

Detection of two urinary hormones by a new home ovulation test to identify the wider fertile window: a randomised comparative laboratory study of home ovulation tests

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Study Question:

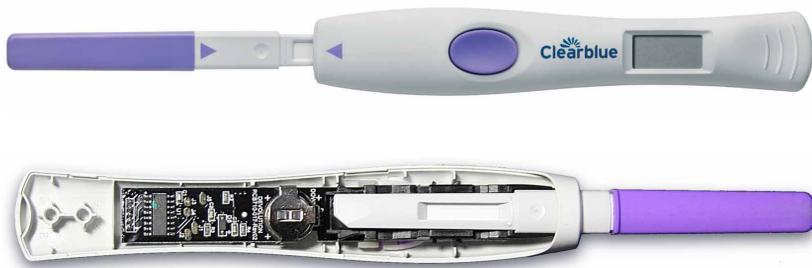
A new home ovulation test (Clearblue Dual-Hormone Digital Test) detects both the pre-ovular urinary rise in estrone-3-glucuronide (E3G) and luteinising hormone (LH). The device aims to identify a wider fertile period than other home ovulation tests. This study examines the number of fertile days detected by a variety of home ovulation tests.

Introduction:

- Many women have an inaccurate perception of when they ovulate, even when actively trying to conceive¹.
- Home ovulation tests are a popular and convenient way for women to time intercourse in order to facilitate a natural conception and can assist with timing of artificial insemination.
- A variety of tests are available, which provide either a visual (line) or digital test result, however it has been demonstrated that 1 in 4 women can interpret line tests incorrectly².
- Conventional home ovulation tests detect the luteinising hormone (LH) surge, enabling women to time intercourse to their two most fertile days to assist conception.

The Dual-hormone Test:

Whilst the probability of conception is highest on the day of the LH surge (day -1), and day of ovulation (day 0) (0.31 and 0.33 respectively)⁴, conception is also possible on the preceding days (0.1, 0.16, 0.14, 0.27 for days -5 to -2). Identifying this wider fertile window would provide women more information on when timing of intercourse can lead to pregnancy. The architecture of the dual-hormone test, including its internal configuration is shown below.



As with other ovulation tests, the dual-hormone test detects the LH surge with ovulation predicted to occur the following day⁵; the test terms these two days as 'PEAK' fertility as they are the days when chances of conception are highest⁴.

The rise in E3G typically occurs a few days before the LH surge, therefore by tracking this hormone, the new dual-hormone test is able to identify the additional days of 'HIGH' fertility before the LH surge, where conception is possible. This is communicated in the following easy-to-understand format:



Objective:

This study aimed to compare the number of days of fertility identified by a variety of home ovulation tests including the dual-hormone test.

Methodology:

Complete menstrual cycles of daily urine samples were tested with the Clearblue Dual-Hormone Digital Test, two digital tests (A: First Response, B: Clearblue), 3 visual (A: First Response, B: Clearblue, C: Answer). For each ovulation test, testing was conducted sequentially across the menstrual cycle according to the manufacturer's instructions for use (including determination on the first cycle day to start testing). Testing was conducted by technicians, with menstrual cycle and ovulation test order randomised. Technicians were blinded to the samples.

Discussion:

Home ovulation tests differ in their ability to detect the LH surge. This study found that the dual-hormone test produced results that agreed most with the reference surge day.

Compared to LH-only tests, the dual-hormone test detected an additional 2 (or more) days of high fertility in 80% of cycles, via detection in the rise in urinary E3G that marks the onset of the fertile window.

References:

- 1 Zinaman M *et al* (2012) *Curr Med Res Opin* 28:749
- 2 Johnson S *et al* (2011) *Expert Opin Med Diagn.* 5:467
- 3 Robinson J *et al* (2007) *Fertil Steril* 87:329
- 4 Wilcox A *et al* (1995) *NEJM* 333:1517
- 5 Behre H *et al* (2000) *Human Reproduction* 15:2478

STUDY FUNDING AND COMPETING INTERESTS:

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Summary Answer:

The new test typically identifies 4 or more fertile days in 80% of cycles, compared with 2 days for comparator home ovulation tests. The LH surge was accurately detected in 90% of cycles; no other ovulation test was more accurate.

- However, the fertile phase begins before the LH surge, and its onset can be determined from the pre-ovular rise in urinary estrone-3-glucuronide (E3G, a urinary metabolite of estradiol).
- A new dual-hormone test is available that tracks both LH and E3G across a woman's menstrual cycle.
- A fertility monitor similarly detecting both LH and E3G demonstrated a more rapid time to conception, compared to a control group using no method to time intercourse³.

The reference day of LH surge was determined by quantitative measurement of LH by AutoDELFA. Only cycles where a surge was present by reference method (n=87, each from a different woman), were analysed using the home tests. The menstrual cycles had been collected from women aged 18-45 with no reported history of infertility. All cycles used were non-conceptual (as cycle length data was needed), although some volunteers had been seeking to conceive. Ethics approval had been provided for sample collection and their use for examining reproductive endocrinology.

Results:

The dual-hormone test displayed at least 2 additional days of fertility (displayed as "HIGH DAYS") prior to the LH surge (displayed as "PEAK DAYS") in 80% (95% CI: 69-88%) of cycles. No other test was able to identify this wider fertile window.

Detection rates of LH surge ranged from 86% to 95% in the cycles tested using the different ovulation tests. However, with some tests, the surge was inaccurately identified compared with the reference method, with some tests detecting a surge many days before ovulation and there were several occasions where surge was not detected until after the reference surge. Therefore, accurate surge detection rate was calculated and found to range from 78% to 90%, with the dual-hormone test matching that of the best LH only test at 90%. The accuracy in surge detection by different tests is shown in figure 1.

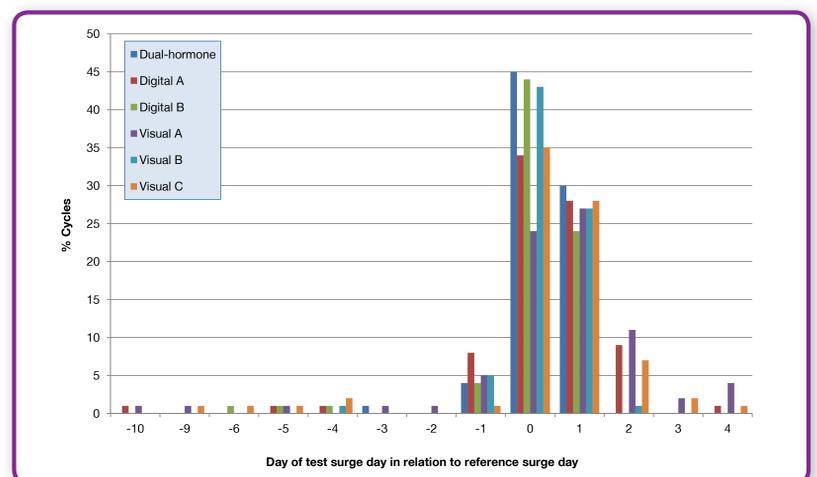


Figure 1: Difference between reference surge and surge detected by home ovulation tests (0=surge detection on the same day as reference surge).

Although characteristics of the menstrual cycles collected compare to published data, the exact percentages reported in this study may vary slightly with a different sample set. This study included 18 cycles (21%) where maximal levels of LH did not exceed 40mIU/ml (lowest peak level 14.6mIU/ml, complete quantitative data only available on 85 cycles). This is a higher proportion than that seen in other studies conducted, so in a wider population, accurate surge detection may be greater.

The benefits are:

- identifying more days where pregnancy is possible to maximise chances of a natural conception
- helping with planning of intercourse for a natural conception, which can be important for some couples with busy lifestyles
- remove the focus of intercourse on just the day of ovulation which may benefit relationships
- planning of artificial insemination.