®] Fertility Monitor. Zetek's Electrolyte Method relies on changes in the electrolytes in saliva to predict ovulation (the key indicator of fertility) up to seven days in advance. Changes in the electrolytes in vaginal mucus are monitored by the OvaCue to confirm ovulation. Comparisons can be grouped into the following categories:

I. Accuracy

The "fertile window" is defined as the days in a woman's cycle in which she can actually conceive. For this evaluation, we use the definition of the "fertile window" from Wilcox, et al.¹, i.e., the day of ovulation and the five days just preceding it, as well as the same authors' conclusion that the urinary leutinizing hormone (uLH) tests are positive on the day of, not the day before, ovulation.

The Clearplan Easy (CPE) test is based on detection of a pre-determined level of estrogen (E3G) in the urine. Unipath's studies are described on page 23 of the company's physicians' manual. In 352 cycles, this level of estrogen was detected before the "fertile window" 13% of the time. It was not seen until after the actual day of ovulation in 14% of the cycles. For the remaining 73% of cycles, the fertile signals happened within the fertile window, where "...the mean location of the first High Fertility day was 3.01+/- 2.33 days before the Clearplan Easy Fertility Monitor identified the [urine] LH surge..."², a very wide standard deviation. This means that the Clearplan accurately identifies fertile days within the fertile window only 73% of the time.

The uLH positive signal is most frequently seen on the day of ovulation. CPE uses this signal as the start of its 3 "peak" days, even though at least one, and usually 2 or 3 of these "peak" days are after the fertile window has closed when it is too late to achieve conception. In Zetek's NIH Phase II³ study, using various uLH tests, the uLH threshold for a positive reading was not

¹ Wilcox, Allen J., Clarice R. Weinberg, and Donna D. Baird. New England Journal of Medicine, 333, 23, p. 1517-1521.

² Unipath, Ltd. Professional Manual: Clearplan Easy Fertility Monitor. p. 23.

³ "Saliva and Cervical Mucus Monitor to Define Ovulation", Ranjit S. Fernando, Ph. D., SBIR Phase II Report to the National Institutes of Health, December, 1988 (Grant Number: 2 R44 HD20222-02)

reached at all in 24% (72 of 300) of the cycles tested, which demonstrates the fact that the uLH used in the Clearplan method is not particularly useful as a predictor of ovulation.

OvaCue vaginal readings indicate the response of the vaginal mucus to estrogen and progesterone, rather than directly to LH. The nadir of Cue readings is associated with the preovulatory peak in estrogens. The rise immediately thereafter signals the shift from estrogen to progesterone dominance. The rise in Cue vaginal readings thus occurs on the day of the serum (blood) LH peak, or about 12 hours before the detection of the uLH signal. In conclusion, it seems that by using uLH, CPE misses defining the fertile window accurately in a significant number of cases, while Zetek's Electrolyte Method more accurately defines the fertile window, and thus a woman's peak fertility.

II. Convenience

OvaCue offers a significant consumer advantage, when compared to the Clearplan Easy, in that inconvenient or unsanitary urine handling is not required. The OvaCue simply requires that a teaspoon-shaped oral sensor be placed on the tongue for 3 seconds every morning. The monitor stores those readings and automatically computes a woman's fertility status for any day of the present cycle. A vaginal sensor may also be used for about 5 days of the fertile window to confirm ovulation. Vaginal readings also are completed in 3 seconds, in addition to the brief time necessary to prepare for the reading. Because both sensors are sealed (water-tight) and not exposed to urine, they can be easily cleaned and prepared for the next day's reading, with little or no inconvenience.

III. Cost

The retail prices of the Cue and OvaCue are \$198 and \$298, respectively. The retail price of the Clearplan Easy is \$230. However, the Clearplan also requires that additional test strips be purchased at a cost of \$20-\$40 per cycle. Therefore, within 2-3 months the Clearplan becomes more expensive, with the cost rising with each purchase of test strips. Zetek sensors are sealed and sterilized before shipping, and can be cleaned with mild detergents or Isopropyl Alcohol. Because the OvaCue can be used effectively for years with nothing more to buy, it provides a substantial cost savings when compared to the annual cost of CPE test strips, which can add over \$400 per year to the CPE unit cost.

IV. Advance Notice of Ovulation

Advance notice of ovulation is crucial for monitoring fertility, independently of a consumer's particular fertility goals. For avoiding pregnancy, a couple must know well in advance when ovulation will occur, so that they may abstain during all six days of the fertile window⁴. For couples seeking to achieve pregnancy, advance notice is important to plan for the timing of

⁴ The OvaCue is not approved by the US FDA as a contraceptive.

intercourse or for the scheduling of in-vitro fertilization or artificial insemination. The OvaCue offers a significant advantage by giving up to 7 days advance notice of ovulation, more than CPE or any other ovulation prediction method.

V. Support

All customers of Zetek are welcome to call a toll-free helpline at any time during the first year of use of the OvaCue. Questions about the specific use of the monitor or general questions about fertility and reproductive science are answered by experienced staff at no cost to the consumer. Zetek's trained fertility experts also are available to track a woman's cycle every day if necessary, to identify the proper time for her to attempt conception. CPE offers no such customer support.

VI. History

Zetek has been helping couples meet their fertility goals since 1983. For almost 20 years, Zetek has pioneered the way in electronic ovulation prediction and fertility monitors. Over 17 articles about Zetek and the Electrolyte Method have been published in noted scientific and peer-reviewed journals, and over 2,000 cycles of Cue data have been collected and analyzed. These articles document extensive independent scientific research conducted with Zetek's methodology. Also during that period, two NIH funded studies were completed at the University of Colorado Health Sciences Center, which proved the efficacy of Zetek's method and determined that the OvaCue is 98% accurate in predicting and confirming ovulation, i.e., determining the optimum time for intercourse or insemination.

VII. Approval

The OvaCue and the Electrolyte Method have been approved for use as an aid to conception by the U.S. FDA. The method and device have also been approved by the Vatican as consistent with the teachings of the Catholic Church and finally, the Electrolyte Method has been recommended by numerous doctors specialized in the field of reproductive medicine. The OvaCue has also been recommended by thousands of couples that conceived using the OvaCue when they were unable to conceive using other methods.

VIII. Conclusion

The OvaCue has numerous practical and scientific advantages over the Clear Plan Easy[®] Fertility Monitor. Zetek's method also has numerous advantages over any other existing method of predicting or confirming ovulation. For a complete discussion of the advantages of the Electrolyte Method, and the OvaCue[®] Fertility Monitor, please visit Zetek's website at www.zetek.net or call 1-800-FOR-CUES (800-367-2837).